

Appendices

Appendices

1. Pharmacist Study Information and Consent forms
2. General Practitioner Study Information and Consent forms
3. Patient Study Information and Consent forms
4. Educational training session for pharmacists – including copies of slides and educational protocols
5. Patient Education Booklet
6. Pharmacy Specific Dosing Protocol (adapted from Foss et al, 1999).
7. Pharmacist Recommendation Fax form for Communication to General Practitioners
8. Data collection sheets used in this study
9. Quality of Life Assessment tool (adapted from Sawicki, 1999)
10. Warfarin Knowledge Assessment Questionnaire
11. Individual patient clinical and demographic characteristics
12. Summary of patients recruited into the study and the data they contributed
13. Pharmacy/pharmacist recruitment details
14. Patient Responses to Semi-structured interview on experiences in the study

Appendices 1, 2, 3:



The University of Sydney



Faculty of Pharmacy

Andrew J McLachlan, BPharm PhD MPS MACPP
Chief Investigator, SPAM Project
61 2 9351 4452 (ph)
61 2 9351 4391 (fax)
andrewm@pharm.usyd.edu.au

Megan Spindler
Research Officer, SPAM Project
61 2 9351 6471 (ph)
61 2 9351 4391 (fax)
megan@pharm.usyd.edu.au

Re: A community pharmacy based anticoagulant management service

Name of investigators: Dr Andrew McLachlan, Dr Romano Fois, Dr Ines Krass, Dr Tim Chen, Dr Beata Bajorek and Megan Spindler (Research Officer) from the Faculty of Pharmacy, University of Sydney.

What is the purpose of the study?

This project aims to establish an anticoagulant management service in community pharmacy and to evaluate the health outcomes associated with this activity.

Who will be asked to enter the study?

Patients who are receiving the anticoagulant drug warfarin (called Coumadin[®] and Marevan[®]).

What will happen in this study?

You will be asked to participate by your community pharmacist. If you agree we will contact your general practitioner seeking approval for you to participate in this study which lasts for 12 months. You will be then be allocated to one of two groups depending on your regular pharmacy. If your pharmacy is in group A you will need to agree to visit your pharmacy over the following 12 months to receive follow-up which will include the use of an INRatio[™] monitor to check how well your blood is clotting. The pharmacist may also contact your GP with the result and suggestions for dose adjustment of your warfarin. As part of the service, education about medicines will also be provided to patients. Pharmacies in group B will provide their regular service for 8 months and then provide to an identical service as designed for Group A for 4 months. In either group you will be asked to fill out questionnaires at the beginning and end of the project. We will also obtain test results from your GP at the beginning and end of the project.

Are there any risks?

There are no risks related to this study. The pharmacists will be trained in the use of the INRatio[™] device used to monitor your blood which will ensure there are no risks to you or the pharmacy staff.

Do you have a choice?

Yes! You decide whether or not you want to join the study. Your decision to join or not to join will not affect the care you receive from your doctor in any way. Your involvement is entirely voluntary and you are free to withdraw at any time. All the information that you give us and all the information from your GP or medical records will be completely confidential. Your name will not appear on any of the study results.

Pharmacist Consent form



The University of Sydney



Faculty of Pharmacy

Andrew J McLachlan, BPharm PhD MPS MACPP
Chief Investigator, SPAM Project
61 2 9351 4452 (ph)
61 2 9351 4391 (fax)
andrewm@pharm.usyd.edu.au

Megan Spindler
Research Officer, SPAM Project
61 2 9351 6471 (ph)
61 2 9351 4391 (fax)
megan@pharm.usyd.edu.au

I, _____ hereby voluntarily consent to participate in the study entitled "Sydney Pharmacy Anticoagulant Management". This project is being conducted by Dr Andrew McLachlan, Dr Romano Fois, Dr Ines Krass, Dr Tim Chen, Dr Beata Bajorek and Megan Spindler from the Faculty of Pharmacy, University of Sydney.

I understand that any of the data collected for the purpose of this study will remain strictly confidential and not be used to identify any general practitioner, pharmacist or patient. I have been informed that the information obtained from this research may be used in future research or published.

Details of the study have been clearly explained by the researcher. I am aware of the purpose of this project and what my involvement entails. My participation is entirely voluntary.

I have been informed of my right to question any part of the procedure or withdraw from the project at any time.

Name _____

Address _____

Signature _____

Date _____

Patient Consent form



The University of Sydney



Faculty of Pharmacy

Andrew J McLachlan, BPharm PhD MPS MACPP
Chief Investigator, SPAM Project
61 2 9351 4452 (ph)
61 2 9351 4391 (fax)
andrewm@pharm.usyd.edu.au

Megan Spindler
Research Officer, SPAM Project
61 2 9351 6471 (ph)
61 2 9351 4391 (fax)
megan@pharm.usyd.edu.au

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I also consent to the collection of data from hospital clinical records, from my GP and my community pharmacist. Data will include the results and a record of dispensed medication from the pharmacy.

I understand that any of the data collected for the purpose of this study will remain strictly confidential and not be used to identify any general practitioner, pharmacist or patient. I have been informed that the information obtained from this research may be used in future research or published.

Details of the study have been clearly explained by the researcher. I am aware of the purpose of this project and what my involvement entails. My participation is entirely voluntary.

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Name _____

Address _____

Signature _____

Date _____

General Practitioner Subject Information sheet (Group A)



The University of Sydney



Faculty of Pharmacy

Andrew J McLachlan, BPharm PhD MPS MACPP
Chief Investigator, SPAM Project
61 2 9351 4452 (ph)
61 2 9351 4391 (fax)
andrewm@pharm.usyd.edu.au

Megan Spindler
Research Officer, SPAM Project
61 2 9351 6471 (ph)
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A community pharmacy based anticoagulant management service

Name of investigators: Dr Andrew McLachlan, Dr Romano Fois, Dr Ines Krass, Dr Tim Chen, Dr Beata Bajorek and Megan Spindler from the Faculty of Pharmacy, University of Sydney.

What is the purpose of the study? This project aims to evaluate a community pharmacy program to manage, monitor and educate patients on anticoagulant therapy.

Who will be asked to enter the study? Patients undergoing long term warfarin therapy (longer than 12 months) and who are receiving community based care will be identified by the community pharmacist and you will be asked to provide your consent for that patient to participate.

What will happen in this study? Consenting patients who have the consent of their GP will be asked to participate in a study of 12 months duration. Participating pharmacists will undergo specialised education and training on the clinical aspects of warfarin use and dose adjustment, skills in counselling patients receiving warfarin and use of the INRatio™ device for monitoring INR. After a 2 month baseline phase an educational intervention will be provided to patients on entry into the trial and at the 2-and 4-month pharmacy visit. Pharmacists will see patients to check their INR, advise patients on dietary and lifestyle issues, and monitor patient adherence to the prescribed regimen. Monitoring may be more frequent depending on the stage of therapy and whether a dose change is initiated or new concomitant medicines are started. Dose adjustment (based on an approved protocol) or recommendations will be made by the pharmacist to maintain INR levels within the target range. Results and pharmacist's recommendations will be communicated to the patient's general practitioner for vetting or discussion by fax. Clinical information relevant to the use of anticoagulants will be requested including episodes of adverse events including both haemorrhagic and thromboembolic events.

You will be offered remuneration of \$50 per patient for your time in providing documentation retrieval and communicating with the pharmacist.

Your involvement is entirely voluntary and you are free to withdraw your activity or your patients at any time. All the information that you give us and all the information from your records will be completely confidential. Neither you nor your patient's names will appear in any of the study results.

General Practitioner Subject Information sheet (Group B)



The University of Sydney



Faculty of Pharmacy

Andrew J McLachlan, BPharm PhD MPS MACPP
Chief Investigator, SPAM Project
61 2 9351 4452 (ph)
61 2 9351 4391 (fax)
andrewm@pharm.usyd.edu.au

Megan Spindler
Research Officer, SPAM Project
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61 2 9351 4391 (fax)
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General Practitioner Consent form



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Faculty of Pharmacy

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Chief Investigator, SPAM Project
61 2 9351 4452 (ph)
61 2 9351 4391 (fax)
andrewm@pharm.usyd.edu.au

Megan Spindler
Research Officer, SPAM Project
61 2 9351 6471 (ph)
61 2 9351 4391 (fax)
megan@pharm.usyd.edu.au

Patient Name: _____

I, _____ hereby provide my consent for the above named patient to participate in the study entitled "Pharmacy Anticoagulant Management". This project is being conducted by Dr Andrew McLachlan, Dr Romano Fois, Dr Ines Krass, Dr Tim Chen, Dr Beata Bajorek and Megan Spindler from the Faculty of Pharmacy, University of Sydney.

I consent to allow the researchers to collect data from my clinical records for the above named patient.

I understand that any of the data collected for the purpose of this study will remain strictly confidential and not be used to identify any general practitioner, pharmacist or patient. I have been informed that the information obtained from this research may be used in future research or published.

Details of the study have been clearly explained by the researcher. I am aware of the purpose of this project and what my involvement entails. My participation is entirely voluntary.

I have been informed of my right to question any part of the procedure or withdraw from the project at any time.

Name of GP _____

Address _____

Signature _____

Date _____

Pharmacist Subject information sheet (Group A)



The University of Sydney



Faculty of Pharmacy

Andrew J McLachlan, BPharm PhD MPS MACPP
Chief Investigator, SPAM Project
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61 2 9351 4391 (fax)
andrewm@pharm.usyd.edu.au

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What is the purpose of the study? This project aims to evaluate a community pharmacy program to manage, monitor and educate patients on anticoagulant therapy.

Who will be asked to enter the study? Patients undergoing long term warfarin therapy (longer than 12 months) and who are receiving community based care will be identified by the community pharmacist and will be entered into the study after consent to participate if approved by their GP.

What will happen in this study? You will be asked to identify patients receiving warfarin and recruit them into this study. Consenting patients who have the consent of their GP will be asked to participate in a study of 12 months duration. Participating pharmacists will undergo specialised education and training on the clinical aspects of warfarin use and dose adjustment, skills in counselling patients receiving warfarin and use of the INRatio™ device for monitoring INR. After a 2 month run in phase where you will provide your usual service you will provide an educational intervention to patients on entry into the trial and at the 2 and 4 month pharmacy visit. Pharmacists will see patients to check their INR, advise patients on dietary and lifestyle issues, and monitor patient adherence to the prescribed regimen. Monitoring may be more frequent depending on the stage of therapy and whether a dose change is initiated or new concomitant medicines are started. Dose adjustment (based on an approved protocol) or recommendations will be made by the pharmacist to maintain INR levels within the target range. Results and pharmacist's recommendations will be communicated to the patient's general practitioner for vetting or discussion by fax. Clinical information relevant including INR and reports of side effects to the use of anticoagulants will be recorded.

You will be offered remuneration of \$150 per patient for your time in providing this service, documentation retrieval and communicating with GPs.

Your involvement is entirely voluntary and you are free to withdraw your activity and your patients at any time. All the information that you give us and all the information from your records will be completely confidential. Neither you nor your patient's names will appear in any of the study results.

Pharmacist Subject information sheet (Group B)



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Faculty of Pharmacy

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Chief Investigator, SPAM Project
61 2 9351 4452 (ph)
61 2 9351 4391 (fax)
andrewm@pharm.usyd.edu.au

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You will be offered remuneration of \$75 per patient for you time in providing this service, documentation retrieval and communicating with GPs.

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Pharmacist Consent form



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Pharmacy Name: _____

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I consent to allow the researchers to collect data from my dispensing records.

I understand that any of the data collected for the purpose of this study will remain strictly confidential and not be used to identify any general practitioner, pharmacist or patient. I have been informed that the information obtained from this research may be used in future research or published.

Details of the study have been clearly explained by the researcher. I am aware of the purpose of this project and what my involvement entails. My participation is entirely voluntary.

I have been informed of my right to question any part of the procedure or withdraw from the project at any time.

Name of Pharmacist _____

Name of Pharmacy: _____

Address _____

Signature _____

Date _____



The University of Sydney



Faculty of Pharmacy

Andrew J McLachlan, BPharm PhD MPS MACPP
Chief Investigator, SPAM Project
61 2 9351 4452 (ph)
61 2 9351 4391 (fax)
andrewm@pharm.usyd.edu.au

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Re: A community pharmacy based anticoagulant management service

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Patients who are receiving the anticoagulant drug warfarin (called Coumadin[®] and Marevan[®]).

What will happen in this study?

You will be asked to participate by your general practitioner. If you agree we will contact you seeking approval for you to participate in this study which lasts for 12 months. You will be then be allocated to one of two groups depending on your regular pharmacy. If your pharmacy is in Group A you will need to agree to visit your pharmacy over the following 12 months to receive follow-up which will include the use of an INRatio[™] monitor to check how well you blood is clotting. Patients who are part of Group B will be kept under their usual warfarin management with their general practitioner while data is collected. However at the conclusion of this study you will be invited to attend free information and education sessions regarding warfarin management. In either group you will be asked to fill out questionnaires at the beginning and end of the project.

Do you have a choice?

Yes! You decide whether or not you want to join the study. Your decision to join or not to join will not affect the care you receive from your doctor in any way. Your involvement is entirely voluntary and you are free to withdraw at any time. All the information that you give us and all the information from your GP or medical records will be completely confidential. Your name will not appear on any of the study results.

Appendix 4:



The University of Sydney

Faculty of Pharmacy

Pharmacy Building, A15
The University of Sydney NSW 2006
61 2 9351 6471 (ph)
61 2 9351 4301 (fax)



Sydney Pharmacy Anticoagulant Management Project

Training Seminar - Program

16th November 11.00am to 4.30pm

11.00 – 11.30am

Dr Andrew McLachlan

- Introduction and Welcome
- Overview of project
- Pharmacy Protocol and expectations

11.30am – 1.00 pm

Dr Beata Bajorek

- Warfarin
- Contraindications ect
- INR and Dosing Protocol

1.00pm – 1.45pm

LUNCH

1.45pm – 3.30pm

Dr Beata Bajorek

- Patient Assessment
- Patient Education
- Discussion and Case Studies

3.30pm – 3.45pm

TEA BREAK

3.45pm – 4.15pm

Dr Lorraine Smith

- Communication Strategies

4.15pm – 4.30 pm

Discussion and Questions

4.30pm

Close of Seminar



The University of Sydney

Faculty of Pharmacy

Pharmacy Building, A15
The University of Sydney NSW 2006
61 2 9351 6471 (ph)
61 2 9351 4301 (fax)



Sydney Pharmacy Anticoagulant Management Project

Training Seminar - Program

18th November 7.00pm to 9pm

7.00pm – 7.15pm

Dr Beata Bajorek

- Introduction and Welcome

7.15pm – 8.15pm

Sean Gray and Megan Spindler

- INR Monitoring and Testing
- Demonstration of meter
- Demonstrate finger-prick technique

8.15pm – 8.30pm

TEA BREAK

8.30pm – 9.00pm

Exercise on Case Studies and Paper work

9.00pm – 9.15pm

Wrap up and Discussion

9.15pm

Close of Seminar



The University of Sydney

Faculty of Pharmacy

Pharmacy Building, A15
The University of Sydney NSW 2006
61 2 9351 6471 (ph)
61 2 9351 4301 (fax)



Sydney Pharmacy Anticoagulant Management Project

Training Seminar - Program

14 March 10.30am to 4.00pm

10.30 – 11.00am	<i>Dr Andrew McLachlan</i> <ul style="list-style-type: none">• Introduction and Welcome• Overview of project• Pharmacy Protocol and expectations
11.00am – 12.30pm	<i>Dr Beata Bajorek</i> <ul style="list-style-type: none">• Warfarin• Contraindications ect• INR and Dosing Protocol
12.30pm – 1.15pm	LUNCH
1.15pm – 2.45pm	<ul style="list-style-type: none">• Patient Assessment• Patient Education• Discussion and Case Studies
2.45pm – 3.00pm	TEA BREAK
3.00pm – 4.00pm	<ul style="list-style-type: none">• Pharmacy Protocol• Case studies• Discussion and Questions
4.00pm – 4.15pm	<i>Seminar Wrap up</i>
4.15pm	Close of Seminar

*W*arfarin → Patient Education

- What do patients need and want to know?

- what for? why?
- INR? dosing?
- diet? OTCs?
- Ratsak!




What have
been your
experiences?

- How to educate patients?

- verbal versus written
- initial versus ongoing

- How to assess patient knowledge?

- Knowledge questionnaire
- QoL assessment



SPAM Study - November 2003

Warfarin

An overview

Dr Beata V. Bajorek

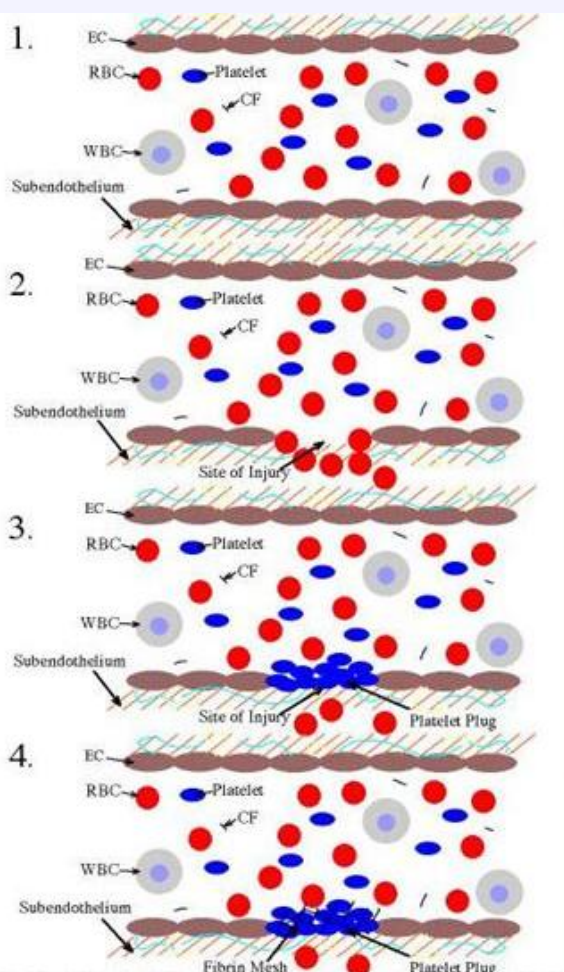
PhD BPharm DipHospPharm MSHP CHP

Faculty of Pharmacy, University of Sydney



Overview

- Coagulation
- Thromboembolism
- Pharmacology of Warfarin
- Indications/Contraindications
- Dosing and therapeutic monitoring

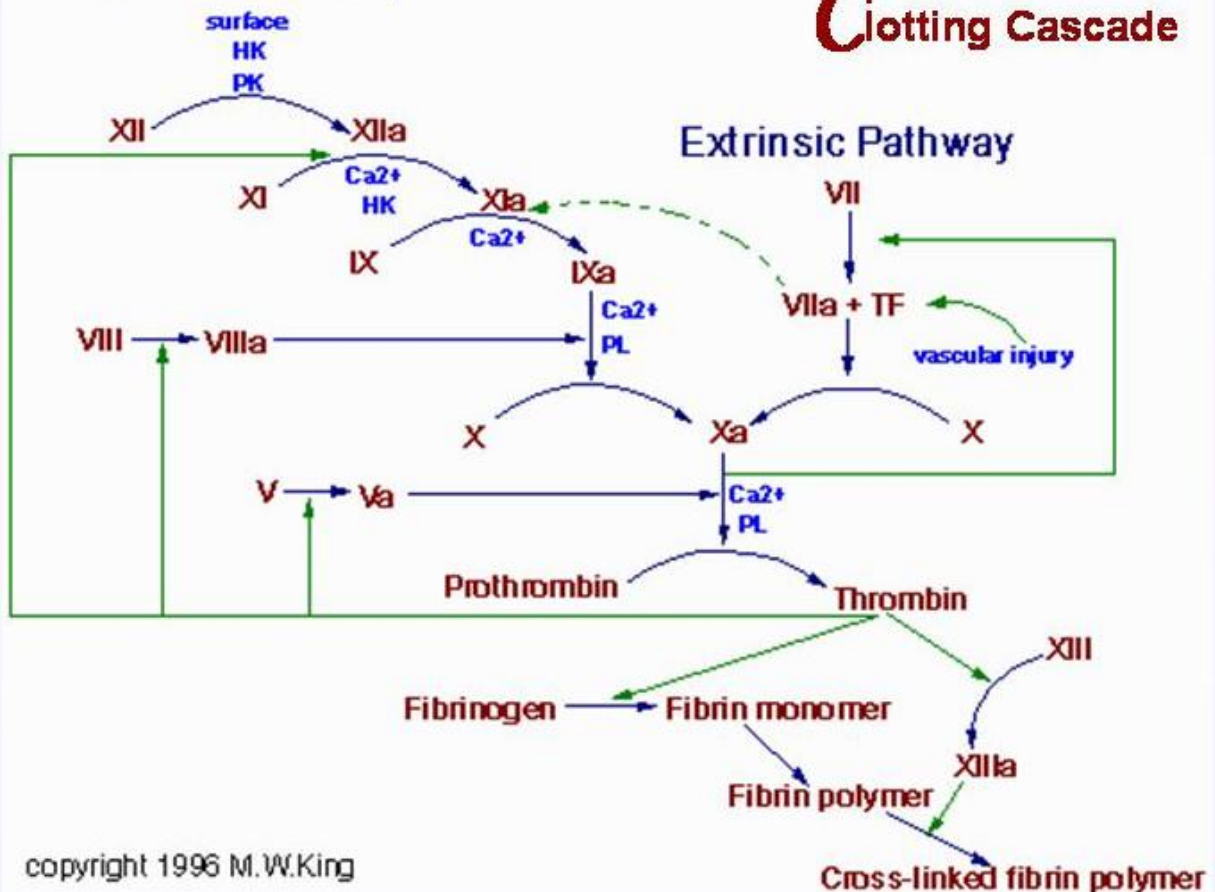


Coagulation → Clot Formation

- 1) Normal vessel
 - endothelial cell (EC)
 - subendothelial layer of collagen etc
 - RBCs, WBCs etc
 - circulating clotting factors (CF)
- 2) Break in EC wall – bleeding
- 3) Platelet aggregation to form platelet 'plug'
- 4) Coagulation cascade – formation of fibrin network to secure 'plug' in place – stop bleeding

Intrinsic Pathway

Clotting Cascade



Thromboembolism

- Disorders of coagulation
- Imbalance between coagulant and procoagulant effects
- Thrombosis = coagulation occurring in the wrong place or at the wrong time
- Embolism = when thrombus dislodges from site of formation and travels to other parts of body
May affect anatomically critical locations
- Composition of the thrombus varies with the site of injury



*V*enous Thrombosis

- Occur in vessels with slow blood flow
- rich in fibrin, trapped red blood cells and few platelets
- red thrombi
- often form in leg veins
e.g., deep venous thrombosis [DVT]
- can break off and embolise (travel) to pulmonary circulation
e.g., pulmonary embolus [PE]



*A*rterial Thrombosis

- Occur in vessels with high blood flow
- mainly composed of platelets and little fibrin
- white thrombi
- commonly occur in association with atheromatous plaque
 - can cause local ischaemia (AMI)
 - may dislodge from arterial wall and embolise to distant sites (brain, eyes, etc)

“Thrombosis is the most common cause of illness and death in Australians”

Dr C.M.Ward, RNSH

Source / Aetiology

Coronary vessels
Cerebral circulation
Venous circulation

Clinical consequences

myocardial ischaemia/infarction
cerebrovascular events (CVA/TIA)
pulmonary embolism

Severe infection
Hepatic disease
Pregnancy complications



generalised thrombosis

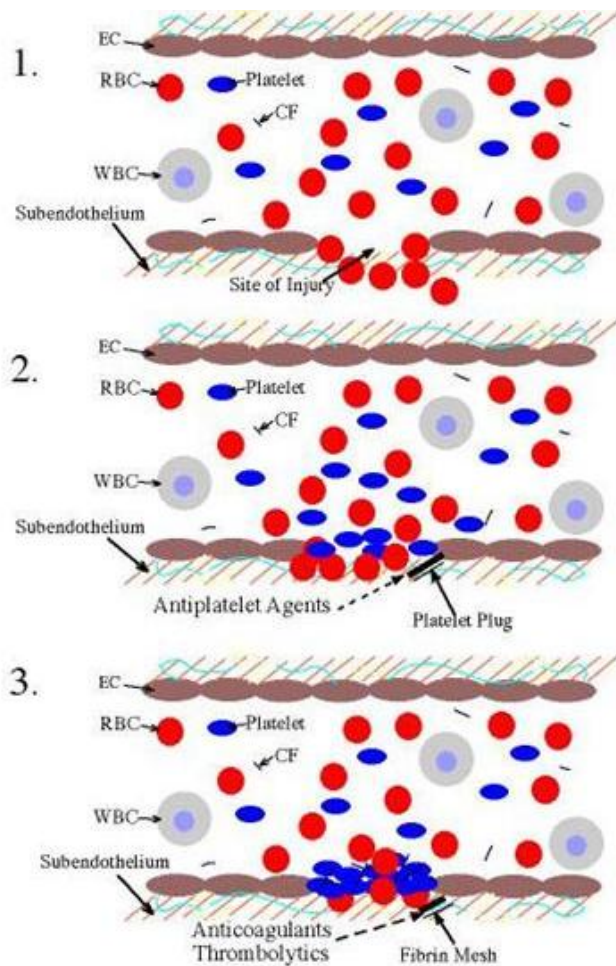


***P*armacotherapy of thrombosis**

- Treatment e.g., AMI, DVT
 - thrombolytics
 - therapeutic anticoagulation
- Prevention e.g., heart valves, AF

Strategy → Antithrombotic therapy:

- antiplatelet
- anticoagulant → WARFARIN



Antithrombotic agents summarised

- **Antiplatelet agents:**
 - prevent formation of the platelet plug at site of injury
- **Anticoagulants:**
 - prevent formation of the fibrin mesh
- **Thrombolytic agents:**
 - break-down fibrin clot after formation



Pharmacotherapy cont.

- **Antithrombotics** \neq "blood thinners"
- NB/ Drugs affecting blood viscosity:
 - e.g., oxpentifylline
 - \uparrow erythrocyte flexibility
 - \downarrow platelet aggregation
 - make it easier for erythrocytes to get through microvascular circulation for perfusion
 - use: PVD

Indications for Anticoagulation

- Treatment of acute thrombosis (therapeutic anticoagulation)
 - DVT, PE
- Prevention of thrombosis
 - prophylaxis of DVT in 'high-risk' patients
 - artificial heart valves
 - cardiac disease (arrhythmia, UAP, post AMI)
 - cerebrovascular disease (carotid artery)
- acute and chronic therapy
- hospital versus community

Coumarins

- Warfarin (Coumadin™, Marevan™)
- Phenindione (discontinued)
- Acenocoumarin (European)
- Dicoumarol
- ORAL anticoagulants (versus parenteral heparins)
 - Heparin – unfractionated (UFH)
 - Low molecular weight heparins (LMWH)
 - Heparinoids

Warfarin

- competitive antagonist of vitamin K-dependent clotting factors
- 1. blocks regeneration of vitamin K from its epoxide
- 2. Vitamin K is necessary for addition of gamma-carboxyglutamic acid residues to clotting factors II, VII, IX, X, Protein C and S
- effect dependent on $T^{1/2}$ of factors 12-36 hrs (interpatient variability)
 - factor VII = 5 hours
 - other factors = 24-48 hours
 - factor VII falls quickly and prolongs PT, but full A/C delayed 3-5 days
- rapid oral absorption (1.5-2 hrs)

Warfarin cont

- 97-99% albumin bound
- metabolised in liver, excreted in urine
- crosses placenta, excreted in breast milk (C/I pregnancy)
- → Drug Interactions:
 - ↓ absorption
 - ↑ or ↓ rate of metabolism
 - ↑ or ↓ synthesis of clotting factors
 - displacement from albumin
 - ↑ or ↓ vitamin K (NB/ dietary intake)
 - altered coagulation (underlying pathophysiology)

Drug Interactions

- numerous and potentially serious
- several different mechanisms involved
- ANY change in medication should ALWAYS be documented (i.e. addition of new medication OR cessation of old medication)

Increased warfarin potency (↑ INR):

- Reduced warfarin clearance
 - Disulfiram, Metronidazole, Trimethoprim-sulfamethoxazole
- Reduced albumin (protein) binding
 - Phenylbutazone (NSAIDS)
- Additive haemostatic effect of certain drugs or disorders
 - Aspirin, Heparin
 - Liver disease
 - Thrombocytopenia
 - Vitamin K deficiency
- Increased turnover of vitamin K
 - Clofibrate
 - Hypermetabolism (e.g., hyperthyroidism)

Decreased warfarin potency (↓ INR):

- Accelerated warfarin clearance-induction of hepatic metabolizing enzymes
 - Barbiturates
 - Rifampicin
- Reduced absorption
 - Cholestyramine
- Impaired metabolism
 - Genetic coumarin resistance

Warfarin – Adverse effects

● Adverse reactions:

- haemorrhage (internal, external)
- N & V, diarrhoea, abdominal cramps
- rash, skin necrosis, alopecia
- allergy
- agranulocytosis

● Overdose:

- antidote: vitamin K (phytomenadione) **injection** (10mg/mL IV, 10mg **oral** tablets)
- effect not immediate, but long lasting (synthesis of new clotting factors)
- action: INR dependent (↓dose, withhold dose, vit K, blood transfusion)

Warfarin - Dosing

- Tx and prophylaxis (CVA, DVT)
 - dose and duration dependent on indication (dose to target INR)
 - 4-5 days for effect
 - Treatment: initiate with heparin/LMWH overlap
 - Start warfarin: 10mg, 5mg, 5mg vs 5mg, 5mg, 5mg
- maintenance dose? 0.5mg – 15mg/day
- many things can alter warfarin effect (compliance, diet → vitamin K, concurrent illness, liver function, medications)
- monitor with International Normalized Ratio (INR) – NB/ change of warfarin dose not reflected in INR until ~ 48 hours later

International Normalised Ratio (INR)

- Monitoring important:
- risk versus benefit parameters - low therapeutic index
 - aim to decrease clotting ability by 2-3x normal
 - measure with clotting time
 - prothrombin time (PT), activated partial thromboplastin time (APTT)
 - commercial thromboplastins: different potencies (PT varies)

INR cont

- **International Normalised Ratio (INR):**

= current blood clotting power : normal clotting power

= patient's PT : standardised normal (mean PT for N individuals)

= uses standardised reagents – ratio adjusted for sensitivity of labs thromboplastin by International Sensitivity Index (ISI)

$$\text{Thus, INR} = (PT_{\text{patient}} / PT_{\text{normal}})^{\text{ISI}}$$

- indirect test of liver function (hepatic production of coagulation factors)
- narrow therapeutic window: dosing (INR 2-3, usually)
- monitoring: daily → weekly → fortnightly → monthly
- blood test ! implications for the patient?

INR and Dosing: ASTH recommendations

MJA June, 2000

<u>Condition</u>	<u>INR range</u>
Prevention of DVT	2.0-3.0
Treatment of DVT/PE	2.0-3.0
Prevention of arterial embolism	2.0-3.0
Mechanical heart valves (high risk)	3.0-4.5
Thrombosis in antiphospholipid syndrome	3.0-4.5

INR and Adverse Effects: Increased INR +/- bleeding

Clinical setting	Action
INR > 5.0 but < 9.0 (no bleeding)	Stop warfarin, give 1-2.5mg Vitamin K1, measure INR in 6-12 hours, restart warfarin at reduced dose once INR < 5.0
INR ≥ 9.0 (no bleeding)	Stop warfarin, give 5mg Vitamin K1, measure INR in 6-12 hours, restart warfarin at reduced dose once INR < 5.0, clotting factor replacement of high risk of bleeding
Major bleeding (any level of INR)	Stop warfarin, give 5mg Vitamin K1, clotting factor replacement, measure INR as required, assess need to restart warfarin

INR and SPAM Dosing Protocol

(refer to handout)



Warfarin → Contraindications

- **Contraindications:**

- medical
- functional
- cognitive
- iatrogenic
- social

*Assessing
patients'
contraindications*

(refer to handouts)



Point of Care Testing

Occupational Health and Safety Issues

➤ **Working with blood products and human tissue:**

- Protective clothing
- Prevention of needle stick injuries
- Blood splatter and contamination issues
- Patient Safety

“Regard all blood and blood products, body fluids and human tissue as if they were infected with pathogens – and use appropriate handling and containment precaution.”

Fullick et al, (1996)

Equipment

➤ Make sure all supplies for testing are easily accessible:

- *Point of care device, including test strips.*
- *Disposable Lancets*
- *Alcohol wipes*
- *Cotton balls*
- *Gloves*
- *Small round bandaid*
- *Biohazard/sharps bin*
- *Disposable surface protector*

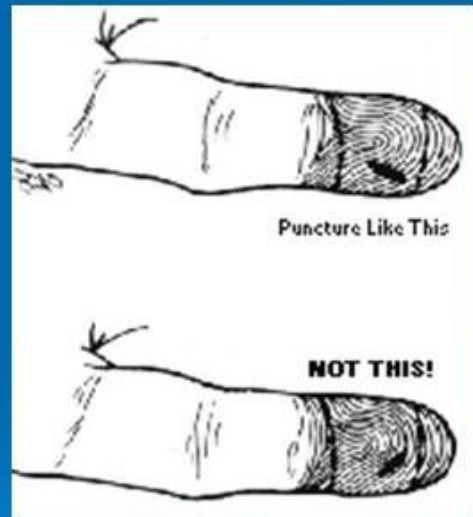
Testing Steps

1. Wash your hands with warm soapy water
2. Put on single use gloves and then place a new surface protector on the table
3. Get the patient to palpitate their hands (to increase blood flow to finger tips).
4. Clean the fingers surface with an alcohol wipe, Dry with cotton ball
5. Insert the test strip into the Glucometer



Testing Steps Continued...

6. Place new lancet on the side of the finger tip, not in the middle. Press down on the lancet trigger and then remove lancet directly into the sharps bin.
7. Press the finger for 3 seconds below the incision. Wipe away the first drop.
8. When the second drop has formed place patients finger over the window on the test strip and drop blood onto it.



Testing Steps Continued...

9. Wipe away excess blood from finger and hold the cotton ball onto the incision with pressure to stop the bleeding.
10. Remove cotton ball and replace with a small bandaid.
11. Roll up surface protector into a ball and wrap them in your gloves as you remove them.
12. Wash hands at the end of each procedure.



Tips for difficult bleeds

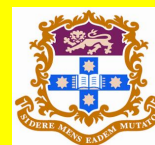
- Hang patients hands down at their side for at least 30 seconds beforehand to increase the blood flow
- Massage their hand to bring the blood to the fingertips, massaging from the base of the hand to the tip is the most effective method.
- Squeeze the finger testing area for at least three seconds before testing
- Wash the patients hands vigorously with warm water
- Use a heat compress or simply a washcloth soaked with hot water to warm the patients hands.

A. John Smith is an 86 year old male taking warfarin because he suffers from Atrial Fibrillation. He has recently commenced Erythromycin tablets to treat a bacterial infection. His last two INR results were both within therapeutic range at 2.2 and 2.4. When tested his current INR level is 2.9.

- Discuss how this medication will affect Mr Smith's INR level?
- Explain the interaction and recommend dosing changes if needed.
- Is there another way to avoid this interaction?

This image shows a single sheet of white paper with horizontal blue ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

- B. Barbara is a 74 year old female who has been on warfarin for the past 6 months for recurrent deep vein thrombosis after a hip replacement 2 years ago. Her INR levels have not been very stable. The last three INR results have been slightly above the therapeutic range at 3.2, 3.5, and 3.8. The patient is known to be unreliable when it comes to always keeping to dietary and medication requirements for warfarin. You have just tested her INR level and the result is 2.8.**
- a. How would you assess this result?
 - b. What action would you recommended in relation to dosing and scheduling of next INR test and why?
 - c. In making your decisions what information would you take into account?



WARFARIN

Medication Information

Booklet

For

Patients and their Carers



SPAM Project (2003): Adapted from "Optimising the Use of Antithrombotic Therapy in Elderly Patients with Atrial Fibrillation" Study.

Your doctor has prescribed warfarin for you to help prevent blood clots

This booklet will help you lead a normal life whilst on this therapy.

Some common questions patients ask:

- What is the medication supposed to do?
- How do I take it?
- For how long do I keep taking it?
- Are there any foods, drinks, or other medications I should avoid?
- What if I miss a dose?
- Are there any side effects, and what do I do if they occur?

This booklet will help answer these questions. If you have any further questions, please ask your health carer.

Also, remember that your local pharmacist is available to help you with your day-to-day medication-related queries.



By following your health carers directions carefully, and referring to this booklet, you will help avoid any problems.



What
is
warfarin?

Warfarin is an anticoagulant – it is a medication that helps stop blood clots from forming.

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

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

Anticoagulants (sometimes called “blood thinners”) slow down the clotting process.

About taking warfarin

Dosage:

- ◆ Take the **exact number of tablets** as prescribed by your doctor.
- ◆ **Don't stop** taking the medication or change the dose unless your doctor tells you to.
- ◆ Take dose at **same time each day**

What if you miss a dose?

If you forget to take a dose at the normal time but then remember within about three hours, you should still take the tablets.

If you forget for a longer time DO NOT take the tablets to catch up, but take your next dose when it is due.

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

DO NOT TAKE A DOUBLE DOSE!

Contact your pharmacist or doctor if you are unsure of what to do.

If you have trouble remembering to take your warfarin, ask someone for help. You can use a calendar or special tablet boxes to remind you. Maybe a friend or relative can help with this.

Speak to your doctor or pharmacist.

Warfarin

The dose of warfarin that your doctor has prescribed for you is in milligrams (mg).

The tablets come in two different brands:

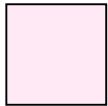
COUMADINTM and **MAREVANTM**

Your doctor and pharmacist will tell you which brand you are taking.

You **MUST** always use the same brand – do not change brands unless advised by your doctor.

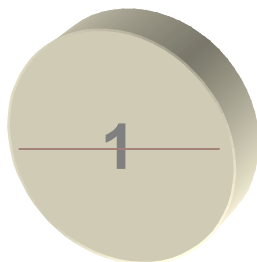
Be sure you are taking the right tablet by checking the:

Brand, colour & strength.

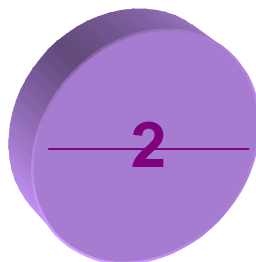


COUMADIN™

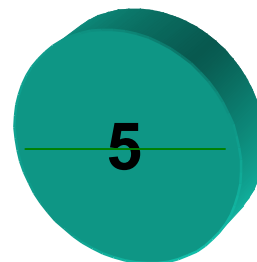
As shown below, the tablets come in three different strengths - each has a separate colour and mg dose to distinguish it from the others.



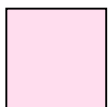
LIGHT TAN
1mg



LAVENDER
2mg

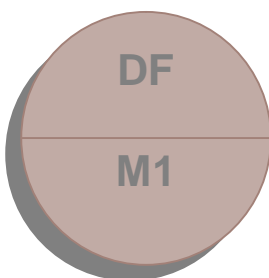


GREEN
5mg

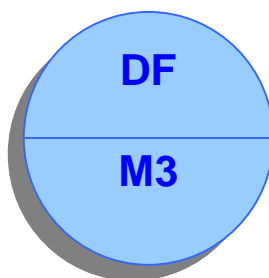


MAREVAN™

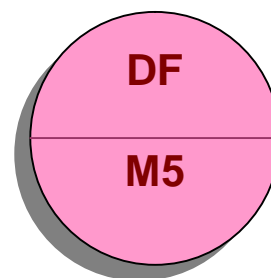
As shown below, the tablets come in three different strengths - each has a separate colour and mg dose to distinguish it from the others.



Light BROWN
1mg



Light BLUE
3mg



PINK
5mg

LABORATORY TESTS ARE IMPORTANT!

Different people require different amounts of warfarin to control their blood's clotting power.

To work out the right dose for each person, a blood test is necessary.

This simple test is called an INR = *International Normalised Ratio*. It shows how long it takes your blood to clot.

Your doctor will ask you to have a blood test from time to time, to check that the warfarin is keeping the clotting process at the correct level.

Remember to: -

- have a test done every time you visit your pharmacist.
- record the test results in this booklet.

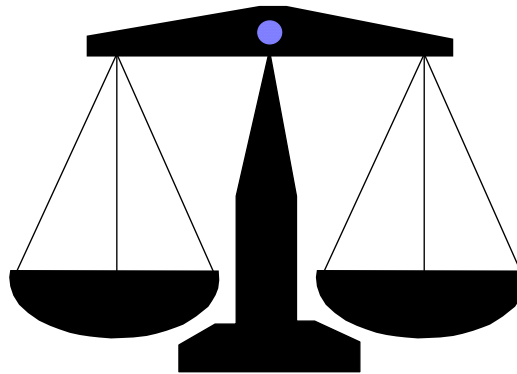
Reducing the chances of problems

The warfarin dose that your doctor prescribes is **balanced** to make sure that blood clots can be prevented, but at the same time making sure that the dose is not too high as to allow bleeding.

Your warfarin dose

The INR blood test helps your doctor to do this.

Stop blood clots

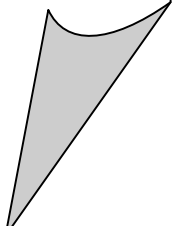


**Avoid
bleeding**

People who are not on warfarin, can usually ignore slight bleeding such as nosebleeds, small cuts etc.

In your case, because you are on warfarin, slight bleeds may in fact become larger bleeds.

It is important for you to be extra careful in looking for signs of this.



Signs of bleeding –what to look for...

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

*Call your doctor
immediately
if you notice any
signs of bleeding
whilst on warfarin*

*The earlier a problem
is detected, the more
easily it is solved!*



Also, tell your Pharmacist or Doctor if you develop:

- an illness (e.g. vomiting, diarrhoea, infection, fever) as this may affect the warfarin dose that you need.
- any unusual symptoms such as pain, swelling or discomfort.

Be careful when doing activities where you may injure yourself and then cause bleeding.

Inform other health carers

You should tell all:



- **doctors, including specialists**
- **dentists**
- **nurses**
- **other health workers and assistants**
- **friends & relatives who look after you**

that you are on warfarin, especially before undergoing any procedure or surgery.

To help let people know, you can order a MedicAlert bracelet from your pharmacist.

Dose adjustment

Other medication, alcohol, and diet, may affect how warfarin works. When there is a big change to any of these things e.g. **when you leave hospital and go home**, you must tell your pharmacist or doctor.

1. Other medications

This includes:

- Prescription medicines - old and new medicines
- Items you may buy in the chemist or supermarket:
 - cough & cold medicines
 - pain relievers, especially aspirin
 - stomach remedies (e.g. antacids)
 - laxatives
 - vitamins
 - herbal preparations.

Before taking ANY medication, you MUST ASK your doctor or pharmacist :

“is it okay for me to use this medication whilst I am on warfarin?”

2. Natural & Herbal Preparations

Do not use any natural or herbal products without talking to your doctor first.

Avoid:

- Garlic supplements
- Ginkgo Biloba
- Herbal teas, especially ‘*Green Tea*’
- Chinese herbs, especially “*Dan Shen*”
- other herbal products

3. Vitamin Supplements

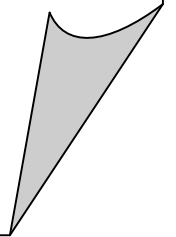
Do not take vitamin supplements without talking to your doctor first. **Vitamins C, E, and K** can affect the way your warfarin works.

Eating a well-balanced diet will keep your intake of vitamins adequate.

4. Alcohol

Drink alcohol in moderation (no more than 2 units per day) & avoid binge drinking.

Discuss with your doctor a safe amount to suit you



5. Your Diet

Maintain a healthy balanced diet

Avoid crash dieting or binge eating - your dosage of warfarin has been adjusted to match your current eating pattern.

Stabilize your intake of vitamin K - vitamin K has the opposite effect to warfarin. A **HIGH** intake of vitamin K can affect the way your warfarin works.

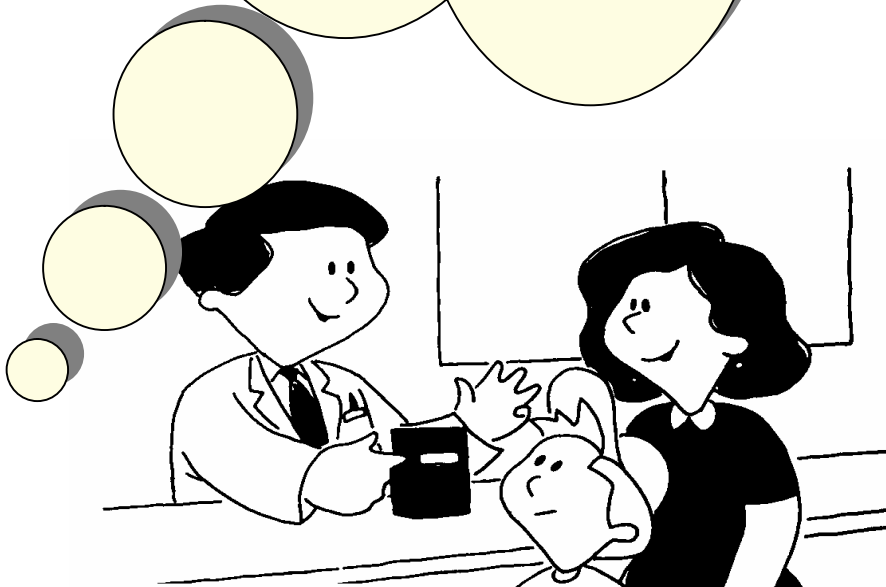
A constant intake of vitamin K to match your dose of warfarin is the key to good control!

Foods which are high in vitamin K include green leafy vegetables (spinach, alfalfa, broccoli, lettuce, cabbage). Make sure your intake of these is stable.

A moderate amount of vitamin K is found in meats and dairy foods.

Low vitamin K foods include: fruits, cereals, & other vegetables.

Those foods
*containing high
levels of vitamin K*
SHOULD be eaten
in normal amounts
✓
- do not binge eat!



Patient Details

Name of patient	
Address	
Telephone	
Name of Doctor	
Telephone	
Name of Pharmacy	
Telephone	

Details of Therapy

Anticoagulant prescribed (& brand)	Warfarin
Reason	
Duration of therapy	Long Term
Date started	/ /
Target INR	
Other details or special instructions	

DATE	INR	Mon	Tues	Wed	Thur	Fri	Sat	Sun	Next visit or test

DATE	INR	Mon	Tues	Wed	Thur	Fri	Sat	Sun	Next visit or test

DATE	INR	Mon	Tues	Wed	Thur	Fri	Sat	Sun	Next visit or test

DATE	INR	Mon	Tues	Wed	Thur	Fri	Sat	Sun	Next visit or test
		Dose prescribed (mg)							

DATE	INR	Mon	Tues	Wed	Thur	Fri	Sat	Sun	Next visit or test
		Dose prescribed (mg)							

DATE	INR	Mon	Tues	Wed	Thur	Fri	Sat	Sun	Next visit or test

Your pharmacist is here to help you.

What will I do for you?

Review your medications

I will review your medication orders every time you see me. I will work with your doctor to maximize the benefits and the safety of the medications you are receiving.

Teach you about your medications

I will tell you the purpose of your medications, how to take them, possible side effects, and any other important information you may need to know.

What can you do for me?

Whilst you are involved in the project I may ask you to tell me:

- the names of all the medications you have been taking at home (including medications that you bought from another pharmacy, supermarket, or health food shop), and
- if you have had any unexpected reactions or allergies to any medications in the past.

The other thing I would like you to do is:

- ***Ask me questions about anything you don't understand about your medications.***

This information booklet has been updated specifically for use in the project:

“Sydney Pharmacy Anticoagulant Management (SPAM)”

For further information regarding the project, please contact:

Megan Spindler (Research Officer)
Pharmacy Department, University of Sydney NSW
Phone: (02) 9351-6471
Email: megan@pharm.usyd.edu.au

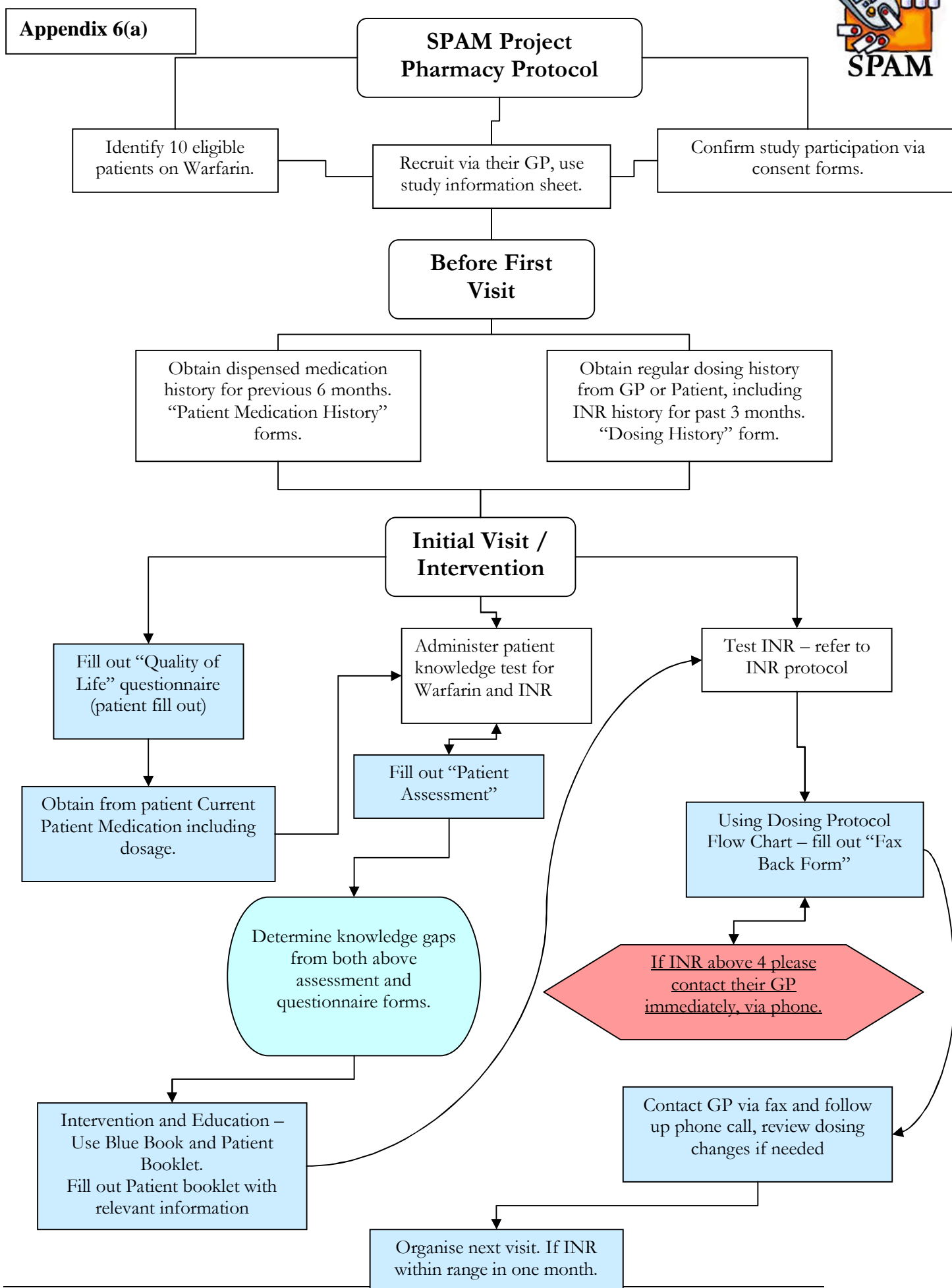
OR

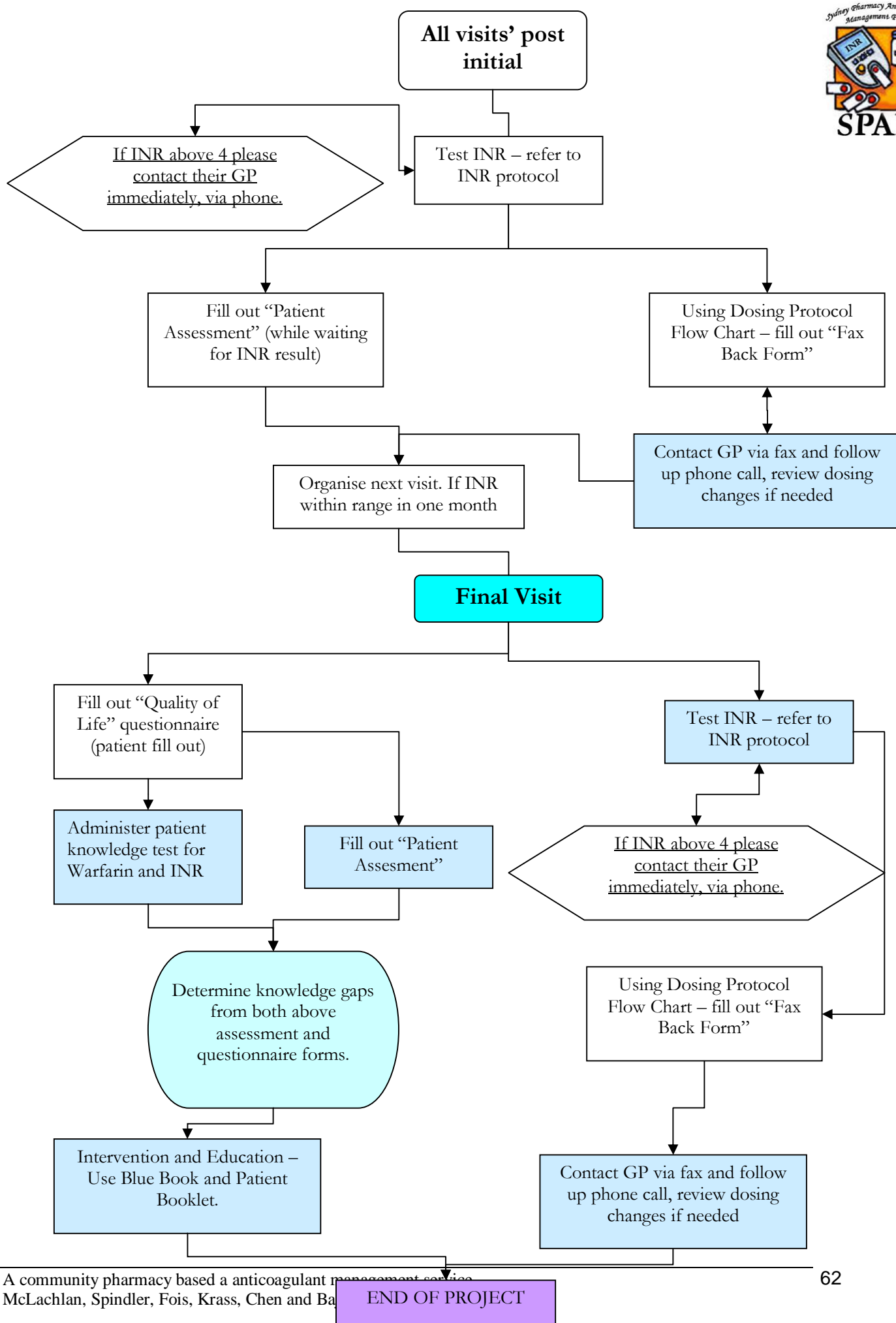
Dr Andrew McLachlan (Chief Investigator)
Pharmacy Department, University of Sydney NSW
Phone: (02) 9351-4452
Email: andrewm@pharm.usyd.edu.au

Acknowledgements:

This booklet was from the original version, with permission, from the “Optimising the Use of Antithrombotic Therapy in Elderly Patients with Atrial Fibrillation” Study.

B.V.Bajorek. “Stroke prevention in elderly patients with atrial fibrillation.” [Thesis] Faculty of Pharmacy, University of Sydney, 2002. Sydney, Australia.





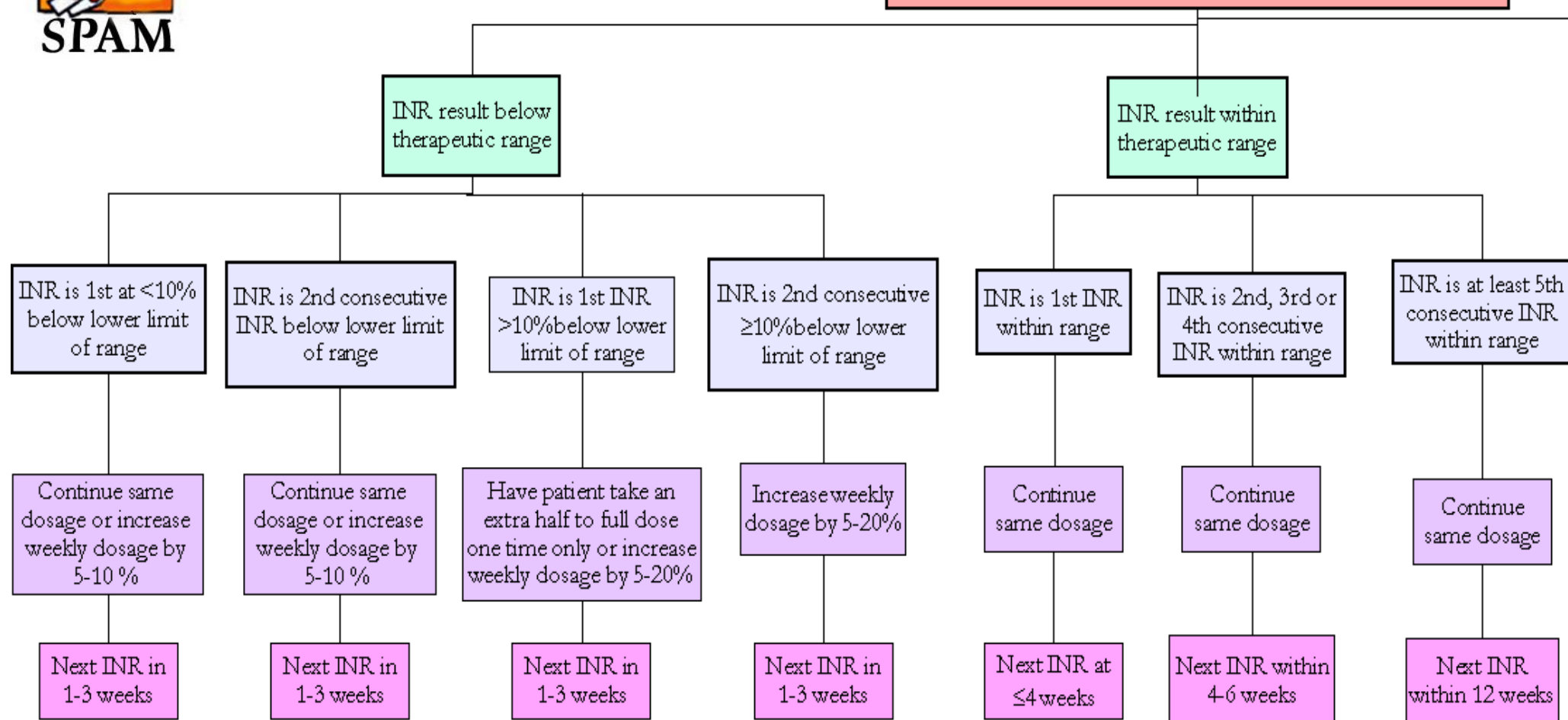
Appendix 6(b):

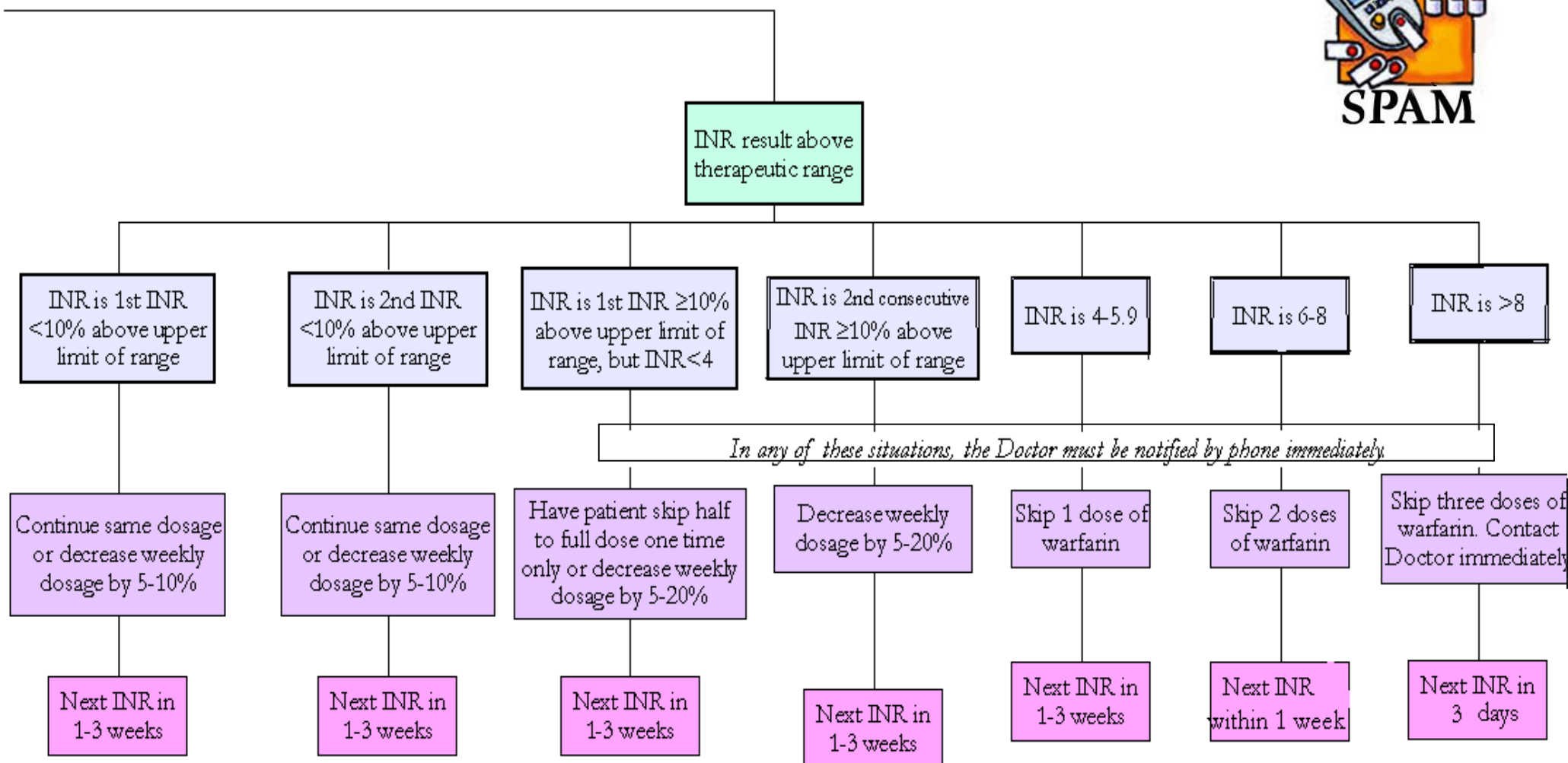


Expected INR range:

Deep Vein Thrombosis, Pulmonary Embolism, Arterial Disease, Atrial Fibrillation = 2.0 - 3.0

Cardiac Prosthetic Valves = 2.5 - 3.5





Patient Code



Appendix 7:

Confidential INR Results and Dose Recommendations

Attention: _____

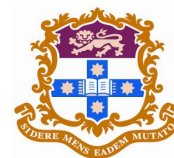
From; Pharmacy: _____ **Pharmacist:** _____

Phone Number: _____ **Fax Number:** _____

To be filled out by pharmacist at every visit and faxed to the patient's Doctor.

Patient Details:

Surname:	First name:
Phone Number:	Date of Birth:



Results:

Date:	Current INR Result	Last INR Result	Previous INR History is Attached

Dose Recommendations:

- ☐ Continue Current Dosage
- ☐ Recommended Changes: *(If changes are made please contact patient's Doctor by both phone and fax)*

Please note any interventions raised : *(Pharmacists please include information regarding changes in patient diet, medications and lifestyle)*

Pharmacist Signature: _____ **Date:** _____

Physician Feedback:

- ☐ Agree with recommendations
- ☐ Alternative suggestions *(please specify below)*

Physician Signature: _____ **Date:** _____

Please Fax this form back at your earliest convenience with any further recommendations and your signature.

If you have any queries or problems do not hesitate to call either Megan Spindler on (02) 9351 6471, 0410468855 or Dr Andrew McLachlan on (02) 9351 4452.

Appendix 8:

INR Result Chart

Patient Code

To be filled out by pharmacist at each visit and then faxed with covering fax back form to Patient's Doctor.

<u>Surname:</u>	<u>Date of Birth:</u>
-----------------	-----------------------

[illegible]

If you have any queries or problems do not hesitate to call either Megan Spindler on (02) 9351 6471, 0410468855 or Dr Andrew McLachlan on (02) 9351 4452.

Medical Status Form

Patient Code



Medical status details to be filled out by Doctor on entry into the project.
Patients and Pharmacists details to be filled out by the Pharmacist.

Patient Details:

<u>Surname:</u>	<u>First name:</u>	<u>DOB:</u>
<u>Address:</u>		
<u>Post Code:</u>	<u>Phone Number:</u>	<u>Patient Code:</u>

Pharmacist Details:

<u>Name:</u>	<u>Address:</u>
<u>Fax Number:</u>	<u>Phone Number:</u>

Physician Details:

<u>Name:</u>	<u>Address:</u>
<u>Fax Number:</u>	<u>Phone Number:</u>

Patient History:

Reason for Warfarin Therapy:

Expected Duration of Therapy:

Start Date: _____ Expected End Date: _____

Please specify details of Current Medical conditions:

Please include history of bleeding or clots, pre or post commencement of Warfarin:

Please Specify Current Medication (other than Warfarin):

Drug Name	Date Started	Dosing Schedule	Reason for Use

Current Frequency of INR Testing:

- ☐ Every Second Day
- ☐ Weekly
- ☐ Monthly
- ☐ Every Second Month

Current Daily Dose of Warfarin: _____ *(if not consistent)*

Current Dosing Protocol: **Mon** **Tues** **Wed** **Thurs** **Fri** **Sat** **Sun**

If you have any queries or problems do not hesitate to call either Megan Spindler on (02) 9351 6471, 0410468855 or Dr Andrew McLachlan on (02) 9351 4452.

Date

Patient Code



Patient Assessment

To be filled out by pharmacist at every visit during the study.

<u>Surname:</u>	<u>Date of Birth:</u>

Please fill out the following while waiting for INR results.

Current Daily Dosage for Warfarin: _____

(If different for each day please state below)

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
_____	_____	_____	_____	_____	_____	_____

Has the patient missed any Warfarin doses since their last INR test?

If so, when? _____

Has the patient had any recent episodes of bleeding or related discomfort?

If so, explain? _____

Has the patient taken or made any changes to any of the following since their last INR test?

<i>If yes, add explanation.</i>	Yes	No	Explanation
Vitamin:	<input type="checkbox"/>	<input type="checkbox"/>	_____
Antibiotics:	<input type="checkbox"/>	<input type="checkbox"/>	_____
Cough/cold medication:	<input type="checkbox"/>	<input type="checkbox"/>	_____
Stomach Medications:	<input type="checkbox"/>	<input type="checkbox"/>	_____
Pain Medications:	<input type="checkbox"/>	<input type="checkbox"/>	_____
Alcohol:	<input type="checkbox"/>	<input type="checkbox"/>	_____
Change in Diet:	<input type="checkbox"/>	<input type="checkbox"/>	_____
Other Medications:	<input type="checkbox"/>	<input type="checkbox"/>	_____

If you have any queries or problems do not hesitate to call either Megan Spindler on (02) 9351 6471, 0410468855 or Dr Andrew McLachlan on (02) 9351 4452.

Patient History: Warfarin

Patient Code

Patient Details:

<u>Surname:</u>	<u>First name:</u>	<u>DOB:</u>



To be filled out by Patient's Doctor. Please include information for the last twelve months.

Please specify the number of visits to your practice over the last 12 months:

Have there been any adverse events over the last twelve months? If so please specify.

If you have any queries or problems do not hesitate to call either Megan Spindler on (02) 9351 6471, 0410468855 or Associate Professor Andrew McLachlan on (02) 9351 44

Patient Details:

<u>Surname:</u>	<u>First name:</u>	<u>DOB:</u>
-----------------	--------------------	-------------

*To be filled out by Patient's Doctor or photocopied from the patients warfarin records (i.e. their blue book)
Please include the Dosing History for the last twelve months.*

[illegible]

If you have any queries or problems do not hesitate to call either Megan Spindler on (02) 9351 6471, 0410468855 or Dr Andrew McLachlan on (02) 9351 4452.

Patient History: Warfarin Dosing



Patient Code

Patient Details:

<u>Surname:</u>	<u>First name:</u>	<u>DOB:</u>
-----------------	--------------------	-------------

To be filled out by Patient's Doctor or photocopied from the patients warfarin records (i.e. their blue book)
Please include the Dosing History for the last twelve months.

Date:	INR	Mg/day (please specify if alternate day dosing)	Date:	INR	Mg/day (please specify if alternate day dosing)

If you have any queries or problems do not hesitate to call either Megan Spindler on (02) 9351 6471, 0410468855 or Associate Professor Andrew McLachlan on (02) 9351 4452.

Patient Code



Patient History: Other Medications

Patient Details:

<u>Surname:</u>	<u>First name:</u>	<u>DOB:</u>

Please list the Patients Recent Medication History from your records

On initial visit please confirm any changes to this record with the patient.

Medication Name and Dose	Start Date	Dose Regiment	Regularly Used (Y/N)	Currently Used (Y/N)

If you have any queries or problems do not hesitate to call either Megan Spindler on (02) 9351 6471, 0410468855 or Dr Andrew McLachlan on (02) 9351 4452.

Appendix 9:

Quality of Life Questionnaire

(Revised Version February 1999; R. Steihoff and P.T. Sawicki)

There are a lot of personal fears connected with the anticoagulation treatment. We would like to know your thoughts and feelings during the treatment so we can give you adequate support in dealing with anticoagulation.

The following sentences originate from patients on anticoagulation treatment. Please mark spontaneously the statements which were personally most relevant to you during the last few weeks.

Which statement applied to you during the last weeks...

		doesn' t apply	hardly applies	doesn' t quite apply	applies a little	applie s a great deal	applies fully
1	My treatment causes me to feel worried or stressed.	•	•	•	•	•	•
2	The effort in controlling my blood coagulation values bothers me when away from home.	•	•	•	•	•	•
3	Despite my treatment I am able to organize my free time as I wish.	•	•	•	•	•	•
4	I am dissatisfied with the amount of time I have to invest in checking my blood values.	•	•	•	•	•	•
5	I feel I've learned to cope with my treatment.	•	•	•	•	•	•
6	Despite the risk of injury, I can carry out my housework without feeling restricted.	•	•	•	•	•	•
7	I avoid doing certain activities (i.e. riding a bike) because of the risk of accidents.	•	•	•	•	•	•
8	My treatment worries my relatives.	•	•	•	•	•	•
9	I can cope well with the problems related to my treatment which can occur.	•	•	•	•	•	•
10	I worry about my future health.	•	•	•	•	•	•
11	Due to the high risk of injury I'm scared of doing spontaneous physical exercise.	•	•	•	•	•	•

		doesn' t apply	hardly applies	doesn' t quite apply	applies a little	applies a great deal	applies fully
12	I am dissatisfied with the length of time needed before getting the results of my blood coagulation values.	•	•	•	•	•	•
13	I'm worried that my treatment could shorten my life.	•	•	•	•	•	•
14	I dislike having to plan in detail my activities in advance.	•	•	•	•	•	•
15	The uncertainty that I experience while waiting for my blood coagulation results, bothers me.	•	•	•	•	•	•
16	I have less contact with friends since undergoing my treatment.	•	•	•	•	•	•
17	I avoid going on holiday because I'm unable to estimate the negative effects the different food could have on my treatment results.	•	•	•	•	•	•
18	I'm well informed as to what I must do in order to achieve a blood coagulation value within target limits.	•	•	•	•	•	•
19	I feel dependent on my anticoagulant medication.	•	•	•	•	•	•
20	I avoid traveling as I'm afraid of not receiving adequate treatment, in case of my blood coagulation value being too low or too high.	•	•	•	•	•	•
21	I'm fed up with the amount of time spend on visiting the doctor.	•	•	•	•	•	•
22	I would take a more active interest in sport if I didn't have to take anticoagulants.	•	•	•	•	•	•
23	I have problems at work because I'm often absent (due to my treatment).	•	•	•	•	•	•
24	Sometimes I'm not sure if I can cope with my treatment.	•	•	•	•	•	•
25	I tend to worry about things.	•	•	•	•	•	•

		doesn' t apply	hardly applies	doesn' t quite apply	applies a little	applies a great deal	applies fully
26	Despite regular visits to the doctor, I don't feel restricted.	•	•	•	•	•	•
27	It upsets me that most people don't understand the problems connected with my treatment.	•	•	•	•	•	•
28	When going to the dentist or other doctors, I'm worried about them not knowing enough about anticoagulation.	•	•	•	•	•	•
29	My treatment has affected my sex life.	•	•	•	•	•	•
30	It bothers me being treated as an invalid.	•	•	•	•	•	•
31	I am worried about the side effects anticoagulants could have on me.	•	•	•	•	•	•
32	I worry about how others react to my treatment.	•	•	•	•	•	•

Thank you for your support.

MANUAL

Treatment-related quality of life (for patients receiving oral anticoagulation)

R. Steinhoff, P.T. Sawicki

In order to explain treatment-related quality of life patient-centred, the description of feelings with regard to their treatment was collected of members of self-help groups for patients receiving oral anticoagulation. These sentences were specified to five socio-psychological topics of which 40 were combined into a questionnaire. The items covered the following psychological topics: medical treatment satisfaction, self-efficacy, strained social network, daily hassles, and general psychological distress. These constructs were determined because they confirm the reliability and validity to treatment-related quality of life in psychological research (1, 2).

Based on the perceptions of Schwarzer (3) it is shown that specified assessments could better explain and predict behaviors than generalized scales. Therefore items were specially designed for patients receiving oral anticoagulation. 32 items (8 items were cancelled because of low corrected item total-correlations) were factor loaded - varimax rotated - at baseline (t1) and at 6-month follow-up (t2). All scales loaded to five factors as well at baseline as at 6-month follow-up. The 5 factors explain 52,4 % to t1 and 53,6 % to t2 of total variance. The study patients estimated the impact of every item on their self-perceived treatment-related quality of life by a graded scale ranging from doesn't apply /1, hardly applies /2, doesn't quite apply /3, applies a little /4, applies a great deal /5 to applies fully /6. For every topic the total score was divided by the number of items included, resulting in a minimum score of 1 to a maximum of 6 for every factor.

Medical treatment satisfaction

In accordance with face validity the scale medical treatment satisfaction was designed. Items were developed that describe this construct well. In this way it was measured whether the patients after this intervention feel more content inspite of greater self-management and self-adjustment of oral coagulation.

Item	corr it t1	corr it t2
2	.52	.67
4	.64	.73
12	.65	.74
15	.56	.65
21	.48	.53

n = 5

All items have to reverse. High values describe great medical treatment satisfaction.

Self-efficacy

Bandura (4) introduced this construct. It pertains to optimistic self-beliefs about dealing with critical demands that tax an individual's resources. Human functioning is facilitated by a personal sense of control. If people believe that they can take action to solve a problem instrumentally, they become more inclined to do so and feel more committed to this decision. Self-efficacy reflects the belief of being able to control challenging environmental demands by means of taking adaptive action. It can be regarded as a selfconfident view of one's capability to deal with certain life stressors (5, 6).

Self-efficacy has continuously become a more widely accepted psychological construct and pervades psychological research in many domains. It has been found that a strong sense of personal efficacy is related to better health and higher achievement. Therefore it was of great interest to prove the intervention's influence on this factor.

Item	corr it t1	corr it t2
5	.35	.33
9	.51	.43
18	.34	.44
24	.43	.48

n = 4

Item 24 has to reverse. High values describe great self-efficacy.

General psychological distress

The measurement of the construct general psychological distress would be able to give information about the degree of general psychical burden according to their oral anticoagulation. Referring to the assessment „Qualitätsmanagement in der Diabetologie (Fragen zur Lebensqualität)“ corresponding items were specified.

Item	corr it t1	corr it t2
1	.58	.48
10	.64	.56
13	.45	.59
19	.45	.44
25	.56	.58
30	.30	.30
31	.55	.64

n = 7

No Item has to reverse. High values describe great general psychological distress.

Daily hassles

The topic daily hassles informs about theoretical reflections of Lazarus and his colleagues (7) explaining that not only critical life events force distress but also accumulated daily simple disorder. As self-management in accordance with chronical diseases demand frequent self-measurement it is interesting to get specified information about cost and benefit of the intervention. Item 3, 6, 23, 26 and 28 remained in the study because of stabilization of the corrected item values and to obtain the information.

Item	corr it t1	corr it t2
------	------------	------------

3	.24	.39
6	.09	.32
14	.48	.53
23	.53	.24
26	.36	.18
27	.54	.41
28	.26	.39
29	.33	.32

n = 8

Items 3, 6, 26 have to reverse. High values describe great daily hassles.

Strained social network

The quality of social support could be of great importance in accepting the inconveniences of the oral anticoagulation. As shown by the meta-analysis of Schwarzer & Leppin social support is negatively related with health (8). Therefore in this study the items were brought into focus of burden.

Item	corr it t1	corr it t2
7	.59	.49
8	.44	.46
11	.55	.48
16	.49	.35
17	.52	.52
20	.61	.69
22	.54	.49
32	.55	.32

n = 8

No item has to reverse. High values describe highly strained social network.

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Appendix 10:

Warfarin Knowledge Assessment Questionnaire

Patient		Interviewer	Date	Time			
		Question	Correct Answer	Answer Given		Additional Notes	Information References
*§	1	Why are you taking warfarin?	To thin the blood / prevent blood clots	<input type="checkbox"/> Correct	<input type="checkbox"/> Incorrect <input type="checkbox"/> Don't know		Blue Book Pg 3
	2	How long will you be taking warfarin for?		<input type="checkbox"/> Stated _____	<input type="checkbox"/> Don't know		Depends on indication. Refer to Dr information
	3	Which brand of warfarin are you taking?	Coumadin / Marevan	<input type="checkbox"/> Coumadin <input type="checkbox"/> Marevan	<input type="checkbox"/> Incorrect <input type="checkbox"/> Don't know		Mark in Pt booklet.
#	4	What is the strength of your warfarin tablets?	1mg/2mg/5mg – Coumadin 1mg/3mg/5mg – Marevan	<input type="checkbox"/> 1mg <input type="checkbox"/> 2mg <input type="checkbox"/> # 5mg <input type="checkbox"/> 1mg <input type="checkbox"/> 3mg <input type="checkbox"/> 5mg	<input type="checkbox"/> Incorrect <input type="checkbox"/> Don't know		Blue Book Pg 1 – 2 Explain colour differences.
#	5	What is the colour of your warfarin tablets?	Coumadin Marevan	<input type="checkbox"/> Light tan <input type="checkbox"/> Lavender <input type="checkbox"/> Green <input type="checkbox"/> Brown <input type="checkbox"/> Blue <input type="checkbox"/> Pink	<input type="checkbox"/> Incorrect <input type="checkbox"/> Don't know		As above.
	6	Is it OK to switch brands of warfarin tablets?	No, you must NOT change your brand of warfarin tablets	<input type="checkbox"/> Correct	<input type="checkbox"/> Incorrect <input type="checkbox"/> Don't know		As above.
	7	Why do you need to have your INR tested?	To measure how thick or thin the blood is	<input type="checkbox"/> Correct	<input type="checkbox"/> Incorrect <input type="checkbox"/> Don't know		Blue Book Pg 4.

*	8	Can you tell me what your INR was last time it was measured?		<input type="checkbox"/> Stated _____	<input type="checkbox"/> Don't know		Show how and why to keep a record.
*§	9	Do you know what your target INR range is?	3.0-4.5 Older model mech. heart valve 2.5-3.5 newer model heart valve 2.0-3.0 All other indications	<input type="checkbox"/> Stated _____	<input type="checkbox"/> Incorrect <input type="checkbox"/> Don't know		Mark into Pt booklet for them.
*	10	What would happen if your INR were too high?	Bleed too much	<input type="checkbox"/> Correct	<input type="checkbox"/> Incorrect <input type="checkbox"/> Don't know		Explain correspondence of clotting and INR.
*	11	What would happen if your INR were too low?	Blood will clot too much	<input type="checkbox"/> Correct	# Incorrect # Don't know		As above.
†	12	Which of the following things may interfere with the way warfarin works?		<input type="checkbox"/> Other drugs <input type="checkbox"/> Some foods <input type="checkbox"/> Illness/infection <input type="checkbox"/> Alcohol <input type="checkbox"/> Weather			Those not stated, refer to Blue Book Pg 7 – 12.
†	13	Do you take your warfarin at a certain time of the day	Warfarin should be taken at the same time in relation to meals each day	<input type="checkbox"/> Yes, in the evening <input type="checkbox"/> Yes, in the morning	<input type="checkbox"/> No <input type="checkbox"/> Don't know		Blue Book Pg 12 – 13.
*	14	What would you do if you forgot to take your warfarin tablet?	If you forget, but remember within 2-3 hours of the time you should have taken it, you can still take the tablet. If you forget for a longer time, do not take the tablets, but continue taking tablets as normal, and tell your Dr	<input type="checkbox"/> Correct	<input type="checkbox"/> Incorrect <input type="checkbox"/> Don't know		IMPORTANT Do Not Double Dose.
*	15	Which medications should you tell your Dr you are taking while you are taking warfarin?	All	<input type="checkbox"/> Correct	<input type="checkbox"/> Incorrect <input type="checkbox"/> Don't know		
*#	16	Do you know of any OTC or herbal medications which may interact with warfarin		<input type="checkbox"/> Stated _____ _____ _____	<input type="checkbox"/> Don't know		Blue Book, Pg 11

*	17	What other healthcare professionals besides your Dr should you tell you are taking warfarin	All	<input type="checkbox"/> Dentist <input type="checkbox"/> Pharmacist <input type="checkbox"/> Specialist <input type="checkbox"/> Other_____	<input type="checkbox"/> Don't know		Inform of those not stated.
*§	18	What side effects of warfarin should you watch out for?	Bleeding	<input type="checkbox"/> Correct	<input type="checkbox"/> Incorrect <input type="checkbox"/> Don't know		Remind them to always keep you and Dr informed.
	19	What signs or symptoms of bleeding might you notice?		<input type="checkbox"/> Excessive bleeding <input type="checkbox"/> Black stools <input type="checkbox"/> Dark-red/brown urine <input type="checkbox"/> Vomit/cough up blood <input type="checkbox"/> Bleeding gums <input type="checkbox"/> Excessive bruising	<input type="checkbox"/> Incorrect <input type="checkbox"/> Don't know		Inform of those not stated. Use Pt booklet as reference.
	20	What would you do if you experience any of these symptoms?	Report to your GP and Pharmacist.	<input type="checkbox"/> Correct	<input type="checkbox"/> Incorrect <input type="checkbox"/> Don't know		As above.
*	21	When you have a question about your warfarin, whom would you ask?	Doctor, pharmacist	<input type="checkbox"/> Doctor <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other_____	<input type="checkbox"/> Don't know		As above.
	22	Where did you obtain your information about warfarin?		<input type="checkbox"/> Local GP <input type="checkbox"/> Dr in hospital <input type="checkbox"/> Blue warfarin book <input type="checkbox"/> Internet <input type="checkbox"/> Friends <input type="checkbox"/> Other_____	<input type="checkbox"/> Nowhere <input type="checkbox"/> Don't know		

Appendix 11: Clinical data for patients in the *intervention* arm of the study

Patient	Disorders
A-01-01	Atrial Fibrillation, Hypertension, Osteoarthritis, Skin cancers
A-01-02	Atrial Fibrillation, Osteoarthritis
A-01-04	Atrial Fibrillation, Hypertension, Gout, Hyperglycaemia, Hyperlipidaemia, Coronary Artery Bypass Graft, Ischemic Heart Disease
A-01-05	Atrial Fibrillation , Angina, Hypertension, Demyelination, Pulmonary vein disease, Squamous Cell Carcinoma (Skin Cancer), Acne
A-01-06	Osteoporosis, Myocardial infarction, Irritable bowel syndrome
A-01-07	Dysfunctional Mitral valve, Osteoarthritis, Scoliosis, Hypertension, Hyperlipidaemia
A-01-08	Recurrent deep vein thrombosis, Transient Ischaemic Attacks, Ischaemic Heart Disease, Hyperlipidaemia, Hypertension
A-01-09	Atrial Fibrillation
A-02-01	Sleep Apnea, Dilated left atrium, Recurrent Transient Ischaemic Attacks Hypertension, Ischaemic Heart Disease, Cardiomyopathy, Hyperlipidaemia Glaucoma, Gout
A-02-02	Atrial Fibrillation, Cardiomyopathy, breast carcinoma (mastectomy), congestive cardiac failure, cellulitis, mitral regurgitation
A-02-03	Atrial Fibrillation, Pacemaker, Hypertension, Hyperlipidaemia, <i>Lentigo maligna</i>
A-02-04	Benign prostatic hypertrophy, Atrial Fibrillation, Hyperlipidaemia, Hypertension, Hyperuricaemia, Cardiomyopathy, Diabetes
A-02-05	Atrial Fibrillation , Diabetic neuropathy, Hepatitis, Diabetes Mellitus
A-02-06	Atrial Fibrillation, Glaucoma, Hypothyroidism, Hypertension
A-02-08	Deep vein thrombosis, Atrial Fibrillation, Hyperlipidaemia, Hypertension
A-02-09	Atrial Fibrillation, Hypertension, Hyperlipidaemia, Hyperuricaemia
A-02-10	Hypertension, Diabetes mellitus, Hyperlipidaemia
A-03-01	Atrial Fibrillation, Hypertension
A-04-02	Aortic valve replacement, Coronary bypass, Diabetes Mellitus, Angina Hyperlipidaemia
A-04-03	Asthma, Sinusitis, Hypertension, Mechanical heart valve, Heart failure,
A-05-01	Atrial Fibrillation, Hyperlipidaemia, Irritable bowel syndrome, Hypertension
A-05-02	Atrial Fibrillation , Hypertension, Hyperlipidaemia, Insomnia
A-05-03	Atrial Fibrillation, Congestive cardiac failure, Hypertension, Asthma, Alzheimer's disease, Hyperlipidaemia
A-05-04	Atrial Fibrillation, Depression, Hypertension, peptic ulcer
A-05-06	Atrial Fibrillation, Hypertension
A-05-07	Atrial Fibrillation, Deep vein thrombosis, Hyperlipidaemia, Hypertension Myocardial infarction, Osteoarthritis
A-05-08	Heart valve replacement, Hypertension, Angina
A-05-09	Atrial Fibrillation, Hyperlipidaemia, Hypertension
A-07-01	Heart failure, Glaucoma, Osteoarthritis, Congestive cardiac failure, Hyperlipidaemia, Atrial flutter, Mild renal impairment, Hypertension
A-07-02	Deep vein thrombosis, Coronary Artery Bypass Graft, Hypertension, Hyperlipidaemia, Angina, Oedema
A-07-03	Atrial Fibrillation, Pulmonary atrial embolism, Diabetes, Depression, enlarged prostate, Hypertension, Hyperlipidaemia, Bladder carcinoma
A-07-04	Atrial Fibrillation, Hypertension, Hyperlipidaemia, Asthma
A-07-05	Atrial Fibrillation
A-07-06	Atrial Fibrillation, Hypertension, Angina pectoris
A-07-07	Atrial Fibrillation, Hyperlipidaemia, Hypertension, Reflux/ulcer

A-07-08	Asthma, Hypertension, Hyperlipidaemia, Cardiomyopathy
A-07-09	Coronary Artery Bypass Graft, Ischemic Heart disease, Atrial Fibrillation Asthma, Hypertension, Hyperlipidaemia
A-07-10	Mitral valve replacement, Hypertension, Atrial Fibrillation, transient ischaemic attacks, Gallstones, Pancreatitis, Hyperlipidaemia
A-08-01	Atrial Fibrillation
A-08-02	Atrial Fibrillation , Gout, Hiatus hernia, Hypertension, Lobectomy - adenocarcinoma lung, Related cardiomyopathy, Hyperlipidaemia
A-08-03	Atrial Fibrillation, Asbestosis pleural plaques, Glaucoma, Gout, Hypertension Melanoma (arm), Sleep apnoea, Tinnitus, Intraocular Lenses (bilateral)

Concomitant medications taken by patients in the intervention group (other than warfarin)

A-01-02	Nil
A-01-04	Carvedilol, Lipitor, Felodur, Diaformin, Karvezide, Aldactone ,Diamicon, Lamisil tab, Ibilex
A-01-05	Cosopt Eye Drops, Eryacne gel, Coversyl, Dilatrend, Vit C, Vit B, Vit E, Magnesium plus, Folic Acid, Chromium
A-01-06	Karvea, Lipex, Sotacor, Viagra, Normison
A-01-07	Ramipril, Simvastatin, Amiodarone
A-01-08	Iscover, Menorest, Imdur, Prinivil, Zandip, Zocor, Provera, Betaloc, Lanoxin
A-01-09	Fosamax, Karvezide
A-02-01	Corbeton, Lipex, Somac, Tritace, Xalatan eye drops, Zylprim, Vitamin B12, folate
A-02-02	Lasix, Amiodarone, Carvedilol, Tritace, Tamoxifen, Sotalol, Ramipril, vit C, vit E
A-02-03	Cardizem CD, Coversyl, Sotalol, Zocor, Genteal gel eye drops
A-02-04	Coversyl, Dilatrend, Lipitor, Zylprim
A-02-05	Actrapid, Avapro, Flixotide accuhaler, Novorapid, Protaphane
A-02-06	Alphagan eye drop, Aristocort cream, Betoptic eye drops, Lanoxin, Oroxine, Plendil ER, Xalatan Mareye dropsevan
A-02-08	Magnesium, vit C, multifibre, Luteim/ Bilberry
A-02-09	Aldactone, Carvedilol, Diamicon, Digoxin, Frusemide, Metformin, Tritace, Zocor, Zylorim
A-02-10	Lasix, Norvasc, Capoten, Minidiab, Lanoxin
A-03-01	Caltrate, Panamax, Isoptin, Provera, Premarin, Cephalexin
A-04-02	Aspirin, Amaryl, Metformin, Atorvastatin, Protaphane, Ramipril, Daonil, Lipitor, Diabex, Zolof, Minidiab
A-04-03	Coversyl, Seretide, Rhinocort nasal spray, Amoxil
A-05-01	Coumadin, Colgout, Avapro, Vagifem pessaries, Pravachol, Dapa-tabs, Panamax, Lisodur, Topical powder (boric acid 5%, Zinc oxide 5% in talc), Alphamox, Celestone –M cream
A-05-02	Temaze, Tramal SR, Flarex eye drop, Lipitor, Hycor eye drops

A-05-03	Spiractin, Lasix-M, Flixotide accuhaler, Dilantin sodium, Lanoxin, Inza, Prednisone, Exelon, Span-K, Dexamethasone, Cilopen VK, Ferrosig AMP, Tramal, Digoxin, Pravachol, Quinbisul, Iblex
A-05-04	Lexapro, Zanicid, Prodeine forte, Karvezide, Acimax
A-05-06	Felodur ER, Bactigras Dressing
A-05-07	Iscover/ Plavix, Lipex, Coversyl plus, Polytears eye drops, Lumigan eye drops, Patanol eye drops, Mobic, Elocon ointment, Waxsol eye drops Celestone cream, Hycor eye drops, Advantan cream, Travatan eye drop
A-05-08	Norvasc, Coversyl, Lasix
A-05-09	Atacand, Lipex, Accupril, Nexium, Lanoxin, Polytears eye drops, Alphamox, Amoxil
A-07-01	Dilatrend, Frusid, Neocytamen injection, Keflex
A-07-02	Aspirin, Amiodarone, Uremide, Imdur, Zocor, Tritace
A-07-03	Karvezide, Mogadon, Luvox, Refresh tears plus, Diabex, Lanoxin – PG, Hytrin, Alodorm, Metformin, Vioxx, Panamax
A-07-04	Tritace, Zocor, Curam, Seretide Metered Dose Inhaler , Anpec, Quinsul, Zocor, Temaze, Caltrate, Zinnat, Panadeine forte, quinate
A-07-05	
A-07-06	Cefkor-CD, Seretide Metered Dose Inhaler, Acimax, Nitroderm patch, Lanoxin, Folic acid, Frusid, Aldactone
A-07-07	Dilatrend, Pravachol, Aldactone, Tazac, Lasix
A-07-08	Asmol nebs, Curam, Seretide accuhaler, Amiodarone, Coversyl, Temaze Ipratropium, Normison, Lanoxin PG, Ventolin inhaler, Vibra-tabs
A-07-09	Amiodarone, Seretide accuhaler, Nexium, fish oil, Bilberry, Zocor, Co-enzyme Q10, Atacand, Curam, Chlorsig eye ointment, Hydrozole cream Cardizem CD, Panamax
A-07-10	Avapro, Anpec, Coversyl, Lanoxin, Lasix, Advantan ointment
A-08-01	Somac, Eutroxig, Midamor, Sigmacort cream, Panamax
A-08-02	Carvedilol, Celebrex, Lipitor, Normison, Panamax, Renitec, Zylprim, Colgout, Allopurinol, Zantac, Indocin prn, Lanoxin
A-08-03	Trusopt eye drops, Lipitor, Lumigan Eye drops, Timoptic XE eye drops, Atacand plus, Cosopt Eye drops, Viskin
A-08-04	nil

Appendix 12: Summary of Patients recruited into the study

Patient	Baseline INR and Dosing	Medications History	Medical History	Quality of Life	Knowledge Assessment	Status at end of Study
A-01-01	10	Complete	Complete	Complete	Complete	fully completed
A-01-02	8	Complete	Complete	Complete	Complete	fully completed
A-01-03	0	Complete	Withdrawn	none	none	no INR data collected prior to withdrawal by dr
A-01-04	4	Complete	Complete	pre only	pre only	withdrawal due to Doctor (no reason stated)
A-01-05	10	Complete	Complete	Complete	Complete	fully completed
A-01-06	3	Complete	Complete	pre only	pre only	withdrawal due to Doctor (no reason stated)
A-01-07	12	Complete	Complete	Complete	Complete	Withdrawal due to Doctor (reason stated)
A-01-08	4	Complete	Complete	Complete	Complete	Withdrawal by patient (reason stated)
A-01-09	3	Complete	Complete	pre only	pre only	Patient refused to finalise study
A-02-01	8	Complete	Complete except DOB and Rx Length	pre only	pre only	Withdrawal due to Doctor (reason stated)
A-02-02	1	Complete	Complete	Complete	Complete	fully completed
A-02-03	4	Complete	Complete	Complete	Complete	fully completed
A-02-04	12	Complete	Complete	Complete	Complete	fully completed
A-02-05	12	Complete	Complete	Complete	Complete	fully completed
A-02-06	12	Complete	Complete	Complete	Complete	fully completed
A-02-07	none	Complete	Withdrawn	none	none	no INR data collected prior to withdrawal by dr
A-02-08	1	Complete	Complete except DOB and Rx Length	Complete	Complete	fully completed
A-02-09	12	Complete	Complete except Rx Length	Complete	Complete	fully completed
A-02-10	1	Complete	Complete except DOB and Rx Length	Complete	Complete	fully completed
A-03-01	1	Complete	Complete	Complete	Complete	fully completed
A-04-02	6	Complete	Complete	Complete	Complete	fully completed
A-04-03	1	Complete	Complete except DOB	Complete	Complete	fully completed
A-05-01	0	Complete	Complete except DOB	Complete	Complete	fully completed
A-05-02	0	Complete	Complete except DOB	Complete	Complete	fully completed

A-05-03	0	Complete	Complete except DOB	Complete	Complete	fully completed
A-05-04	0	Complete	Complete except DOB and Rx Length	pre only	pre only	.
A-05-06	0	Complete	Complete except DOB and Rx Length	pre only	pre only	.
A-05-07	1	Complete	Complete except DOB and Rx Length	pre only	pre only	.
A-05-08	2	Complete	Complete except DOB and Rx Length	pre only	pre only	Withdrawal by patient due to relocation/uncontactable
A-05-09	1	Complete	Complete except DOB	Complete	Complete	fully completed
A-07-01	9	Complete		pre only	pre only	.
A-07-02	8	Complete		pre only	pre only	.
A-07-03	1	Complete	Complete except Rx Length	Complete	Complete	fully completed
A-07-04	0	Complete	Complete except DOB and Rx Length	Complete	Complete	fully completed
A-07-05	0	Complete	Complete except DOB and Rx Length	pre only	pre only	.
A-07-06	0	Complete	Complete	pre only	pre only	.
A-07-07	1	Complete	Complete			fully completed
A-07-08	1	Complete	Not completed	pre only	pre only	.
A-07-09	9	Complete	Complete except Rx Length	pre only	pre only	.
A-07-10	9	Complete	Complete	pre only	pre only	.
A-08-01	7	Complete	Complete except DOB and Rx Length	Complete	Complete	fully completed
A-08-02	12	Complete	Complete	Complete	Complete	fully completed
A-08-03	0	Complete	Complete except DOB and Rx Length	Complete	Complete	fully completed
A-08-04	0	Complete	Withdrawn	none	none	Withdrawal by patient (reason stated)
B-03-01	15	Complete	Complete	Complete	Complete	N/A
B-03-02	33	Complete	Complete	Complete	Complete	N/A
B-03-04	17	Complete	Complete except DOB and Rx Length	Complete	Complete	N/A

<i>B-03-05</i>	15	Complete	Complete except DOB	Complete	Complete	N/A
<i>B-07-01</i>	Dosing only	Complete	Complete	Complete	Complete	N/A
<i>B-07-02</i>	Dosing only	Complete	Complete	Complete	Complete	N/A
<i>B-08-01</i>	0	Complete	Complete except Rx Length	Complete	Complete	N/A
<i>B-08-02</i>	0	Complete	Complete except Rx Length	Complete	Complete	N/A
<i>B-09-01</i>	6	Complete	Complete except Rx Length	Complete	Complete	N/A
<i>B-09-03</i>	6	Complete	Complete except Rx Length	Complete	Complete	N/A
<i>B-09-04</i>	0	Complete	Complete except Rx Length	Complete	Complete	N/A
<i>B-09-05</i>	0	Complete	Complete except Rx Length	Complete	Complete	N/A

Appendix 13: Patient Feedback recorded from semi-structure interviews

Transcribed data by Investigators

Numbers indicate unique patient code

(1) How long did the visit to the pharmacy take?

A0101

10 to 20 min

A0102

15 min

A0108

5 to 10 min

A0109

10 min

A0204

10-15 min

A0205

15 min

A0206

15 to 20 min

A0209

15 min on average

A0501

10mins

A0502 and A0503

20mins on average, however it was for both my husband and I so it was very fast if you count both of us.

A0509

10mins

A0702

5 to 10mins, depending on my result

A0705

10mins

A0801

5min

I would get priority – I just tick my finger up!

(2) What did you like most about the service?

A0101

The convenience of just going to the local pharmacy was great

The pharmacy service was good when I was well controlled but when it was low I still went to the doctor.

A0102

The convenience of going to the pharmacy in my local shops

I like the close relationship with the pharmacist

Helpful advice offered

The pharmacy service was a very quick and provided me with reassurance and the factors that influence warfarin

A0108

More convenient

Reassurance about INR

A0109

Very flexible – we would chat about things as we went. The pharmacist did all the right precautionary stuff

There was a three-way communication between me, the pharmacist and the doctor.

Handy at the local pharmacy and convenient

Being in the study helped me to remember to take the medicine

I was able to develop a routine

A0204

Immediate result

The finger prick was more acceptable to me as I do not like blood tests

It was convenient to visit the pharmacy in my local area

The regular interaction with the pharmacist and the chance to ask questions was good

A0205

It was quick and easy, no waiting and no booking

The immediacy of the results was a real advantage compared to queuing up at the pathology lab.

I thought it was excellent

A0206

I made an appointment so there was no waiting – the pharmacist was very careful

A finger prick is better than the needle

There was no waiting – it was more convenient and timely

I like the opportunity to ask the pharmacist's questions

A0209

No more convenient than the current GP and Hospital - I see my doctor regularly and am closely monitored – I have been on warfarin for 16 years

A0501

It was lovely to have a more involved INR testing. I felt like I was actually being given some say in my treatment. It was not more convenient, as my doctor is just upstairs. I am happy that I was given more information because sometimes my therapy can worry me when I'm not fully informed.

A0502/A0503

It was fast and easy for my husband and I to have it done together. The pharmacist did not rush me and always gave me more personal time. It was not in and out like in pathology, because even though the pharmacist is always busy he always had time to talk.

A0509

Fast and easy, learnt a lot more about why my doses need to change and became more informed about other medications that could cause problems.

A0702

Fast and friendly, more understanding of my actual therapy.

A0705

For me it was about the same as going to the Dr, however the finger prick testing made it less painful so I was happy about that.

A0801

No waiting and very convenient

(3) Do you feel the service improved your understanding of warfarin therapy?

A0101

I liked the booklet, it helped me understand the things that influence my warfarin

A0102

I have a good working knowledge of warfarin – I previously ended up in hospital with an internal bleed. I did find the information helpful but I am very aware of my levels

I feel I have a better understanding of how to avoid problems and why my doses are adjusted

A0108

Reinforce what I know – especially how to avoid problems and diet

A0109

It allowed me to revise issues and talk through these – I feel I understand what influences my warfarin better. It reinforced what I knew.

By being in regular contact with the pharmacist and doctor I could ask questions – it gave me a greater understanding of INR and what influenced it for me.

I had good feedback on diet. It was a motivator.

A0204

The pharmacist and the booklet gave me more information that I had previously. This reaffirmed what I know and reminded me what was important

Discussing things that influenced my warfarin or why my dose adjusted was great. You can't always talk to the doctor about why (changes are made) especially when he has many patients. (The pharmacist) had a more personal approach.

A0205

I don't remember being given any booklets. Talking to the pharmacist did reinforce what I knew about warfarin.

A0206

Talking to the pharmacist reinforced what I already knew and addressed some of the "folklore" about warfarin

I think I have a better understanding of INR and the dose changes through talking to the pharmacist

A0209

Reinforced what I knew about warfarin – I am closely monitored anyway

A0501

I learnt a lot more about how my diet affects my warfarin. I could ask more questions while I was being tested, because that is when I think of the questions. I feel my knowledge has improved about my warfarin.

A0502/A0503

Learnt a lot more about dosing and how it works, and learnt a lot more about the medications I take and how they affect the warfarin. It was good for me and my husband to have that information.

A0509

Reinforced my understanding of warfarin, but now I know more about OTC medications and how much they can affect me.

A0702

Yes, I learnt a lot.

A0705

I already knew a lot but it was good to have it reinforced.

A0801

The pharmacist reinforced what I knew about warfarin – especially the information about diet

(4) What aspects were not helpful?

A0101

It was all good – the pharmacist could have been a bit more organised

Use a bigger needle to make it easier to collect blood

A0102

None

A0108

Hard to get blood sometimes

A0109

None

A0204

The need for re-analysis sometimes

A0205

No

A0209

None

A0501

None

A0502/A0503

Having to wait for the Dr to confirm.

A0509

None

A0702

Sometimes it was hard to get my blood

A0705

It was about the same as the Dr.

A0801

None

(5) Do you think being in the pharmacy trial improved the control of your INR?

A0101

No difference

A0102

Yes as I was more closely monitored over this time – I became very aware of what influenced my warfarin

A0108

It provided reassurance about my INR

A0109

About the same

A0204

Overall I think I was better controlled. The pharmacists were meticulous on dose adjustments and very conscientious pharmacist.

A0205

It was steady – about the same

A0206

Slighter better control with closer monitoring and advice on doing within only one hour!

A0209

No, I am closely monitored

A0501

I am about the same, but I know more now.

A0502/A0503

Yes, because I know more I have become more controlled. My husband was the same.

A0509

Overall yes, but I was happy with that.

A0702

Yes, it felt that way.

A0705

No about the same.

A0801

I am already well controlled

(6) How does this compare to your previous experience of INR monitored by your GP and the Pathology lab?

A0101

More convenient

A0102

More convenient

A0108

same

A0109

I would need to make an appointment to see the nurse at the surgery – often waiting 45 min – this is more convenient

The pharmacist was quicker and easier

A0204

A. No response

A0205

No response

A0206

Firmer direction and prompt

A0209

No response

A0501

About the same, but a little faster and I learnt a lot more.

A0502/03

Faster and more convenient, pathology have never asked me about what I have done different to see how it affects me. It was closer to home, which is good because my husband can not walk very far.

A0509

About the same, just faster no real waiting.

A0702

It takes longer to get results from pathology, so now I'm out of the trial I worry a little because I was used to getting them so quickly. I didn't have to wait at the pharmacy very long.

A0705

Its all about the same, but I learnt more.

A0801

I have been less well controlled recently (after the trial)

The pathology results aren't ready until 5 or 6 pm and then the doctor has to ring all the people.

There is a problem if dosing requirements change.

(7) Overall how do you feel about the warfarin management service at your pharmacy? On a 1 to 5 where 1 is "extremely dissatisfied" to 5 "extremely satisfied"

A0101

4 - Satisfied

A0102

5 – extremely satisfied

A0108

4 - Satisfied

A0109

5 – extremely satisfied

A0204

4 - Satisfied

A0205
4 - Satisfied
A0206
4 - Satisfied
A0209
4 – Satisfied
A0501
4- Satisfied
A0502/A0503
4-Satisfied
A0509
5-Extremely Satisfied
A0702
3-No opinion
A0705
4-Satisfied

(8) *Would you like to continue to receive this service if it was offered by the pharmacy?*

A0101
Yes
A0102
Yes
A0108
Yes
A0109
Yes
A0204
Yes
A0205
Yes
A0206
Yes

A0209

No, I am monitored by my doctor every 2 weeks anyway and the hospital has a pathology clinic at the local shops

A0501
Yes
A0502/A0503
Yes
A0509
Yes
A0702
Yes
A0705
Yes, but only if it was bulkbilled
A0801
Yes

(9) *Could the service be improved?*

A0102

The pharmacist could be more organised

A0108

Just the same

A0204

More flexible times to visit the pharmacy – perhaps during the working day

A0205

Facilities could be better and flexibility of sampling times to fit in with patients

A0206

No

A0209

No

A0501

No

A0502/A0503

Faster confirmation of dosing would be better.

A0509

No

A0702

Maybe faster communication with Dr

A0705

No

A0810

Yes, get the doctors on side

(10) *Would you pay for this service? If yes, how much?*

A0101

Yes, \$10 per visit

I think it should be subsidised as I am a pensioner

A0102

Yes, \$10 - \$20 per visit

The fee should recognise the pharmacist time and maybe subsidised by medicare

A0108

Yes, \$25 for initial the \$20 each visit

Should be bulk billed

A0109

\$10 per test

should be subsidized by Medicare

A0204

As a DVA patient I would not expect to pay for this service by it should be subsidized.

A reasonable payment would be \$20 per visit

A0205

No, I have a pension. I could not put a price on this but I think it should be available and subsidized by Medicare

A0206

No, should be subsidized – same as any blood test

A0209

No, but it should be funded as another monitoring option for people on warfarin

A0501

I am on a pension so I would expect that it would be bulk billed. However, I would be willing to pay \$5 per visit on rare occasions.

A0502/A0503

Not unless it was bulk billed or subsidized, because both my husband and I get them done, it would get very expensive.

A0509

No, but I think it should be available and covered by Medicare

A0702

It should be covered by Medicare, like pathology.

A0705

I get bulk billed, so I wouldn't but \$15 would be a good price.

A0801

Should be subsidized

(11) General comments

- I would be interested in self monitoring using the device
- I am interested in monitoring myself like the blood sugar levels
- Quite happy – it suited me better
- I was unclear about the specific aims of the study and my GP expressed some concern. Are pharmacists trying to take over from doctors.
- This service would benefit people in rural areas who do not have access to testing places
- Marvelous service
- The doctors have started doing the same testing and there has been some problems
- Initially doctor was a bit hesitant. He didn't think it had the accuracy of the lab. I did see a change in the doctors attitude.
- Monitoring was really good to know what is going on
- Had a poor control after leaving study
- I think that this would be a good service for those in the outback, more convenient.
- I liked that I was able to have a say in my therapy.

Appendix 15: Pharmacists feedback from open-ended survey.

Transcribed responses from Pharmacists feedback from open-ended survey.

What do you feel were the positive aspects of the anticoagulant management service provided in this study?

- The Pharmacist/Patient relationship was enhanced. Patient knowledge improved and the convenience of immediate results was appreciated by patients.
- Patient contact – quality time with the patient. Patient interest in their medication and health.
- A closer relationship with patient. More time to explain and educate. Closer ties with the local GP.
- Patients can obtain instant INR results and then they get to understand the correlation between the INR reading, doses of Warfarin and the thickness of blood.

(2) How have you, as a pharmacist, benefited from being involved in this service/study?

- Improved my knowledge and gave me a hands on feeling. Very good for pharmacist and patient rapport.
- Increased knowledge and confidence in dealing with drug interactions with Warfarin, increased confidence in advising if patient and doctors on Warfarin and Warfarin management.
- Increases my knowledge and confidence in dealing with patients receiving anticoagulant medication.
- Better understanding of the doses of Warfarin and INR readings. Built up a better relationship with the General Practitioners and the patients.

(3) How do you believe that your patients have benefited from being involved in this service/study?

- More aware of INR testing and its interpretation. Patients liked to see the results.
- Convenience, increased contact with pharmacist and time to discuss all elements of medication management.
- Only had one patient, but a lot easier to visit the patient at home. Result available instantly.
- When they request for extra tests when they feel unwell and when they have had different food or medications.

(4) How did your patients respond to this service/study?

- Most patients were very keen about the study.
- Very positive although resistant at first.
- Very obliging. Happy to see it work.
- A third of my patients were eager in regular test and the study, but two thirds often were not very responsive.

(5) How do you believe that your local doctors have benefited from the service you provided to patients?

- Still a lot of resistance by the local doctors, although the results were faxed through on time and patients were keen on the trial.
- Doctors liked the service so much they are to employ own nurse to do it directly for them.
- We have taken a lot of the decisions away from the GP. Created a closer alliance, which this particular GP was most happy about.
- Doctors may have believed that pharmacists have educated their patients with regards to the effects of Warfarin on INR, thickness of blood and how diet can effect the INR results.

(6) How did your local doctors respond to this service/study?

- Doctors responded well considering their resistance.
- Generally well though not much interest.
- Quite pleased to be involved in study. Never felt threatened by the pharmacist
- Half of them were fairly responsive.

(7) How important do you feel the anticoagulant management service is to your pharmacy practice?

- Patients level of appreciation for the service and knowledge of the pharmacist improved.
- Invaluable service. We are in a high tourist are and received many enquiries from travelers.
- Very! Would be great to make it a regular service.
- Can be a source of income in the future. This service helped me to better understand my customers and built up a better relationship.

(7) Regarding the training offered in this study:

a) What could be improved in terms of training for the future?

- Maybe some more testing of the type of patient that was involved in the trial.
- Excellent
- We had in store training as we joined the study late. It was more than adequate – although I personally would have liked to have been involved from day 1.
- We should be shown at the first interview with the patients.

(8) Regarding your participation in this service/study, what do you feel made it easier or more difficult to be fully involved?

- The patient made it easy while the doctor resistance was a little bit difficult at times.
- All easy

- Ease of use of meter, compliance of patient, willingness of GP to be involved and support from Megan
 - **We should be paid a lot more for the time we were involved in this study.**

(9) How could this anticoagulant management service and or study be improved in the future?

- Greater support from the doctors required. Need to attack the resistance of encroaching on their territory.
- Quality of the questionnaire difficult to administer, parameters caused confusion.
- Canvass the GPs this time. The only problem GP I had was one that didn't think the meter would give the same results. Due to this attitude lost a potential 3 participants.

(10) Any other comments you would like to make regarding this service/study?

- Enjoyed participating in this trial. Pity about the resistance from the doctors.
- Hope it goes well.