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Appendices

Appendix 1:

Initial Questionnaire for Patients

Initial Questionnaire for Patients

An Investigation of the Management of the International Normalised Ratio (INR) in Warfarin Therapy During the First Five months of Treatment

Review of the management of the blood thinner warfarin during the first five months of treatment

Patient number in study……..

Date……..

1. Have there been any major changes in your normal eating habits (including alcohol intake) in the last week?

   ❑ Yes
   ❑ No

2. If you answered yes, what were those changes?

   .....

   .....

   .....

   .....

3. Have you suffered from any of the following illnesses in the last week?

   - Diarrhea for at least 2 consecutive days…
     ❑ Yes
     ❑ No

     If yes, was doctor managing your warfarin treatment informed?
     ❑ Yes
     ❑ No

   - Vomiting for at least 2 consecutive days…
     ❑ Yes
     ❑ No

     If yes, was doctor managing your warfarin treatment informed?
     ❑ Yes
     ❑ No

   - Increased temperature or fever that you were aware of…
     ❑ Yes
     ❑ No

     If yes, was doctor managing your warfarin treatment informed?
     ❑ Yes
     ❑ No

   - Newly diagnosed illness. That is, any new ailment that has been diagnosed by a doctor who is not managing your warfarin treatment….
     ❑ Yes
     ❑ No

     If yes, was doctor managing your warfarin treatment informed?
     ❑ Yes
     ❑ No

     Comment.....

     .....

     .....

- Any other health problem in the last week that has not been mentioned?
  - ❑ Yes
  - ❑ No

    If yes, was Dr managing your warfarin treatment informed?
    - ❑ Yes
    - ❑ No

    Comment.....

    .....

    .....

- Have you let the doctor managing your warfarin treatment know about all of the tablets including vitamins, homeopathic medications, herbal preparations and food supplements you take?
  - ❑ Yes
  - ❑ No

4. If the answer was no, which ones did you forget to tell the doctor about?.....

   .....

   .....

5. Have you started on any new tablets in the last week?

   - ❑ Yes
   - ❑ No

     If yes, was doctor managing your warfarin treatment informed?
     - ❑ Yes
     - ❑ No

6. Have you increased the dose of any of your medicines that you only take occasionally, e.g. pain killers?

   - ❑ Yes
   - ❑ No

     If yes, which medicines?

     .....

     .....

     How many per week?.....

7. If yes, does your doctor managing your warfarin treatment know?

   - ❑ Yes
   - ❑ No

8. Do you understand why you have been started on warfarin therapy?

- ❑ Yes
- ❑ No

Comments.....

.....

.....

9. Do you think you understand basically how warfarin works?

- ❑ Yes
- ❑ No

Comments.....

.....

.....

10. Are you aware of the main side effects of warfarin?

- ❑ Yes
- ❑ No

Comments.....

.....

.....

11. Do you understand why your dose of warfarin may change?

- ❑ Yes
- ❑ No

Comments.....

.....

.....

12. Do you keep a written record of your blood tests and warfarin doses that you take?

- ❑ Yes
- ❑ No

13. Do you get the same brand of warfarin every time from the chemist?

- ❑ Yes
- ❑ No
- ❑ Don't know

14. Do you take your warfarin at approximately the same time each day?

- ❑ Yes
- ❑ No

15. How often do you miss a dose?

- ❑ Never
- ❑ Once a month
- ❑ Once a week
- ❑ Twice a week
- ❑ Other

Comment.....

.....

16. If you ever do miss a dose, what do you do?

.....

.....

.....

.....

.....

17. Are you aware of what the signs and symptoms of bleeding caused by warfarin are?

- ❑ Yes
- ❑ No

Comments.....

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.....

.....

18. Have you had any of those signs of bleeding while on warfarin?

- ❑ Yes
- ❑ No

If yes, was doctor managing your warfarin treatment informed?

- ❑ Yes
- ❑ No

Comments.....

.....

.....

.....

.....

19. How does the doctor let you know what dose of warfarin you need to take?

.....

.....

.....

20. How easy to follow are the instructions for what dose of warfarin you should be using?

1	2	3	4	5
Very Easy	Uncertain	Difficult	Very Easy	Difficult

21. If difficult, can you tell me in what way?

.....

.....

.....

.....

.....

22. Do you know how long you will be required to take warfarin for?

- ❑ Yes
- ❑ No

Kerrie Westaway – Researcher

Telephone: 0419851856

Appendix 2:

Subsequent Episode of Over-anticoagulation Questionnaire for Patients

Subsequent Episode of Over-anticoagulation Questionnaire for Patients

An Investigation of the Management of the International Normalised Ratio (INR) in Warfarin Therapy During the First Five months of Treatment

Investigation of the management of the blood thinner warfarin during the initial five months of treatment

Patient number in study.....

Date.....

1. Have there been any major changes in your normal eating habits (including alcohol intake) in the last week?

   ❑ Yes
   ❑ No

2. If you answered yes, what were those changes?

   .....

   .....

   .....

3. Have you suffered from any of the following conditions in the last week?

   - Diarrhea for at least 2 consecutive days…
     ❑ Yes
     ❑ No

     If yes, was doctor managing your warfarin treatment informed?
     ❑ Yes
     ❑ No

   - Vomiting for at least 2 consecutive days…
     ❑ Yes
     ❑ No

     If yes, was doctor managing your warfarin treatment informed?
     ❑ Yes
     ❑ No

   - Increased temperature or fever that you were aware of…
     ❑ Yes
     ❑ No

     If yes, was doctor managing your warfarin treatment informed?
     ❑ Yes
     ❑ No

   - Newly diagnosed illness. That is, any new ailment that has been diagnosed by a doctor who is not managing your warfarin treatment…
     ❑ Yes
     ❑ No

     If yes, was doctor managing your warfarin treatment informed?
     ❑ Yes
     ❑ No

     Comment.....

     .....

- Any other health problem in the last week that has not been mentioned?
  - ❑ Yes
  - ❑ No

    If yes, was doctor managing your warfarin treatment informed?
    - ❑ Yes
    - ❑ No

    Comment.....

    .....

    .....

4. Have you let the doctor managing your warfarin treatment know about all of the tablets including vitamins, homeopathic medications, herbal preparations or homeopathic food supplements you take?

   - ❑ Yes
   - ❑ No

   If the answer was no, which ones did you forget to tell the doctor about?.....
   .....
   .....
   .....

5. Do you get the same brand of warfarin every time from the chemist?

   - ❑ Yes
   - ❑ No
   - ❑ Don't know

6. How often do you miss a dose?

   - ❑ Never
   - ❑ Once a month
   - ❑ Twice a month
   - ❑ Twice a week
   - ❑ Once a week
   - ❑ Other.....

7. If you ever do miss a dose, what do you do?

   .....

   .....

   .....

8. How easy to follow are the instructions for what dose of warfarin you should be using?

1	2	3	4	5
Very Easy	Uncertain	Difficult	Very Easy	Difficult

9. Is there anything about your warfarin therapy that you would like to comment on?

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Kerrie Westaway – Researcher

Telephone: 0419851856

Appendix 3:

Initiation of Warfarin Therapy Questionnaire for Doctors

Initiation of Warfarin Therapy Questionnaire for Doctors

An Investigation of the Management of the International Normalised Ratio (INR) in Warfarin Therapy During the First Five months of Treatment

Investigation of the management of the blood thinner warfarin during the initial five months of treatment

Date.....

Dr ID number.....

Patient number in study.....

Please tick relevant box:

- ❑ General Practitioner
- ❑ Registrar
- ❑ Resident Medical Officer
- ❑ Medical Intern
- ❑ Other.....

1. Have you, in 2005, attended any of the thrombolytic/anticoagulant educational programs by the National Prescribing Service?
   - ❑ Yes
   - ❑ No
2. Do you routinely set a target INR prior to commencement of warfarin therapy for each patient?
   - ❑ Yes
   - ❑ No
3. If yes, what is your normal INR target range?

   .....

   .....

   .....
4. Are there any situations where you would alter this target range?

   .....

   .....

   .....
5. Do you determine the duration of the warfarin therapy for each patient in advance of commencing therapy?
   - ❑ Yes
   - ❑ No
   - ❑ Sometimes

   Comments.....

   .....

   .....

   .....

6. With regard to warfarin initiation, would you use a recognised algorithm or would you be guided by your own clinical judgment?

   - ❑ Recognised algorithm
   - ❑ Own clinical judgment

   Comment.....

   .....

   .....

   .....

7. Do you routinely assess each patient for risk of bleeding prior to the commencement of warfarin therapy?

   - ❑ Yes
   - ❑ No

   If yes, what factors would you take into account?

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   .....

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   .....

8. Do you use a scoring system to stratify the risk of bleeding?

   - ❑ Yes
   - ❑ No

   Comments.....

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   .....

9. What barriers do you face, if any, in the management of warfarin therapy?

   ....

   ....

   ....

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10. Do you periodically re-evaluate the patient's harm: benefit ratio for warfarin during the course of their therapy?

- ❑ Yes
- ❑ No

Comment.....

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.....

11. Do you inform the patient of the risk of bleeding on commencing warfarin therapy?

- ❑ Yes
- ❑ No

Comment.....

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12. Are you able to predict or foresee instability of an INR?

- ❑ Yes
- ❑ No

Comment.....

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.....

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.....

13. If the INR>4.0, do you attempt to identify the cause?

- ❑ Yes
- ❑ No

Comment.....

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14. If yes, and the cause is identifiable, do you attempt to correct the cause?

- ❑ Yes
- ❑ No

Comment.....

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15. Would you consider an increased INR above 4.0 to be an acceptable occurrence during warfarin therapy?

- ❑ Yes
- ❑ No

Comment.....

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16. If your patient has an INR>4.0, would you consider the possibility of lowering the target range?

- ❑ Yes
- ❑ No

Comment.....

.....

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.....

17. If the patient's INR is above the target range, would you adjust the dose?

- ❑ Yes
- ❑ No

Comment.....

.....

.....

.....

.....

18. Do you routinely order baseline blood tests prior to commencement of warfarin therapy?

- ❑ Yes
- ❑ No

19. If yes, what blood tests would you order?

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.....

.....

20. If dose adjustment is required, do you increase the frequency of INR monitoring for a time after?

- ❑ Yes
- ❑ No

Comment.....

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.....

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21. If there is a change in the patient's health, lifestyle or medications, do you increase the frequency of INR monitoring for a time after?

- ❑ Yes
- ❑ No

Comment.....

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22. How is the patient informed of their warfarin dose and by whom?

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23. What education does the patient receive regarding their warfarin therapy that you are aware of?

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24. Which lifestyle factors do you commonly discuss with the patient?

- ❑ Consistency of dietary intake of vitamin K
- ❑ Minimizing alcohol intake
- ❑ Avoidance of binge drinking
- ❑ Reduction of activities with considerable risk of injury, including risk of falls in the elderly population.
- ❑ Reporting of acute illnesses to the doctor
- ❑ Reporting any new medications/over-the-counter/alternative medications to their doctor
- ❑ Other

Comments.....

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Kerrie Westaway – Researcher

Telephone – 0419851856

Appendix 4:

Subsequent Episode of Over-anticoagulation Questionnaire for Doctors

Subsequent Episode of Over-anticoagulation Questionnaire for Doctors

An Investigation of the Management of the International Normalised Ratio (INR) in Warfarin Therapy During the First Five months of Treatment

Investigation of the management of the blood thinner warfarin during the initial five months of treatment

Patient number in study.....

Dr ID number.....

Date.....

Please tick relevant box:

- ❑ General Practitioner
- ❑ Registrar
- ❑ Resident Medical Officer
- ❑ Medical Intern
- ❑ Other.....

1. INR value:.....

2. Bleeding event at time of episode of over-anticoagulation:
   - ❑ Yes
   - ❑ No

3. What did you perceive to be the contributing factors to this patient's episode of INR>4.0?

   .....

   .....

   .....

   .....

   .....

   .....

   .....

   .....

4. What did you perceive to be the most important aspects of managing this episode of INR>4.0? (i.e. how did you treat the INR>4.0?).

   .....

   .....

   .....

   .....

   .....

Kerrie Westaway – Researcher

Telephone: 0419851856

Appendix 5:

Participant Information Sheet for Patients

UNE
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Participant Information Sheet for Patients

An Investigation of the Management of the International Normalised Ratio (INR) in Warfarin Therapy During the First Five months of Treatment

This is a research project, and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way.

You are invited to take part in a study exploring the management of your warfarin therapy during the first five months of treatment. Warfarin, which is a blood thinner, is a very effective medicine that helps treat and prevent harmful blood clots from forming in the body by decreasing the clotting power of the blood. To do this, we monitor the blood by doing a test called an INR (the risk of bleeding increases when the INR is above 4.0). This is so that your doctor can prescribe the correct dosage.

We hope this will provide important information that will help doctors improve the management guidelines of warfarin therapy and help reduce side effects while you are on warfarin.

If you choose to participate:

- The following information will be collected from your medical records: Your GP's name, your phone number, date of birth, weight, sex, reason for admission to hospital or to see your GP, reason for starting warfarin, medicines you are presently taking, your medical history and details of your warfarin and any side effects from warfarin.

- After you have been commenced on warfarin therapy, I will contact you once a month by phone and I will conduct an interview if your INR value has been above 4.0. This will be to ask questions about your warfarin treatment. It will take approximately 15-20 minutes. It will be done at a time that is convenient to you.
- After that initial interview, each subsequent time your INR value goes above 4.0, I will again conduct further short interviews. These interviews will require approximately 5-10 minutes of your time to complete. These questions will be about your warfarin treatment only.
- I will contact your doctor to gain consent to access your medical records in order to obtain data pertaining to your warfarin therapy. In addition, I will contact him/her to complete a questionnaire on completion of collection of your data.

You are free to refuse to answer any questions presented to you that you are unable to answer or you find to be intrusive in any way.

Duration of participation in the study will be for a period of 5 months or less if the warfarin is ceased before five months. It is unlikely that this research will raise any personal or upsetting issues but if it does you may wish to contact your local Community Health Centre.

You must be 18 years or older to participate in this study.

You will not be required to participate in any additional procedures, other than the interviews, than would normally be expected of you if commenced on warfarin therapy. No risk of physical or emotional harm, including discomfort, anxiety or pain to you is anticipated as a direct result of the study.

Your participation in the study is entirely voluntary and you have the right to withdraw from the study, you may do this freely without prejudice to any treatment at Flinders Medical Centre or in your general practitioner's rooms.

All records containing personal information will remain confidential and no information that could lead to your identification will be released. The data collected will be coded to remove personal identification and kept in a locked cabinet at all times, accessible only by the investigators. On completion of data collection, the information will be compiled and written up as a thesis. Thereafter, the information will be given to those institutions involved in the study, that is, Flinders Medical Centre, the University of New England

and the Southern Division of General Practice Inc. In accordance with usual practice, study results become the property of the sponsor and may be published in scientific journals at a later date. It is possible that the results may not be published for commercial, scientific or other reasons. The data will be kept for 5 years whereupon it will then be destroyed.

Should you require further details about the project, before, during or after the study, you may contact:

Kerrie Westaway
Phone: mobile: 0419851856, home: 82741217
Email: kwestaway@tpg.com.au

This study has been approved by the Flinders Clinical Research Ethics Committee. Should you wish to discuss the project with someone not directly involved, in particular in relation to matters concerning policies, your rights as a participant, or should you wish to make a confidential complaint, you may contact the Administration Officer – Research, Ms. Carol Hakof on 8204 4507.

This project has been approved by the Human Research Ethics Committee of the University of New England (Approval No.HE04/169, valid to 31/10/2006). Approval extended until 28/4/2007.

Should you have any complaints concerning the manner in which this research is conducted, please contact the Research Ethics Officer at the following address:

Research Services, University of New England, Armidale, NSW 2351
Telephone: (02) 67733449, Facsimile (02) 67733543, Email: Ethics@metz.une.edu.au

As a PhD student conducting research I am legally and ethically unable to discuss any aspects of your condition or treatment with you.

My Supervisors:

Dr Mary Cruickshank
School of Health, University of New England, Armidale, NSW, 2351
Telephone: (02) 67733640, Email: mmacarty@metz.une.edu.au

Mr Greg Roberts
Senior Pharmacist
Repatriation General Hospital, Daws Road, Daw Park, 5041
Telephone: (08) 8751632, Email: greg.roberts@rgh.sa.gov.au

Thank you for taking the time to read this information.

Yours Sincerely,

Kerrie Westaway

Appendix 6:

Participant Information Sheet for Doctors

Participant Information Sheet for Doctors

My name is Kerrie Westaway and I am undertaking a research project in order to complete a Doctor of Philosophy I am presently studying through the School of Health at the University of New England, Armidale, New South Wales.

The title of the project is: 'An investigation of the management of the International Normalised Ratio (INR) in warfarin therapy during the initial five months of treatment'.

This is a research project, and you do not have to be involved. If you do not wish to participate, your position will not be affected in any way.

You are invited to take part in a study investigating the anticoagulant control and the management of patients receiving warfarin therapy. Specifically, the objectives of this project are to:

1. Determine the frequency of INR monitoring that currently occurs in both the hospital setting and GP rooms.
2. Evaluate the number of episodes of over-anticoagulation that were potentially preventable and the number of episodes of over-anticoagulation that were unforeseeable.
3. Determine the rate of over-anticoagulation during the initial five months of warfarin therapy, specifically the rate in the first month compared with subsequent months.
4. Determine the number of major bleeds associated with episodes of over-anticoagulation.
5. Assess the concepts of medical management and current trends in the treatment of patients receiving warfarin.
6. Determine patient compliance and degree of understanding of warfarin therapy.

If you choose to participate:

- You will be asked to complete a questionnaire regarding questions about the patient's warfarin management. This questionnaire will take approximately 20 minutes of your time to complete. This will be completed at a time that is convenient to you. General Practitioners only, will receive remuneration for their time in accordance with the Southern Division of General Practice's policy of GPs participation in divisional activities. This fee will be paid for time spent in completing the questionnaire by the GP.
- Data will be analysed collectively. Individual performance will not be analysed or compared.

Data will be collected from the patient for a period of 5 months or less if the warfarin is ceased prior to this time. Your participation in the study is entirely voluntary and you have the right to decline participation or withdraw, you may do this freely without prejudice.

All records containing personal information will remain confidential and no information that could lead to your identification will be released. The data collected will be coded to remove personal identification and kept in a locked cabinet at all times, accessible only by the researcher. On completion of data collection, the information will be compiled and written up as a thesis. Thereafter, the information will be given to those institutions involved in the study, that is, Flinders Medical Centre, the University of New England and the Southern Division of General Practice Inc. In accordance with usual practice, study results become the property of the sponsor and may be published in scientific journals at a later date. It is possible that the results may not be published for commercial, scientific or other reasons. The data will be kept for 5 years whereupon it will then be destroyed. Should you require further details about the project, before, during or after the study, you may contact:

Kerrie Westaway

Phone: 0419851856

Email: kwestaway@tpg.com.au

This study has been reviewed by the Flinders Clinical Research Ethics Committee. Should you wish to discuss the project with someone not directly involved, in particular in relation to matters concerning policies, your rights as a participant, or should you wish to make a confidential complaint, you may contact the Administration Officer – Research, Ms. Carol Hakof on 8204 4507.

This project has been approved by the Human Research Ethics Committee of the University of New England (Approval No.HE04/169, valid to 31/10/2006). Extension provided until 28/4/2007).

Should you have any complaints concerning the manner in which this research is conducted, please contact the Research Ethics Officer at the following address:

Research Services, University of New England, Armidale, NSW 2351
Telephone: (02) 67733449, Facsimile (02) 67733543, Email: Ethics@metz.une.edu.au

My Supervisors:

Dr Mary Cruickshank
School of Health, University of New England, Armidale, NSW, 2351
Telephone: (02) 67733640, Email: mmacarty@metz.une.edu.au

Mr Greg Roberts
Senior Pharmacist
Repatriation General Hospital, Daws Road, Daw Park, 5041
Telephone: (08) 8751632, Email: greg.roberts@rgh.sa.gov.au

Thank you for taking the time to read this information.

Yours Sincerely,

Kerrie Westaway

Appendix 7:

Patient Consent Form

UNE
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OF NEW ENGLAND

Consent to Participate in Research

(Patient Consent Form)

I, _____ request and give consent to my
First or given names surname
involvement in the research project: 'An investigation of the management of the International Normalised Ratio (INR) in warfarin therapy during the initial five months of treatment".

I acknowledge that the nature, purpose and contemplated effects of the research project, especially as far as they affect me have been fully explained to my satisfaction by _____ and my consent is given voluntarily. First or
given names surname

I acknowledge the detail(s) of the following procedure(s):

1. Access to medical records to collect basic patient demographics, relevant medical information pertaining to warfarin therapy and treatment and outcomes of any episodes of over-anticoagulation (INR above 4.0).
2. An initial phone interview conducted if the INR value is above 4.0.
3. Shorter successive interviews each subsequent episode of the INR above 4.0

have been explained to me, including indications of risks; any discomfort involved; anticipation of length of time and the frequency with which the procedure(s) will be performed.

I have understood and am satisfied with the explanations that I have been given.

Page 1 (continued on page 2)

I have been provided with a written information sheet.

I understand that my involvement in this research project and/or the procedure(s) may not be of any direct benefit to me and that I may withdraw my consent at any stage without affecting my rights or the responsibilities of the researchers in any respect.

I acknowledge that I have been informed that should I receive an injury as a result of taking part in this study, I may need to start legal action in order to receive compensation.

I declare that I am over the age of 18 years.

Signature of research participant:_____ Date:_____

Signature of Witness:_____

Printed name of Witness:_____

I, ...(name) have described to..... .....(patient's name)

the research project and the nature and effects of the procedure(s) involved. In my opinion he/she understands the explanation and has freely given his/her consent.

Signature:_____ Date:_____

Status in project:_____

Appendix 8:

General Practitioner Consent Form

UNE
THE UNIVERSITY
OF NEW ENGLAND

Consent to Participate in Research

(General Practitioner Consent Form)

I, _____ request and give consent to my
first or given names surname
involvement in the research project: 'An investigation of the management of the International Normalised Ratio (INR) in warfarin therapy during the initial five months of treatment'.

I acknowledge that the nature, purpose and contemplated effects of the research project, especially as far as they affect me have been fully explained to my satisfaction by _____ and my consent is given voluntarily. First or
given names surname

I acknowledge the detail(s) of the following procedure(s):

1. Access to medical records to collect basic patient demographics, relevant medical information pertaining to warfarin and INR treatment and outcomes of any episodes of over-anticoagulation (INR>4.0).

have been explained to me, including indications of risks; any discomfort involved; anticipation of length of time and the frequency with which the procedure(s) will be performed.

I have understood and am satisfied with the explanations that I have been given. I have been provided with a written information sheet.

Page 1 (continued on page 2)

I understand that my involvement in this research project and/or the procedure(s) may not be of any direct benefit to me and that I may withdraw my consent at any stage without affecting my rights or the responsibilities of the researchers in any respect.

I declare that I am over the age of 18 years.

Signature of research participant:_____ Date:_____

Signature of Witness:_____

Printed name of Witness:_____

I, _____ have described to _____

the research project and the nature and effects of the procedure(s) involved. In my opinion he/she understands the explanation and has freely given his/her consent.
Signature:_____ Date:_____

Status in project:_____

Appendix 9:

Doctor Consent Form

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OF NEW ENGLAND

Consent to Participate in Research

(Doctor Consent Form)

I, _____ request and give consent to my
first or given names surname
involvement in the research project: 'An investigation of the management of the International Normalised Ratio (INR) in warfarin therapy during the initial five months of treatment".

I acknowledge that the nature, purpose and contemplated effects of the research project, especially as far as they affect me have been fully explained to my satisfaction by _____ and my consent is given voluntarily. First or
given names surname

I acknowledge the detail(s) of the following procedure(s):

1. Completion of questionnaire pertaining to the management of warfarin and requiring approximately 15-20 minutes of my time.

has been explained to me, including indications of risks; any discomfort involved; anticipation of length of time and the frequency with which the procedure(s) will be performed.

I have understood and am satisfied with the explanations that I have been given. I have been provided with a written information sheet.

Page 1 (continued on page 2)

I understand that my involvement in this research project and/or the procedure(s) may not be of any direct benefit to me and that I may withdraw my consent at any stage without affecting my rights or the responsibilities of the researchers in any respect.

I acknowledge that I have been informed that should I receive an injury as a result of taking part in this study, I may need to start legal action in order to receive compensation.

I declare that I am over the age of 18 years.

Signature of research participant:_____ Date:_____

Signature of Witness:_____

Printed name of Witness:_____

I, _____ have described to _____

the research project and the nature and effects of the procedure(s) involved. In my opinion he/she understands the explanation and has freely given his/her consent.

Signature:_____ Date:_____

Status in project:_____

Appendix 10:

University of New England Ethics Consent

UNE
NEW ENGLAND

RESEARCH SERVICES

Armidale NSW 2351 Australia
Telephone (02) 6773 2070, Fax (02) 6773 3543

HUMAN RESEARCH ETHICS COMMITTEE

MEMORANDUM TO: Dr M Ulrich-Lai, Mr G Roberts & Ms K Westaway
School of Health

This is to advise you that the Human Research Ethics Committee has approved the following:

PROJECT TITLE: Investigation of the management of the International Normalised Ratio (INR) in warfarin therapy during the initial four months of treatment

COMMENCEMENT DATE: [illegible] 2003

COMMITTEE APPROVAL No.: HE03/[illegible]

APPROVAL VALID TO: 28/[illegible] 2003

COMMENTS: No Conditions attached.

The Human Research Ethics Committee may grant approval for a maximum of three years. For approval periods greater than 12 months researchers are required to submit an application for renewal at each twelve month period. All researchers are required to submit a Final Report at the completion of their project. The Progress/Final Report form is available at the following web address: http://www.une.edu.au/research-services/ethics/page3.html#pprotocol

The *NHMRC National Statement on Ethical Conduct in Research Involving Humans* requires that researchers must report immediately to the Human Research Ethics Committee anything that might affect ethical acceptance of the protocol. This includes adverse reactions of participants, proposed changes in the protocol and any other unforeseen events that might affect the continued ethical acceptability of the project.

In issuing this approval number, it is required that all data and consent forms are stored in a secure location, for a minimum period of five years. These documents may be required for compliance audit processes during that time. If the location at which data and documentation are retained is changed within that five year period, the Research Ethics Officer should be advised of the new location.

[illegible] 2003

Jo-Ann Sozou
Secretary

Appendix 11:

Candidate's Letters Advising Approval by the *Human Research and Ethics Committee* of the relevant Health Care Facility for Pilot Study and (actual) Study

Pilot Study

I, the researcher, hold an approval from the Human Research and Ethics Committee of the health care facility in which the pilot study was conducted. For reasons of confidentiality these documents have been withheld from the appendices but are available if required.
Approval number: F/N 3.180405

Study

I, the researcher, hold an approval from the Human Research and Ethics Committee of the health care facility in which the study was conducted. For reasons of confidentiality these documents have been withheld from the appendices but are available if required.
Application number: 84/045

Appendix 12:

Data Collection Form for Patients

Data Collection Form for Patients

An Investigation of the Management of the International Normalised Ratio (INR) in Warfarin Therapy During the First Five months of Treatment

Patient number in study:..... Dr ID number:.....

Date:.....

1. Place of Initiation of warfarin therapy:

   GP rooms:

   Hospital: Adm Date:..... D/C date:..... Name of GP.....

   Discharge letter to GP?

   - ❑ Yes
   - ❑ No

   OPD appointment on discharge from hospital:

   - ❑ Yes – Appointment date:.....
   - ❑ No

2. Initial date seen by GP.....
3. Patient's phone number.....
4. UR number.....
5. Date of Birth.....
6. Sex:
   - ❑ Male
   - ❑ Female

7. Reason for Admission / see GP:

   ....

   ....

8. Reason for starting warfarin:

   AF.....DVT/PE... ...Vascular Surg... ...Post

   Infarct... ...Other... ...Prosthetic Heart Valve.....

9. Present medications: NSAIDs.....SSRIs..... COX

   Iis..... ANTIPLATELETS: type (s):.....

10. Other Medications.....

11. Previous warfarin therapy?

    - ❑ Yes – Reason:.....
    - ❑ No

12. Medical history: TIA..... Haem. Stroke..... Emb. Stroke..... Diabetic.....

    CCF..... IHD..... HT (uncontrolled) ..... GIT bleed/ulceration.....

    Genito-urinary bleed..... Cerebrovascular disease..... Peripheral vascular

    disease..... Renal insufficiency..... Anemia..... Liver disease.....

    Malignant disease..... Platelet dysfunction..... Coag defect .....

13. Date commenced on warfarin .....

14. Pre-dose INR..... 15. Pre-dose Hb .....

16. Pre-dose platelets..... 17. Serum Albumin .....

18. Weight..... 19. Check Hb near end of study period:.....

    date.....

Warfarin Doses and INR results

Treatment if INR>4.0 Code:

H=hold
* = Number of days warfarin held
# = Lower dose given
Vit K = Vitamin K given
P-HT = Prothrombinex HT given
FFP = Fresh frozen plasma given
T = Blood transfusion given

Date	Warfarin dose	INR result	Txif INR >4.0	New dose yes/no	M. Bleed yes/no	Hb done yes/no

Researcher: Kerrie Westaway

Telephone: 0419851856

Supervisors: Dr Mary Cruickshank

Mr. Greg Roberts

Date of commencement of data collection at study hospital: September 2005