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Appendix 1: Veterans Information Statement

CAN YOU HELP US TO IMPROVE WARFARIN MANAGEMENT?

The Department of Veterans Affairs and the University of Tasmania's School of Pharmacy are researching the management of veterans taking warfarin. We aim to investigate several aspects of warfarin management to identify whether warfarin management in veterans can be improved. This study involves pharmacist researchers at the School of Pharmacy using DVA data to assess each of these factors in one thousand DVA veterans over a two-year period.

The aspects of warfarin management we are investigating are:
- how often people taking warfarin visit their doctor, medical specialists or hospitals;
- how often they have blood tests performed;
- what other illnesses people taking warfarin experience;
- what other medicines they use, and
- if a medication review by a pharmacist affects any of these factors.

To participate in this study, we require your consent for us to obtain information involving your medical records from DVA and pathology laboratories (where blood tests are analysed). The information we will obtain will be:
- your age, gender, state of residence and whether you live in a rural or metropolitan area;
- your medical conditions and the medications you have taken;
- how often you visited general practitioners and medical specialists;
- how often you had medical investigations (such as blood tests) performed;
- the results of your INR (warfarin) blood tests;
- how many times, if any, you were admitted to hospital; and
- whether or not you have had a Home Medicines Review with a pharmacist.

We will use this information to establish how veterans taking warfarin are currently managed, and whether medication reviews by pharmacists improve warfarin management.

Participation in this study is very simple. To participate, please read the included consent form and sign both copies provided to you. Please return one signed copy of this form and return it in the addressed postage paid envelope provided. Keep the second copy for your records. After we receive your consent form, the pathology laboratories where your blood tests have been analysed will be contacted in order for us to access your warfarin blood test results (INRs).

If you would like to find out more about this study, please call Dr. Luke Bereznicki on (03) 6226 2195.

UTAS
PROJECT FUNDED BY THE AUSTRALIAN GOVERNMENT DEPARTMENT OF VETERANS AFFAIRS

323

Ella Claire van Tienen
Appendix 2: Pathology Provider Information Statement

The Current Status of Management of Australian Veterans Taking Warfarin

PATHOLOGY PROVIDER INFORMATION SHEET

August 2009

Dear Sir/Madam

You have been contacted as we require your assistance in retrieving some INR values in a research project being conducted through the Department of Veterans Affairs in collaboration with the School of Pharmacy at the University of Tasmania. This project is entitled ‘The Current Status of Management of Australian Veterans Taking Warfarin’.

The aim of this study is to assess the current trends in the management of veterans taking warfarin. We are also investigating whether medication reviews undertaken by pharmacists improve the management of these patients. Ultimately, the intention is to assess the safety and efficacy of warfarin therapy, with the intention of making recommendations and planning interventions, if needed.

We would be grateful if you could please take the time to send us the given patient’s INR values for the last 24 months. The data will be used to assess the percentage of veterans on warfarin therapy with a therapeutic INR, including the time spent within the therapeutic INR range.

Please see the attachment from the patient that gives their consent for us to retrieve their INR values for the last 24 months.

This project has received ethical approval from the Department of Veterans Affairs Human Research Ethics Committee, which is constituted under the National Health & Medical Research Council. If you have any concerns of an ethical nature or complaints about the manner in which the project is conducted, you may contact the Executive Officer of the DVA Human Research Ethics Committee on <ph> or <email>. You will need to quote ethics reference number “X00”

Please send us the INR values as soon as possible using the reply-paid envelope.

We thank you for taking the time to read this information letter and hope that you will be willing to help us.

If you have any questions, please don’t hesitate to contact me.

Yours sincerely,

[Signature]

Dr Luke Bereznicki
Lecturer in Pharmacy Practice
Tasmanian School of Pharmacy
University of Tasmania
Appendix 3: ‘Warfarin and you’ Information Leaflet

WARFARIN AND YOU
Consumer Information Leaflet

Warfarin is a medicine that is used to increase the time it takes for your blood to clot. It belongs to a class of medicines called anticoagulants. These medicines help to prevent unwanted blood clots which may cause a stroke, heart attack or vein blockages.

In Australia there are two brands of warfarin.

They are called MAREVAN® and COUMADIN®.

<table>
<thead>
<tr>
<th>MAREVAN® brand warfarin tablets</th>
<th>COUMADIN® brand warfarin tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 mg tablet (brown)</td>
<td>1 mg tablet (light tan)</td>
</tr>
<tr>
<td>3 mg tablet (blue)</td>
<td>2 mg tablet (lavender)</td>
</tr>
<tr>
<td>5 mg tablet (pink)</td>
<td>5 mg tablet (green)</td>
</tr>
</tbody>
</table>

These two brands of warfarin are not the same and should not be swapped or changed unless advised to do so by your doctor.

How does warfarin work and how much should I take?

Normally the body balances bleeding and clotting activities but some conditions can alter this balance and increase the risk of an unwanted blood clot.

Warfarin works by reducing the formation of certain blood clotting factors produced by your liver. To produce these clotting factors the liver needs vitamin K and warfarin interferes with the liver’s ability to use vitamin K.

Because everybody is different it makes sense that everybody reacts differently to warfarin. This also means that the dose of warfarin that works best is different for everybody. Your doctor will find the best dose for you based on the results of your blood tests.

The dose of warfarin needed is that which prevents clots but doesn’t cause unwanted bleeding.
What is the INR?

A blood test is needed to determine the effect of warfarin for each person and this is measured as the International Normalised Ratio or INR. The INR is a measure of how long it takes for blood to clot.

The INR for a person not taking warfarin is 1. The higher the INR, the longer it takes for blood to clot. The desired INR for you will depend on the reason for which you are taking warfarin.

Your doctors will try and keep your INR within a range – called the target INR range.

The target INR range is different for different conditions. For example, for people with atrial fibrillation – an irregular heart beat in the top chambers of the heart – the target INR range is 2 to 3. Higher INR ranges are recommended for people who have a mechanical heart valve or for those with some irregular clotting conditions.

Clotting is necessary to stop bleeding when you cut yourself. When taking warfarin your clotting time is increased so it takes longer for a clot to form. Having your INR in the correct range reduces the risk of potentially dangerous bleeding.

Generally regular blood tests are essential to check that your INR is within the correct range. Your doctor will tell you the correct range for your condition.

Your doctor will also tell you how often you will need to have a blood test. When you first start taking warfarin these tests will be frequent, often every one or two days for the first week. Once your warfarin levels have stabilised, testing is usually only repeated every 4 weeks, or as often as your doctor tells you. Your dose of warfarin may be changed based on the blood test results.

How do I take warfarin?

Warfarin is usually taken once a day, with or without food. Some doctors prefer that their patients take their dose in the evening. This allows the dose to be changed if necessary on the day that the INR results are obtained.

After each blood test you should contact your doctor for instructions and write down any dosage changes for your records. One suggested option is to use an INR record form (a sample is attached at the back of this leaflet) writing the dose you need to take in the appropriate day and then circling this dose when you have taken it (see below). This will help to both remind you of the correct dose and indicate to you that you have taken that day’s dose.

Example of an INR record form:

```
<table>
<thead>
<tr>
<th>Date</th>
<th>INR</th>
<th>Mon</th>
<th>Tue</th>
<th>Wed</th>
<th>Thur</th>
<th>Fri</th>
<th>Sat</th>
<th>Sun</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/12</td>
<td>2.5</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18/2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
```

*x* shows where you would write your warfarin dose.
When should I take warfarin?

You should take your dose exactly as your doctor tells you and not miss any doses.

If you do forget to take a dose and then remember within a few hours, take your dose. If it is more than a few hours - for example the next day - just take your next dose at the usual time and make a note of the missed dose to tell your doctor.

You should not take a double dose.

In the event you miss more than one dose contact your doctor for advice.

Why is my diet important?

Because vitamin K and warfarin tend to work against each other, it is important to be aware that changes in diet can have an impact on warfarin activity within the liver.

As vitamin K is essential for a healthy diet you should not try and eliminate vitamin K from your food intake. In fact, the recommended daily intake of vitamin K remains the same for people taking warfarin and for those who don't.

Aim to balance your vitamin K intake by being consistent with the foods that you eat.

You don't have to eat the same types of food everyday!

Having a diet with a variety of foods is important. Remember vitamin K is needed for a healthy diet and foods containing vitamin K should be included.

Foods high in vitamin K include broccoli, brussel sprouts and leafy green vegetables like spinach, cabbage and kale. Generally the greener the vegetable the higher the vitamin K content. Canola and soybean oil also have high vitamin K content. Most fruits, meats, dairy and grains products have low vitamin K content.

Dietary supplements such as Sustagen® and Resource® which may be recommended by your doctor for extra calories or nutrients are quite low in vitamin K.

From time to time you may wish to eat something not usually in your diet. A list of foods and their vitamin K content is provided on the next page.
**Warfarin and other medications**

There are many more medicines that can affect warfarin that are not listed here. Check with your doctor or pharmacist before starting any new medication including complementary products purchased from health food stores.

These are examples of medicines and complementary products which may increase your clotting risk. This is not a complete list – if you are concerned about a medicine you are taking, please talk to your healthcare professional.

<table>
<thead>
<tr>
<th>Medicine type</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription</td>
<td>Anti-epileptics like carbamazepine (Tegretol®) and phenytoin (Dilantin®)</td>
</tr>
<tr>
<td></td>
<td>Anti-thyroids like carbimazole (Neo-Mercazole®) and propylthiouracil</td>
</tr>
<tr>
<td>Complementary products</td>
<td>Ginseng</td>
</tr>
<tr>
<td></td>
<td>Green Tea</td>
</tr>
<tr>
<td></td>
<td>St. John’s Wort</td>
</tr>
<tr>
<td></td>
<td>Vitamin K (in some multivitamins)</td>
</tr>
</tbody>
</table>

These are examples of medicines and complementary products which may increase your bleeding risk. This is not a complete list – if you are concerned about a medicine you are taking, please talk to your healthcare professional.

<table>
<thead>
<tr>
<th>Medicine type</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription</td>
<td>Antibiotics like co-trimoxazole (Bactrim®) and erythromycin (Ery®)</td>
</tr>
<tr>
<td></td>
<td>Anti-inflammatories like indomethacin (Indocid®) and celecoxib (Celebrex®)</td>
</tr>
<tr>
<td></td>
<td>Ulcer and reflux medicines like omeprazole (Losec®) and cimetidine (Tagamet®)</td>
</tr>
<tr>
<td></td>
<td>Heart and cholesterol medicines like amiodarone (Cordarone®) and simvastatin (Zocor®)</td>
</tr>
<tr>
<td>OTC medicine</td>
<td>Aspirin and pain relievers</td>
</tr>
<tr>
<td></td>
<td>Cough and cold medicines</td>
</tr>
<tr>
<td></td>
<td>Oral anti-fungals like miconazole (Daktarin oral gel®) and fluconazole (Difucan®)</td>
</tr>
<tr>
<td>Vitamins and herbal products</td>
<td>Vitamin E</td>
</tr>
<tr>
<td>Or complementary products</td>
<td>Co-enzyme Q10</td>
</tr>
<tr>
<td></td>
<td>Garlic supplements</td>
</tr>
<tr>
<td></td>
<td>Ginger supplements</td>
</tr>
<tr>
<td></td>
<td>Ginkgo Biloba</td>
</tr>
<tr>
<td></td>
<td>Glucosamine</td>
</tr>
</tbody>
</table>

**Warfarin and YOU: Consumer Information Leaflet**

The information in this leaflet is provided for general information only. It is not intended as medical advice, and should not be relied upon as a substitute for consultations with qualified health professionals who can determine your individual medical needs.

This information has been downloaded from www.anticoagulation.com.au

Last updated September 2001
Vitamin K

This is NOT a list of foods to avoid or a complete list of all foods containing vitamin K. It provides an idea of those foods with high and moderate vitamin K content as an aid to helping you maintain a consistent dietary intake.

<table>
<thead>
<tr>
<th>Foods with low vitamin K content</th>
<th>Foods with moderate vitamin K content</th>
<th>Foods with high vitamin K content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfalfa</td>
<td>Asparagus</td>
<td>Broccoli (cooked)</td>
</tr>
<tr>
<td>Beans (green)</td>
<td>Avocado</td>
<td>Brussels sprouts</td>
</tr>
<tr>
<td>Carrots &amp; Cauliflower</td>
<td>Red Cabbage</td>
<td>Cabbage (raw)</td>
</tr>
<tr>
<td>Celery, Corn &amp; Potato</td>
<td>Green Peas</td>
<td>Endive (raw)</td>
</tr>
<tr>
<td>Breads, Cereal</td>
<td>Lettuce (iceberg)</td>
<td>Lettuce (gourmet)</td>
</tr>
<tr>
<td>Rice</td>
<td>Pickle, dill</td>
<td>Parsley</td>
</tr>
<tr>
<td>Fruit &amp; juices (mostly)*</td>
<td>Beans (snap)</td>
<td>Silver beet (cooked)</td>
</tr>
<tr>
<td>Cheese (cheddar), Milk</td>
<td>Cheese (blue)</td>
<td>Spinach (cooked &amp; raw)</td>
</tr>
<tr>
<td>Eggs &amp; Butter</td>
<td>Margarine</td>
<td>Mayonnaise</td>
</tr>
<tr>
<td>Sunflower &amp; Sesame oil</td>
<td>Olive oil</td>
<td>Canola &amp; Soybean oil</td>
</tr>
<tr>
<td>Fish, Meat, Pork, Chicken</td>
<td>Abalone</td>
<td>Liver</td>
</tr>
</tbody>
</table>

*Cranberry juice consumption has been linked with increased bleeding with warfarin

What about other medicines?

Many medications may change the anti-clotting action of warfarin. This includes medicines prescribed by your doctor and items you can buy without prescription from your pharmacy, supermarket or health food store.

Assume that any medicine can affect warfarin unless advised otherwise.

To minimise the risk of having a problem with your warfarin:

- Check with your doctor or pharmacist before starting or stopping any medicines
- Tell the pharmacist you are taking warfarin before purchasing any Over The Counter medicines (OTC medicines)
- Ask your pharmacist before buying any vitamins, herbal or natural therapies
- If you visit a different doctor, or see a dentist, be sure to tell them you are taking warfarin
- Wear a MedicAlert® bracelet identifying that you take warfarin (for more information, ask your pharmacist, call 1800 882 222, or visit www.medicalert.com.au)

The following Tables list some of the common medicines and complementary products which can interfere with warfarin.

WARFARIN AND YOU: Consumer Information Leaflet

The information in this leaflet is provided for general information only. It is not intended as medical advice, and should not be relied upon as a substitute for consultations with qualified health professionals who can determine your individual medical needs.

This information has been downloaded from www.anticoagulation.com.au

Last updated September 2008
Other factors that can affect warfarin and your INR

**ALCOHOL**

Generally it is best not to drink alcohol whilst taking warfarin but if you do, you should restrict your daily intake to no more than one or two standard drinks a day, with two alcohol free days a week.

One standard drink is equal to:
- One small glass of wine (100ml)
- One nip of spirits (30ml)
- One middy of normal strength beer (285ml)

Alcohol in excess can affect liver function which can affect the way warfarin works. Alcohol also irritates the lining of your stomach, which may increase the likelihood of a stomach bleed.

**ILLNESS**

Any new illness especially involving:
- Diarrhoea or vomiting
- Fever or infection
- Loss of appetite
- Jaundice
- Medicines you may use to treat your illness

Contact your doctor if you become sick with a fever, the flu, or an infection. Also call if you have diarrhoea or vomiting that lasts for more than one day.

**LIFESTYLE**

Other considerations that should be discussed with your doctor include:
- Changes in your level of exercise
- Trying to stop smoking
- Changes in your diet - fasting or crash diets
- Travelling on long trips — make sure you have enough warfarin tablets and carry identification that indicates that you take warfarin. Because your diet and activity may vary you may need an INR check whilst away.
- Pregnancy must be avoided as warfarin can seriously affect an unborn baby in early pregnancy. All women who may become pregnant should discuss with their doctor the risks and means of reducing those risks. Should you become pregnant whilst taking warfarin you must notify you doctor at the earliest opportunity.
Signs and Symptoms of unusual bleeding

Sometimes, if your INR is too high you may experience some unusual bleeding. These are the signs:

- Severe bruising that gets worse
- Any bleeding that take a long time to stop
- Unexplained bleeding or bruising
- Menstrual bleeding that is much heavier than usual
- Red or dark urine
- Red or black bowel motions
- Coughing up blood, or anything red
- Bloody or dark stained vomit
- Severe headache or dizziness
- Weakness or lethargy
- Unusual pain or swelling

If any of the above symptoms occur, and they are concerning you, you should contact your doctor. If your doctor is unavailable, go to your nearest hospital emergency department.

Living safely with warfarin

While you can perform all your normal daily activities whilst taking warfarin it would be a good idea to avoid contact sports. Any falls, blows or injuries should be reported to your doctor. You might not always see visible signs of bleeding.

Minor cuts and scrapes should be cleaned and covered with an adhesive bandage or pad. Larger cuts should be covered with a clean pad and have pressure applied to help slow the bleeding (this may be in the form of a compression bandage or you may wish to apply the pressure using your hands) and be reported to your doctor.

Around the home:
- Use a non-slip bath mat.
- Use a soft bristle toothbrush.
- Use an electric shaver.
- Wear gloves while gardening.
- Be careful around pets.
- Wear non-slip footwear/sturdy shoes to avoid trips and slips.
- Take care with sharp objects such as kitchen knives.

Options for monitoring your INR

Aside from laboratory monitoring of INR, portable devices are available for home monitoring. While these devices are remarkably accurate and provide results similar to laboratory monitoring, they do require proper training in their use along with periodic comparisons to INR measurements obtained by an external laboratory. Ask your doctor or pharmacist if you are interested in this option and they can help you figure out the best management option for you.
## INR Record Form

<table>
<thead>
<tr>
<th>Name</th>
<th>Referring doctor</th>
<th>Warfarin brand</th>
<th>INR range required</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>INR</th>
<th>Recommended warfarin dose</th>
<th>Next Appointment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mon</td>
<td>Tues</td>
</tr>
</tbody>
</table>

**WARFARIN AND YOU: Consumer Information Leaflet**

This information has been downloaded from [www.anticoagulation.com.au](http://www.anticoagulation.com.au)
Appendix 4: One Page Guide to Warfarin Treatment

One Page Guide to Warfarin Treatment*

1. Warfarin belongs to a class of medications called anticoagulants ("anti-clotting medicines"). Warfarin keeps blood clots from forming or getting larger.

2. Many medications can change the way warfarin works. Ask your doctor or pharmacist about using any other medication, including over-the-counter medications, vitamins and herbal products.

3. Make sure your doctor or pharmacist knows if you are taking aspirin or aspirin-like medications, such as medications for pain relief and the common cold.

4. Avoid drinking large amounts of alcohol.

5. Certain foods will change the way warfarin works. Do not change your diet while taking warfarin. Foods that contain vitamin K (such as lettuce, spinach, broccoli, cabbage, cauliflower or liver) decrease the anti-clotting effect of warfarin. If you eat foods that have vitamin K, do not change the amount of these foods that you normally eat per week. The main point regarding diet is to eat a consistent amount of foods per week that contain vitamin K.

6. It is very important to have regular blood tests while taking warfarin. The test is called an INR, and it measures how fast your blood clots compared to normal.

7. You should carry an identification card that shows you are taking warfarin.

8. Make sure your doctor, dentist, or other health care provider knows you are taking warfarin before you have any surgery or dental work.

9. You should report the following to your doctor immediately:
   - Bleeding from the gums or nose.
   - Coughing up blood.
   - Red or black bowel motions.
   - Red or dark-brown coloured urine.
   - Unusually heavy menstrual bleeding.
   - Any bleeding from cuts or wounds that does not stop.
   - Easy bruising.
   - Severe headache.

10. If you miss a dose: Take the missed dose as soon as possible. If you do not remember until the next day, skip the missed dose. Only take your usual dose for the day. You should not take two doses at the same time.

*Adapted from the Institute for clinical systems improvement (wii.org)

The information in this leaflet is provided for general information only. It is not intended as medical advice, and should not be relied upon as a substitute for consultations with qualified health professionals who can determine your individual medical needs.
Appendix 5: ‘Warfarin Words’ Newsletters

Welcome to the first edition of Warfarin Words! This newsletter aims to answer all your questions about warfarin and related issues. If you have anything you’d like us to cover in future issues please let us know—email: info@anticoagulation.com.au

Make medicine use SAFER

**SPEAK UP**
The more information you give your doctor or pharmacist about you the better they can help you. Tell them about your medical history and all the medicines and treatments you use. It may help to have a written list.

**ASK QUESTIONS**
When you visit your doctor or pharmacist ask questions about your options to help decide the best choice for you. It may help to take a friend or relative along with you.

**FIND THE FACTS**
Before you and your health care professional decide on a medicine, learn and understand as much about it as you can. Find out what it is and what it’s used for, as well as any side effects or precautions.

**EVALUATE YOUR CHOICES**
After you have all the information, think carefully about your choices. Weigh up the risks and the benefits. Talk to your health care team about which decision is best for you.

**READ THE LABEL AND FOLLOW DIRECTIONS**
Find out what the active ingredient in the medicine is. Before you use the medicine make sure it’s the right medicine, for the right patient, in the right amount, at the right time, in the right way (e.g. do you have to swallow the tablet or chew it?). Talk to your doctor if you want to stop a medicine or use it in a different way than directed.

Getting the most out of your visit

Before you go, write a list of the things you want to say, or the questions you want to ask. Take a friend or relative. Ask your doctor or pharmacist to write down any answers or advice.

You might like to ask:
- What is the medicine for?
- How does it work?
- How should I use it?
- How long do I keep taking it for?
- When do I stop it?
- Will I feel any different?
- Is there anything I need to do?
- What about side effects?
- What happens if I miss a dose?
- Are there any medicines I should not take?
- Do you think I’m going to feel better?
- Is this medicine going to stop me feeling worse?
- What can I expect to happen?
- How long will it take?
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen

Warfarin Words

Get to know warfarin — make it work effectively for you

Welcome to the second edition of Warfarin Words. This newsletter aims to answer all your questions about warfarin and related issues. If you have anything you’d like us to cover in future issues please let us know—email: info@anticoagulation.com.au

Warfarin Basics

For more detailed information visit www.anticoagulation.com.au or speak with your doctor or pharmacist.

WHAT IS WARFARIN?
• Warfarin is a medicine that lowers the risk of blood clots forming in your body.
• Blood tests are needed to monitor the effects of warfarin.
• Bleeding is the most common side effect of warfarin.

TAKING WARFARIN SAFELY
• There are two brands of warfarin. These are not the same, so don’t change brands.
• If you plan to become pregnant, talk to your doctor first.

Things that affect warfarin

OTHER MEDICINE
• Many medicines can change the way warfarin works. This includes prescription and non-prescription medicines, vitamins and herbal supplements. Ask your doctor or pharmacist before starting, changing, or stopping medicines.

DIET (this will be covered in more detail in the next edition)
• Certain foods will change the way warfarin works. Do not make significant changes to your diet while taking warfarin; try to eat a regular balanced diet.
• Drink no more than 1-2 standard alcoholic drinks per day, with at least 2 alcohol free days per week.

BLOOD TESTS
• You need to have regular blood tests called INR tests. The frequency of the tests will change over the course of your treatment.
• The dose of warfarin is worked out based on the INR results.

WARFARIN AND BLEEDING
• Contact your doctor if you have any signs of unusual bleeding.
• Tell all health professionals that you are taking warfarin so they can make appropriate decisions about the medicines and medical procedures best for you.
• Think about ways you can do your normal activities without increasing the risk of hurting yourself e.g. wear gloves while gardening.

Always ask “Is this OK to take/do while I am on warfarin?”

This newsletter has been produced by the Tasmanian School of Pharmacy, Unit for Medication Outcomes Research and Education. Information in this resource has been adapted from the Veterans’ Medicine Advice and Therapeutic Education Services and the Institute for Clinical Systems Improvement.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Warfarin Words

Welcome to the third edition of Warfarin Words. This newsletter aims to answer all your questions about warfarin and related issues. If you have anything you’d like us to cover in future issues please let us know—email: info@anticoagulation.com.au

What foods are safe to eat while taking warfarin?
- How much can I eat?
- Do I have to stop eating all green vegetables?
- How do I know what my diet is doing to my INR?

These are some of the most common questions asked by people taking warfarin. The short answer is that all foods are safe in moderation. Because warfarin works against vitamin K in your liver, changes in the amount of vitamin K in your body can change the way warfarin works.

Most vitamin K comes from the food you eat. The issue of vitamin K containing foods causes a lot of confusion. There are a few simple rules to follow.

1. Try to maintain a balanced diet. Eat all foods in moderation and include foods that contain vitamin K. You don’t need to eat the same things everyday, but try and include about the same amount of foods high in vitamin K in your diet from one week to the next.
2. Remember that diet does affect the INR. Big changes in your diet can affect your INR control. If you go on a diet for weight loss, dramatically change the types of food you eat, or are sick and can’t eat for a few days, it’s a good idea to tell your doctor and get your INR checked.
3. Know that vitamin K helps INR control. Cutting foods that contain vitamin K out of the diet completely actually makes it harder to keep the INR stable. Eating a balanced amount of vitamin K regularly (e.g. from week to week) helps to stabilise the INR.

Note: Some people take potassium supplements such as Slow K. Potassium is symbolised by the letter ‘K’. Vitamin K is not the same as potassium.

Dietary advice for people taking warfarin

For more detailed information visit www.anticoagulation.com.au or speak with your doctor or pharmacist.

Vitamin K content of common foods

<table>
<thead>
<tr>
<th>Foods with low vitamin K content</th>
<th>Foods with moderate vitamin K content</th>
<th>Foods with high vitamin K content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fruits &amp; vegetables</td>
<td>Green Peas</td>
<td>Endive (raw)</td>
</tr>
<tr>
<td>Almonds</td>
<td>Lettuce (iceberg)</td>
<td>Lettuce (gastric)</td>
</tr>
<tr>
<td>Beans (green)</td>
<td>Pickle, dill</td>
<td>Parsley</td>
</tr>
<tr>
<td>Carrots &amp; Cauliflower</td>
<td>Red Cabbage</td>
<td>Cabbage (raw)</td>
</tr>
<tr>
<td>Celery, Corn &amp; Potato</td>
<td>Yellow Peppers</td>
<td>Spinach (cooked &amp; raw)</td>
</tr>
<tr>
<td>Bread, Cereal</td>
<td>Bread (white)</td>
<td>Broccoli (cooked)</td>
</tr>
<tr>
<td>Rice</td>
<td>Beans (snaps)</td>
<td>Silver beet (cooked)</td>
</tr>
<tr>
<td>Fruit &amp; juices (most)</td>
<td>Cheese (cheddar)</td>
<td>Cheese (blue)</td>
</tr>
<tr>
<td>Cheese (cheddar) Milk</td>
<td>Egg &amp; Butter</td>
<td>Margarine</td>
</tr>
<tr>
<td>Sunflower &amp; Sesame oil</td>
<td>Olive oil</td>
<td>Canola &amp; Soybean oil</td>
</tr>
<tr>
<td>Fish, Meat, Pork, Chicken</td>
<td>Abalone</td>
<td>Liver</td>
</tr>
</tbody>
</table>

Five things you should do while on warfarin:
1. Aim to eat a healthy, balanced diet.
2. Have your INR checked more often if you make large changes in your diet or if you are sick and unable to eat as much as usual.
3. Know that it is safe to include foods in your diet that contain vitamin K.
4. Try to eat about the same amount of foods with vitamin K from week to week.
5. Speak to your doctor or pharmacist if you have any questions about your warfarin treatment.

This newsletter has been produced by the Tasmanian School of Pharmacy, Unit for Medication Outcomes, Research and Education.
Appendix 6: Warfarin ID Card
Appendix 7: INR Record Book
Optimising warfarin management: An exploration of pharmacist-delivered models of care

1. If you miss a dose: Take the missed dose as soon as possible. If you do not remember until the next day, skip the missed dose. Only take one dose at the normal time.

2. If you bleed, take the following steps:
   - Heavy bleeding from cuts or wounds that does not stop
   - Unusually heavy menstrual bleeding
   - Blood in the stool or urine
   - Coughing up blood
   - Bleeding from the gums or nose

3. You should report the following to your doctor immediately:
   - You are taking warfarin before surgery or dental work
   - You have a heart valve replacement
   - You have any medical condition that requires warfarin

4. The test is called an INR and it measures how fast your blood clot.

5. It is very important to have regular blood tests while taking warfarin.

6. If the test result is abnormal, your doctor will adjust your warfarin dose.

7. You should carry an identification card that shows you are taking warfarin.

8. Make sure your doctor knows the medications you are taking.

9. If you take other medications, tell your doctor.

10. If you have flu-like symptoms, take acetaminophen (Tylenol) or ibuprofen (Advil) with food.

11. If you have questions or concerns about warfarin, contact your pharmacist or a trusted healthcare provider.

For further information about warfarin, visit: www.pharmacopeiam.org or www.medicines.org.uk

Name:
Phone number:
Address:

Pharmacy name:
Phone number:

Journey:

Doctor name:
Phone number:

Target INR range:

Warfarin brand:

UTAS MORE
Quick guide to warfarin treatment

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

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<table>
<thead>
<tr>
<th>Date</th>
<th>INR</th>
<th>Recommended Warfarin Dose</th>
<th>Next appointment</th>
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</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

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Ella Claire van Tienen
Optimising warfarin management: An exploration of pharmacist-delivered models of care

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<table>
<thead>
<tr>
<th>Date</th>
<th>INR</th>
<th>Recommended Warfarin Dose</th>
<th>Next appointment</th>
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<table>
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<tr>
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<th>INR</th>
<th>Recommended Warfarin Dose</th>
<th>Next appointment</th>
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</tr>
<tr>
<td>Date</td>
<td>INR</td>
<td>Recommended Warfarin Dose</td>
<td>Next Appointment</td>
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<tr>
<td>6</td>
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</tbody>
</table>
Appendix 8: INR Record Form

<table>
<thead>
<tr>
<th>Week beginning (date)</th>
<th>Recommended Warfarin Dose</th>
<th>Date of test</th>
<th>INR result</th>
<th>Next appointment/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

INR Record Form

Name
Referring doctor
Warfarin brand
INR range required
Appendix 9: Self-Monitoring Diagram
Appendix 10: INR Record Book for Patient Self-Monitoring
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen

1. If you miss a dose, take the missed dose as soon as possible. If you do not remember when the next dose is due, skip the missed dose. Only take your usual dose for the day. You should not use two doses at the same time.

10. Check for bleeding from cuts or wounds that does not stop.
   - Heavy bleeding from cuts or wounds that does not stop.
   - Unusually heavy menstural bleeding.
   - Red or dark-brown coloured urine.
   - Blood or black bowel motions.
   - Confusing up blood.
   - Bleeding from gums or nose.

You should report the following to your doctor immediately:

6. If it is very important to have regular blood tests while taking warfarin.

7. You should carry an identification card that shows you are taking warfarin.

8. Make sure your doctor updates any summary of current work.
Quick guide to warfarin treatment

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

Tips for INR self-testing

1. Warm hands under warm running water prior to test
2. "Milk" the finger – avoid squeezing
3. Don't prick finger until monitor is ready
4. Avoid calloused areas
5. Prick the side of the finger pad
6. Hold elbow up to promote blood flow to fingertips
7. Touch the drop to the test strip – not the finger to the test strip
8. Never use the same puncture if the first attempt is unsuccessful – try a different finger.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

<table>
<thead>
<tr>
<th>Week beginning (date)</th>
<th>Recommended Warfarin Dose</th>
<th>Date of test</th>
<th>INR result</th>
<th>Next appointment/Comments</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Wed</td>
<td>Thur</td>
<td>Fri</td>
</tr>
<tr>
<td>Date of test</td>
<td>INR result</td>
<td>Next appointment/Comments</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table showing the recommended warfarin dose and test results for each day of the week.

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Optimising warfarin management: An exploration of pharmacist-delivered models of care

| Recommended Warfarin Dose | Communs | Next Appointment | INR Test Date | INR Test Result | Date of Test | Fri | Sat | Sun | Mon | Tue | Wed | Thu | Fri | Sat | Sun |
|---------------------------|---------|-----------------|---------------|----------------|--------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|

| Week | Communs | Next Appointment | INR Test Date | INR Test Result | Date of Test | Mon | Tue | Wed | Thu | Fri | Sat | Sun |
|------|---------|-----------------|---------------|----------------|--------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|

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Appendix 11: Warfarin Counselling Checklist

Checklist for training consumers to self-monitor

**Warfarin education component:**

- Discuss with the patient the reason for warfarin treatment, ensure they are clear of the reason they are taking it.
- Briefly explain warfarin’s mechanism of action:
  - Discuss starting new treatments or changing the dose of current treatment; explain the existence of common OTC medication interactions, such as aspirin, NSAIDs, paracetamol, complementary therapies and laxatives. Emphasize the importance of discussing new treatments with you or another healthcare professional.
  - Explain the role of vitamin K, and the importance of consistency in regards to vitamin K rich foods in the diet, rather than avoidance.
  - Explain the importance of minimizing their alcohol intake and why.
- Explain the INR, the concept of a target range and emphasise the importance of regular testing.
- Emphasize the importance of compliance (discuss the maintenance of an INR diary, and recording doses—especially missed doses).
- Explain the possible effects of poor anticoagulation control:
  - Bleeding or severe bruising.
  - Recurrence of thromboembolism.
- Discuss the appropriate action if excessive bleeding or bruising occurs.
- Discuss the appropriate action if diarrhoea or vomiting occurs.
- Discuss ways to minimise high risk activities associated with an increased risk of physical trauma.
- Suggest wearing a MedicAlert® bracelet/necklace and carrying a warfarin ID card.
- Let them know about www.anticoagulation.com.au if they are interested in finding out more information.

**Practical training component:**

- Train on use of point of care INR monitor:
  - How to use the machine.
  - How to obtain an accurate sample.
  - How to obtain an accurate result.
- Discuss how the INR results is to be transmitted to the GP, preferred times to contact GP, and other details.
- Explain the run in phase (of two INR tests comparing the monitor result to pathology within four hours of one another) and discuss when this will take place.
Appendix 12: Pre Self-Monitoring Assessment Tool

Pre self-monitoring assessment
for consumers who have undergone training

Patient: .................................................................
Doctor: .................................................................
Pharmacist conducting assessment: .........................................................

THEORETICAL ASSESSMENT
Please answer the questions in the space provided

How does warfarin work?
...................................................................................................................
...................................................................................................................
...................................................................................................................
...................................................................................................................

How often should you test your INR?
...................................................................................................................
...................................................................................................................
...................................................................................................................
...................................................................................................................

What is meant by target INR?
...................................................................................................................
...................................................................................................................
...................................................................................................................
...................................................................................................................

What is your target INR?
...................................................................................................................
...................................................................................................................
THEORETICAL ASSESSMENT

What are the signs of too much warfarin?

What are the signs of too little warfarin?

What is QC and when do you need to do it?

PRACTICAL ASSESSMENT
To be completed by accredited pharmacist

Finger pricking technique

Point of Care monitor competency:
  * Placing of sample
  * Two tests recorded with a discrepancy of not more than 15%

Maintenance of POC monitor and test strips

Additional comments:
Appendix 13: Pharmacy Promotional Tools

Dear Pharmacist,

We are excited to announce the launch of a new internet resource for you and your patients: www.anticoagulation.com.au

This website has been developed by the Unit for Medication Outcomes and Research Education (UMORE) at the University of Tasmania’s School of Pharmacy.

The site aims to provide education for people taking warfarin, and support for healthcare professionals through the provision of downloadable information leaflets and other valuable resources.

On this site you will find information leaflets and INR record books that you can print out and supply to your patients. You will also find counselling tips to assist you to provide the best possible service to your consumers.

The site is filled with information on all aspects of anticoagulation, as well as details on INR self-monitoring. The aim is to complement the counselling and education you already offer your consumers by providing easy to understand information that they can access in their own homes and take in at their own pace.

Please find enclosed a starter kit to help you, your staff, and your customers discover the benefits of www.anticoagulation.com.au You have been provided with cards to give to consumers to direct them to the online resource. You will also find card holders which you may find useful to store the cards near your warfarin supplies.

We hope you find this resource a useful one!

For further information, or feedback, contact info@anticoagulation.com.au
Appendix 14: www.anticoagulation.com.au Contents
Optimising warfarin management: An exploration of pharmacist-delivered models of care

In a medical emergency please call an ambulance on 000
If you require information on what to do if you, or someone you know, has taken too much warfarin (or any other medicine) please call the Poisons Information Centre on 13 11 26
For more information about anticoagulation.com.au contact: info@anticoagulation.com.au
For technical support, or help using this website contact: support@anticoagulation.com.au
To contact UMORE, or enquire about UMORE research
Telephone: 03 6331 9122
Fax: +61 3 6226 5027
Email: pharmacist@utas.edu.au
Churchill Avenue, Sandy Bay, Tas, 7005
Optimising warfarin management: An exploration of pharmacist-delivered models of care

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What is Warfarin?

Warfarin is medicine that is used to increase the time it takes for blood to clot. It belongs to a class of medicines called anticoagulants. These medicines help to prevent unwanted blood clots which may cause a stroke, heart attack or vein blockages.

Warfarin is a medicine prescribed to people at increased risk of forming blood clots. It is often given to people who have a medical condition where it is important to reduce the chance of clots forming. These conditions may be an irregular heart beat called atrial fibrillation, a blood clot in the legs or lungs, or having an artificial valve in the heart. Some people are given warfarin after they have a heart attack. There may also be other reasons a doctor has prescribed warfarin.

Warfarin is an amazingly effective medicine for reducing the complications associated with these medical conditions. It has been around since the 1950s and is taken by thousands of Australians every day. Warfarin is a bit more complicated than most other medicines to manage, but the benefits of taking it far outweigh the risks. With a little care and some good warfarin management people can continue to lead a full and active life.

In Australia there are two brands of warfarin.

They are called MAREVAN® and COUMADIN®. These two brands of warfarin are not the same and should not be swapped or changed unless advised to do so by a doctor.
How Does it Work?

While warfarin is often referred to as a ‘blood thinner’, it doesn’t actually make your blood thinner. Warfarin interferes with your body’s ability to form a blood clot, so really should be referred to as an ‘anti-clotting’ medicine. Normally, the blood’s ability to form a clot is helpful in preventing unwanted bleeding if you cut or injure yourself. In some people, the blood clots too easily because of illness. In these people, antithrombotic medications are required.

In order for your blood to form a clot, you have to have certain proteins in your blood called clotting factors. Normally, your liver makes these clotting substances and it requires vitamin K from the diet to do so. Warfarin reduces your liver’s ability to use vitamin K to make these clotting factors, which makes it harder for your blood to clot.

Because everybody is different it makes sense that everybody reacts differently to warfarin. The effects of warfarin are very unpredictable from person to person. As no two people are the same you will probably find that your warfarin dose is likely to change often until your doctor finds the best dose for you. This often involves lots of blood tests to make sure that your warfarin is working the best it can for you.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen
Optimising warfarin management: An exploration of pharmacist-delivered models of care

There are a few numbers associated with taking warfarin and it’s important not to get them confused.

The first number that it is important to know is the dose of warfarin that you need to take. Your doctor may tell you your dose in milligrams (mg) of warfarin or they may tell you the number of tablets to take. It’s important that you know what it is they are telling you and how to take this dose. For example, if you are told to take 4mg of warfarin you could make this up from a combination of tablets. If you take the Marevan® brand you could take one 1mg (brown) tablet and one 3mg (blue) tablet. If you take Coumadin® brand you could take two 2mg (lavender) tablets. This is an example, your healthcare professional will tell you what dose is right for you and which tablets you can take to make up the dose.

Remember that your dose is likely to change often, particularly in the early stages of treatment as the best dose for you is found.

The second number associated with taking warfarin is the INR (International Normalised Ratio). The INR is a blood test used to measure how well the warfarin is working. Do not get these two numbers confused!

It is a really good idea to use a record book to keep track of your INR results and the dose of warfarin that your doctor has said for you to take.

Click here to download a record sheet to help you manage your warfarin dose and record your INR.

Last Updated: 02 Jun 2009

Ella Claire van Tienen
Optimising warfarin management: An exploration of pharmacist-delivered models of care

The INR stands for International Normalised Ratio. It is a test used to check how long it takes for your blood to clot and it has been standardised so that tests done in different laboratories around the world on the same sample of blood will give the same result.

The INR for someone who is not taking warfarin is around 1. The higher your INR is, the longer it takes your blood to clot. The desired INR for you will depend on the reason for which you are taking warfarin.

Your doctor will try and keep your INR within a particular range called the target INR range.

The target INR range is different for different conditions. For example, for people with atrial fibrillation (an irregular heart beat in the top chambers of the heart) the target INR range is 2 to 3. Higher INR ranges are recommended for people who have a mechanical heart valve or for those with some irregular clotting conditions.

It is important to have regular blood tests to check that your INR is within the correct range. As the INR increases above the target range, the risk of bleeding increases. On the other hand, as the INR drops below the target range, the risk of developing a clot is increased.

When you first start taking warfarin you will have your INR tested frequently, often every one or two days for the first week. Once your INR level has stabilised, testing will usually only be repeated every 4 weeks, or as often as your doctor tells you.

Every person requires a tailor-made dose, according to their medications, health and lifestyle. Two people taking warfarin for the same purpose may have very different doses, depending on how their body responds to warfarin. Your doctor will use your INR results to adjust your warfarin to the best dose for you.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen

The correct dose of warfarin is different for every person and depends on the result of your INR blood test, so it is important to follow your doctor's instructions closely.

Warfarin is usually taken once a day, with or without food. Some doctors prefer that their patients take their dose in the evening. This allows the dose to be changed if necessary on the day that the INR results are obtained, rather than waiting until the next day.

Whatever time you choose to take your warfarin, it is easiest to remember if you take it at the same time every day.

Another option to help you remember is to use a record sheet. This is a form where you write in the dose you need to take on the appropriate day and then circle the dose when you have taken it (see below). This will help to both remind you of the correct dose and indicate that you have taken that day's dose. There are also spaces to record your INR results and your next doctor's appointment.

Example of an INR record form:

<table>
<thead>
<tr>
<th>Date (Week)</th>
<th>Mon</th>
<th>Tue</th>
<th>Wed</th>
<th>Thu</th>
<th>Fri</th>
<th>Sat</th>
<th>Sun</th>
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</thead>
<tbody>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

It is important to take warfarin exactly as your doctor tells you. Never skip a dose and never take a double dose. If you miss a dose, take it as soon as you remember. If you don't remember until the next day, please call your doctor for advice. If you can't get hold of your doctor skip the dose and start again with your dose for that day. Mark the dose you missed in a diary or on your record sheet and tell your doctor at your next visit.

Click here to download a record sheet to help you manage your warfarin dose and record your INR.

If you, or someone you know, accidentally takes too much warfarin call your doctor as soon as possible. If you can't contact your doctor call the Poisons Information Centre on 13 11 26 or go to the emergency department at your nearest hospital.

Last Updated: 14 Oct 2009

Ella Claire van Tienen
Optimising warfarin management: An exploration of pharmacist-delivered models of care

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Optimising warfarin management: An exploration of pharmacist-delivered models of care

Vitamin K is one of the essential vitamins found in a healthy balanced diet. Your liver uses vitamin K to produce clotting factors, and as such plays a role in your body’s natural clotting process. Warfarin works against vitamin K and reduces the amount of clotting factors your liver can produce.

Vitamin K is found in some of the foods that we eat, so our diet plays a big part in how much vitamin K is in our body. Changes in the amount of vitamin K in your body will mean that your body needs different amounts of warfarin to have the same effect on your clotting factors. For example, if you reduce the amount of vitamin K you eat, you will have less in your body for warfarin to work against, so even less clotting factors will be made and your INR will increase.

The important thing to remember is not to make radical changes to your diet. If you keep eating the same things as you have always eaten then your vitamin K levels will stay the same and your warfarin shouldn’t be affected. Consistency is the key!

This is NOT a list of foods to avoid or a comprehensive list of all foods containing vitamin K. It provides an idea of those foods with high and moderate vitamin K content as an aid to helping you maintain a consistent dietary intake.

<table>
<thead>
<tr>
<th>Foods with low Vitamin K content</th>
<th>Foods with moderate Vitamin K content</th>
<th>Foods with high Vitamin K content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfalfa</td>
<td>Asparagus</td>
<td>Broccoli (cooked)</td>
</tr>
<tr>
<td>Beans (green)</td>
<td>Avocado</td>
<td>Broccoli (raw)</td>
</tr>
<tr>
<td>Cabbage</td>
<td>Red Cabbage</td>
<td>Cabbage (raw)</td>
</tr>
<tr>
<td>Celery, Cera &amp; Pepper</td>
<td>Green Peas</td>
<td>Endive (red)</td>
</tr>
<tr>
<td>Brussels Sprout</td>
<td>Lettuce (buttered)</td>
<td>Lettuce (grilled)</td>
</tr>
<tr>
<td>Rice</td>
<td>Potatoes</td>
<td>Potato</td>
</tr>
<tr>
<td>Fruit &amp; Juce (preserv*)</td>
<td>Beans (caviar)</td>
<td>Silver beet (preserv)</td>
</tr>
<tr>
<td>Cheese (mascarpone)</td>
<td>Cheese (Blue)</td>
<td>Spr K (sunk &amp; raw)</td>
</tr>
<tr>
<td>Egg &amp; Butter</td>
<td>Margarine</td>
<td>Paprika</td>
</tr>
<tr>
<td>Sunflower Seeds</td>
<td>Olive oil</td>
<td>Canola &amp; Soybean oil</td>
</tr>
<tr>
<td>Tofu, Masc. Pork, Chicken</td>
<td>Almonds</td>
<td>Liver</td>
</tr>
</tbody>
</table>

* Cranberry juice consumption has been linked with increased bleeding with warfarin.

Last Updated: 13 Oct 2009

Ella Claire van Tienen
Side Effects of Warfarin

Side effects from warfarin are uncommon as long as you take it as directed and have your blood level tested regularly. It is also important to tell your healthcare professional about any big changes in lifestyle factors such as your diet.

Bleeding Side Effects

The most common side effect of warfarin is bleeding. This is most likely to occur if your INR is too high, and if you put yourself at risk of injury. The risk of bleeding is greatly reduced by managing your therapy well and keeping your INR inside your target range.

Even when your INR is in your target range, you may see a little bleeding, like bruises on your body, or slight gum bleeding when you brush your teeth.

Signs of slight bleeding that you may notice from time to time:

- Gum bleeding while brushing teeth.
- Occasional nose bleeds.
- Easy bruising.
- Bleeding after a minor cut that stops within a few minutes.
- Menstrual bleeding that is a little heavier than normal.

Signs and symptoms of more serious bleeding to watch for include:

- Severe bruising that gets worse.
- Any bleeding that take a long time to stop.
- Unexplained bleeding or bruising.
- Menstrual bleeding that is much heavier than usual.
- Red or dark urine.
- Red or black bowl motions.
- Coughing up blood, or anything red.
- Bloody or dark stained vomit.
- Severe headache or dizziness.
- Weakness or lethargy.
- Unusual pain or swelling.

If any of the above symptoms occur you should contact your doctor immediately. If your doctor is unavailable, go your nearest hospital emergency department.

Other Side Effects

Occasionally people may experience other side effects associated with taking warfarin. These side effects are rare but include:

- Unusual skin lesions. These usually appears within 3 to 10 days of starting warfarin, and the risk is reduced if heparin is used when warfarin treatment is commenced.
- Purple discoloration of the toes. This usually appears within 3 to 8 weeks of starting warfarin.
- Hair loss
- Rash

If you notice any of the above, or something else that you feel may be caused by your medication, even if it’s not on the list above, speak to your healthcare professional.
In case of an emergency, call an ambulance on 000

Minor Bleeds

If you get scratched or get a small cut, clean the cut with antiseptic and cover it with an adhesive bandage or pad. It's a good idea to apply pressure to try and help the bleeding stop. Most small cuts should stop bleeding in about 10-20 minutes. If the bleeding hasn't stopped, or slowed, in this time, seek medical advice.

Major Bleeds

If you sustain a bigger cut or injury, cover with a clean pad and apply pressure to help slow the bleeding (this may be in the form of a compression bandage or you may wish to apply the pressure using your hands). Remember that taking warfarin means you'll bleed more and for longer than you're expecting. Larger cuts require medical assistance to stop the bleeding. Go to your doctor or a nearby hospital or medical centre.

Falls and Knocks

If you fall, or take a hard knock, you may be bleeding on the inside and not see any blood. It is important to go to the doctor and get checked out. If you fall and hit your head this is especially important in case you are bleeding under your skull.

Last Updated: 13 Oct 2009

Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen

September 1, 2011

www.anticoagulation.com.au

Minimising the Risk of Bleeding

There are a number of things that you can do to help lessen your risk of bleeding while on warfarin:

- Talk to your healthcare professional about your therapy, tell them how you are going, what problems you’re having, and about anything that’s concerning you.
- You should have your INR monitored regularly and make sure you obtain the result, and any change in dose, from your doctor or healthcare professional. It can helpful to record the INR result and any dose changes on a record form. Click here to print a record sheet.
- You should notify your healthcare professional of any changes in factors which may alter the way your warfarin works (such as big changes in diet, other medications you may have started, smoking—or if you start or plan to quit, illnesses, or any plans you have to travel).
- Avoid contact sports and other physical activities that may cause injury or bleeding.
- Report any falls, blows or injuries to your doctor. You might not always see visible signs of bruising.
- Around the home, minimise your risk of bleeding by:
  - Using a non-slip bath mat.
  - Using a soft bristle toothbrush.
  - Using an electric shaver.
  - Wearing gloves while gardening.
  - Being careful around pets.
  - Wearing non-slip footwear/sturdy shoes to avoid trips and slips.
  - Taking care with sharp objects such as kitchen knives.

Managing Bleeding

Minor cuts and scrapes should be cleaned and covered with an adhesive bandage or pad. Larger cuts should be covered with a clean pad and have pressure applied to help slow the bleeding (this may be in the form of a compression bandage or you may wish to apply the pressure using your hands) and be reported to your doctor.

Last Updated: 05 Oct 2009

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Atrial fibrillation (AF) is a rapid heart beat increasing the risk of blood clots and stroke.

Atrial fibrillation is the most common abnormal heart rhythm. The risk of having AF increases with age, with about 8% of people aged over 80 having this condition.

Atrial fibrillation is often asymptomatic (with no noticeable symptoms), and isn’t usually life-threatening. People may notice heart palpitations, fainting, or chest pain as a result of AF.

People with AF have an increased risk of stroke compared to people whose heart is beating in a normal rhythm. The risk of stroke increases in AF because blood may pool and form dots in the heart. It is when these dots break off and travel to the brain that a stroke may occur.

Warfarin reduces the risk of stroke in AF by making it harder for your blood to form clots in the heart.
Deep vein thrombosis (also known as DVT) is the formation of a blood clot (thrombus) in a deep vein. It most commonly affects the veins in the leg. DVT may be asymptomatic, but the classic symptoms of DVT include pain, swelling and redness of the leg.

DVT may form for a number of reasons. The most common reason for developing DVT is recent surgery or hospitalisation where you can't move around a lot and keep your blood flowing. Other reasons DVT may develop include other reasons for immobilisation, such as air travel. Smoking, obesity, some forms of hormone based contraception, and some infections can also increase the risk of DVT occurring.

The usual treatment for DVT is anticoagulation. You may initially be started on heparin while also taking warfarin. Usually, warfarin will be taken for 3 to 6 months to reduce the risk of further clots developing in the legs. If you have had a DVT or pulmonary embolism (PE) in the past you may need to stay on warfarin for longer than this.
An artificial heart valve is a device which is implanted in the heart of someone who suffers from a disease involving a valve in their heart. When one of the valves in the heart malfunctions, the choice is usually to replace the natural valve with an artificial valve.

Replacing the valves in the heart requires open heart surgery.

There are two types of artificial heart valves: mechanical valves and biological valves.

Mechanical heart valves are also called prosthetic heart valves. They are designed to replicate the function of normal heart valves. Modern mechanical valves can last indefinitely but they require lifelong treatment with anticoagulants, such as warfarin.

Biological valves are made of tissues, traditionally from pig heart valves. They have the benefit of improved blood flow and a reduced risk of clots forming so they do not require the lifelong use of warfarin. The disadvantage of these valves is that they last only about 15 years before they need replacing.
A pulmonary embolism (also called a PE) is a blockage of either the pulmonary artery (the main blood vessel carrying blood from the heart to the lungs) or one of its branches. A PE usually occurs when a venous thrombus (a blood clot from a vein) becomes dislodged and travels through the blood to one of the lungs.

Symptoms usually come on suddenly and may include difficulty breathing, pain in the chest during breathing, cough, and even coughing up blood.

The most common sources of pulmonary embolus are DVTs. This means that the risk factors for PEs are the same as those for DVTs. These include any long period of immobilisation (such as hospitalisation or air travel), obesity, some forms of hormone-based contraception, and smoking.

Anticoagulants, such as warfarin, are the main treatment for PE. Usually, you will be started on a heparin while warfarin starts working, and will then stay on warfarin for 3 to 6 months. If you have had a DVT or PE in the past you may need to stay on warfarin for longer than this.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen

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Antiphospholipid Syndrome (also known as Antiphospholipid Antibody Syndrome or APS) is a condition which causes blood clots in both arteries and veins. This disease occurs due to a malfunction of the body’s immune system (also called an autoimmune disease).

Warfarin is often used in this condition to reduce the risk of clot formation.

**Protein C Deficiency**

Protein C deficiency is a genetic trait that increases the risk of forming a blood clot.

Protein C is a natural anticoagulant that usually acts to regulate the clotting process. It usually stops the formation of unneeded blood clots.

People with a deficiency of protein C have an increased risk of DVT. Often if someone has a DVT and is found to have protein C deficiency they will need long-term anticoagulation therapy.

**Factor V Leiden**

Factor V Leiden is a hereditary condition that increases the risk of forming a blood clot.

Normally, the clotting factor V is inactivated by protein C to stop excessive blood clots forming. In this condition, clotting factor V is changed and can no longer be inactivated by protein C. This means the clotting process continues and unneeded blood clots may form.

People with factor V Leiden are at an increased risk of DVT. They may need anticoagulation therapy to reduce their risk of further clots.

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Last Updated: 13 Oct 2009

Ella Claire van Tienen
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen

The INR stands for International Normalised Ratio. It is a test used to check how quickly your blood clots and it has been standardised so that tests done in different laboratories around the world on the same sample of blood will give the same result.

The INR for someone who is not taking warfarin is around 1. The higher your INR is, the longer it takes your blood to clot. The desired INR for you will depend on the reason for which you are taking warfarin.

Your doctor will try and keep your INR within a particular range, called the target INR range.

The target INR range is different for different conditions. For example, for people with atrial fibrillation, an irregular heart beat in the top chamber of the heart, the target INR range is 2 to 3. Higher INR ranges are recommended for people who have a mechanical heart valve or for those with some irregular clotting conditions.

It is important to have regular blood tests to check that your INR is within the correct range. As the INR increases above the target range, the risk of bleeding increases. On the other hand, as the INR drops below the target range, the risk of developing a clot is increased.

Your doctor will tell you the correct INR range for you.

When you first start taking warfarin you will have your INR tested frequently, but once your INR levels have stabilised, testing will usually only be repeated every 4 weeks, or as often as your doctor tells you.

Every person requires a tailor-made dose, according to their medications, health and lifestyle. Two people taking warfarin for the same purpose may have very different doses, depending on how their body responds to warfarin. Your doctor will use your INR results to adjust your warfarin to the best dose for you.
One of the reasons that your INR needs to be monitored so regularly is that there are many factors that can affect your INR.

These factors include changes in your
- Other medications including prescription medicines, herbal preparations, vitamins, and medicines you buy 'over the counter'.
- Diet
- Health for example, if you become ill
- Alcohol intake or smoking habit
- Level of exercise

Because these things all play a role in controlling your INR, changes in any of these may cause changes in your risk of bleeding or clot formation.

It is important to discuss any changes in the things listed above with your healthcare provider, for example, if you are planning to quit smoking, start a new herbal preparation, or start an exercise program.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Because everybody is different and everyone needs a different dose of warfarin when you start taking warfarin, you will have a lot of blood tests to help your doctor find the right dose for you. Initially you will need a blood test daily or every second day until the right dose is found. It takes about a week to find the right dose for most people.

Once you have found the right dose a blood test is usually only needed every few weeks. The frequency of tests is different for everybody.

There are some instances where you will need to have your INR tested more frequently for a while. If you get sick, quit smoking, or start a new diet your INR will probably change with the change in your lifestyle. Your doctor may want to keep a closer eye on your INR at these times.

After each blood test your dose of warfarin may be changed to keep the INR within your target range.
These anticoagulants work by working against vitamin K in the liver. These anticoagulants are generally used to treat patients with deep vein thrombosis, pulmonary embolism, atrial fibrillation, and mechanical prosthetic heart valves.

The most commonly used example of a vitamin K antagonist is warfarin.

Another example available in Australia is phenindione (Bindexan®). This medicine is not commonly used as there are a lot more side effects associated with its use, but it is sometimes a good choice for people who can’t take warfarin.
Heparin is a naturally occurring substance, usually made from pig intestines. It works by activating a protein in the blood (called antithrombin III) to prevent blood clots forming.

Heparin is used as an anticoagulant in atrial fibrillation, pulmonary embolism, deep vein thrombosis, in acute coronary syndrome (also called ‘unstable angina’ or a ‘heart attack’) and heart bypass surgery.

It is usually given by injection, usually in hospital as often many injections are required each day. It can also be given by a ‘drip’ into the veins, which also needs to be done in hospital.

There is a newer class of heparins, called Low Molecular Weight Heparins, which can be given once daily. The most commonly used example of these is enoxaparin (Clexane®).

Enoxaparin is given both to patients in hospital, and also to people in their homes who can be given the injection by a community nurse, or may even be able to give it to themselves.

If long term anticoagulation is required, heparins are often only used until warfarin starts to work and the INR has become stable in the target range.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen

Direct Thrombin Inhibitors

This is a new class of medicines that acts to directly inhibit the enzyme 'thrombin' which is involved in blood clotting.

Currently in Australia there are three of these agents available. Two of these, lepirudin and bivalirudin, are medicines used in specialist situations, usually only in patients in hospital.

The other agent, dabigatran, can be taken orally. It has only recently been released in Australia and is used to prevent the formation of clots following major orthopaedic surgery, such as hip and knee replacement surgery.

The usual dose is 220mg once daily. Some people, such as those with kidney problems or those who take a medicine called amiodarone, may need a lower dose of 150mg daily.

The length of treatment varies but usually dabigatran needs to be taken for 10 days following knee replacement surgery and for 28 to 33 days following hip replacement surgery.

Dabigatran is still a new medicine and further studies are underway to test its use in other conditions.

Direct Factor Xa Inhibitors

This is a new class of medicines that acts to directly inhibit one of the major clotting factors (factor Xa).

Currently rivaroxaban is the only one of these medicines available in Australia. Rivaroxaban can be taken orally and is used to prevent the formation of clots following major orthopaedic surgery of the lower limbs.

The usual dose is 10mg taken once daily. The duration of treatment depends on the type of surgery. Following hip replacement surgery, rivaroxaban is recommended for five weeks. Following knee replacement surgery two weeks of treatment is recommended.

Rivaroxaban is still a new medicine and further studies are underway to test its use in other conditions.
Many medications may change the anti-coagulant action of warfarin. This includes medicines prescribed by your doctor, and items you can buy without a prescription from your pharmacy, supermarket or health food store.

Assume that any medicine can affect warfarin unless advised otherwise by your doctor or pharmacist.

To minimise the risk of having a problem with your warfarin:

- Check with your doctor or pharmacist before starting or stopping any medicines.
- Tell the pharmacist you are taking warfarin before purchasing any over the counter medicines.
- Ask your pharmacist before buying any vitamins, herbal or natural supplements.
- If you visit a different doctor, or see a dentist, be sure to tell them you are taking warfarin.
- Wear a MedicAlert® bracelet or carry a card in your wallet identifying that you take warfarin. (More information on MedicAlert® bracelets can be found at www.medicalert.com.au. A MedicAlert identification card for you to fill in is available here.)

Aspirin

Aspirin also affects blood clotting and small doses of aspirin are used to stop heart attacks and strokes. If you are already taking aspirin when you start warfarin, check with your doctor whether you need to keep taking it. There are some conditions where people will need to take a combination of medicines that affect how their blood clots, for example some people may need to take aspirin and warfarin together, while in other conditions aspirin may only need one or the other.

Aspirin in larger doses is used to treat pain and fevers. It is best to avoid larger doses of aspirin while taking warfarin. For pain or fever, paracetamol is safer than aspirin as long as it is used at the recommended dose. Check with your healthcare professional if you need treatment for long-term pain.

Below are tables, which list some of the more common medicines and complementary products that can interfere with warfarin.

<table>
<thead>
<tr>
<th>Medicine type</th>
<th>Examples</th>
<th>Complementary products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-inflammatory (Ibuprofen) and paracetamol (D倚par)</td>
<td></td>
<td>Gingko</td>
</tr>
<tr>
<td>Anti-inflammatory (Ibuprofen) and paracetamol</td>
<td></td>
<td>Green Tea</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medicine type</th>
<th>Examples</th>
<th>Complementary products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotics (Amoxicillin) and clindamycin (Clenamycin)</td>
<td></td>
<td>St. John’s Wort</td>
</tr>
<tr>
<td>Anti-coagulants (warfarin)</td>
<td></td>
<td>Vitamins K (in some multivitamins)</td>
</tr>
</tbody>
</table>

These are examples of medicines and complementary products which may increase your CLOTTING risk. This list is not comprehensive - if you are concerned about a medicine you are taking, please talk to your healthcare professional.

<table>
<thead>
<tr>
<th>Medicine type</th>
<th>Examples</th>
<th>DTC medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotics (Amoxicillin) and clindamycin</td>
<td></td>
<td>Anemia and clot disorders</td>
</tr>
<tr>
<td>Anti-coagulants (warfarin)</td>
<td></td>
<td>Cough and cold medicines</td>
</tr>
<tr>
<td>Anti-inflammatory medicines (Ibuprofen) and paracetamol</td>
<td></td>
<td>Asthma and related disorders</td>
</tr>
<tr>
<td>Anti-coagulants (warfarin)</td>
<td></td>
<td>Heart and circulatory medicines</td>
</tr>
<tr>
<td>Anti-inflammatory medicines (Ibuprofen) and paracetamol</td>
<td></td>
<td>Antihistamines</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medicine type</th>
<th>Examples</th>
<th>Vitamins and herbal products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamins (B complex) and herbs (Cranberry)</td>
<td></td>
<td>Coenzyme Q10</td>
</tr>
<tr>
<td>Vitamins and herbal products</td>
<td></td>
<td>Garlic supplements</td>
</tr>
</tbody>
</table>

These are examples of medicines and complementary products which may increase your BLEEDING risk. This list is not comprehensive - if you are concerned about a medicine you are taking, please talk to your healthcare professional.
The foods you eat can affect how well warfarin works for you. It is important to be aware that changes in diet can affect your warfarin therapy. The most important thing to remember is to eat what you normally eat and not make any major changes in your diet without talking to your doctor.

Vitamin K is essential for a healthy diet so you should not try and eliminate vitamin K from your food intake. The recommended daily intake of vitamin K is the same for people who take warfarin and for those who don’t.

The aim is to balance your vitamin K intake by being consistent with those foods that you eat. Both vitamin K and warfarin are removed slowly from the body. This means that daily changes in vitamin K intake are less important than weekly totals.

You don’t have to eat the same types of food every day!

Having a diet with a variety of foods is important. Remember vitamin K is needed for a healthy diet and foods containing vitamin K should be included.

Foods high in vitamin K include broccoli, brussel sprouts, and green leafy vegetables like spinach and cabbage. Generally the greener the vegetable the higher the vitamin K content it has. Canola and soybean oil also have a high vitamin K content.

Most fruits, meats, dairy, and grain products have a low vitamin K content.

Dietary supplements such as Sustagen® and Resource® which your doctor may recommend for extra calories or nutrients are quite low in vitamin K.

From time to time you may wish to eat something that is not usually in your diet. A list of foods and their vitamin K content is provided below.

This is NOT a list of foods to avoid or a complete list of all foods containing vitamin K. It provides an idea of those foods with high and moderate vitamin K content as an aid to helping you maintain a consistent dietary intake.

<table>
<thead>
<tr>
<th>Foods with low vitamin K content</th>
<th>Foods with moderate vitamin K content</th>
<th>Foods with high vitamin K content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asparagus</td>
<td>Broccoli (cooked)</td>
<td></td>
</tr>
<tr>
<td>Avocado</td>
<td>Brussels sprouts</td>
<td></td>
</tr>
<tr>
<td>Red Cabbage</td>
<td>Cabbage (raw)</td>
<td></td>
</tr>
<tr>
<td>Green Peas</td>
<td>Endive (raw)</td>
<td></td>
</tr>
<tr>
<td>Lettuce (green)</td>
<td>Lettuce (gourmet)</td>
<td></td>
</tr>
<tr>
<td>Parsley</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beans (flat)</td>
<td>Silver beet (cooked)</td>
<td></td>
</tr>
<tr>
<td>Cheese (shredded)</td>
<td>Spinach (cooked &amp; raw)</td>
<td></td>
</tr>
<tr>
<td>Margarine</td>
<td>Mayonnaise</td>
<td></td>
</tr>
<tr>
<td>Olive oil</td>
<td>Carrots &amp; Sunflower oil</td>
<td></td>
</tr>
<tr>
<td>Chives</td>
<td>Fish, Muz, Pork, Chicken</td>
<td></td>
</tr>
<tr>
<td>Abalone</td>
<td>Liver</td>
<td></td>
</tr>
</tbody>
</table>

Consistency is the key!

Any major changes in what you eat should be discussed with your doctor first. These include diets aimed at weight loss or if you wish to change to a vegetarian diet. Your doctor may want to monitor your INR more closely while you change what you’re eating.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen

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Any new illness may affect your INR in various ways. Illnesses that may have the greatest effect include those which involve:

- Diarrhoea.
- Vomiting.
- Fever or infection.
- Loss of appetite.
- Jaundice.
- Medicines you may use to treat your illness.

If you become sick with a fever, the flu, or an infection, call your doctor. Also call if you have diarrhoea and vomiting which lasts for more than one day.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

September 1, 2011

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Alcohol

Generally it is best not to drink alcohol whilst taking warfarin. This is because alcohol may increase or decrease how fast warfarin is removed from your body. It needs to stay long enough to work but not too long to cause side effects. Whether it increases or decreases your breakdown of warfarin depends on how much you drink and whether the alcohol has damaged your liver. Everyone’s body will react differently. If you do choose to drink while being treated with warfarin you should restrict your daily intake to no more than one or two standard drinks a day, with two alcohol free days a week.

One standard drink is equal to:

- One small glass of wine (100ml)
- One nip of spirits (30ml)
- One middy of normal strength beer (285ml)

As well as affecting your liver, alcohol may irritate the lining of your stomach which may increase the likelihood of a stomach bleed.

Smoking

Smoking can increase the likelihood of a blood clot forming, which may undo the good work your warfarin is doing. Smoking often increases the speed that your body removes warfarin so if you change your smoking habits you can expect that the way your warfarin works will change too. Make sure you keep your doctor informed if you plan to change your smoking habits.

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In case of an emergency, call an ambulance on 000

Minor Bleeds

If you get scratched or get a small cut, clean the cut with antiseptic and cover it with an adhesive bandage or pad. It's a good idea to apply pressure to try and help the bleeding stop. Most small cuts should stop bleeding in about 10-20 minutes. If the bleeding hasn't stopped, or slowed, in this time, seek medical advice.

Major Bleeds

If you sustain a bigger cut or injury, cover with a clean pad and apply pressure to help slow the bleeding (this may be in the form of a compression bandage or you may wish to apply the pressure using your hands). Remember that taking warfarin means you'll bleed more and for longer than you're expecting. Larger cuts require medical assistance to stop the bleeding. Go to your doctor or a nearby hospital or medical centre.

Falls and Knocks

If you fall, or take a hard knock, you may be bleeding on the inside and not see any blood. It is important to go to the doctor and get checked out. If you fall and hit your head this is especially important in case you are bleeding under your skull.
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  - Wearing gloves while gardening.
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  - Wearing non-slip footwear/sturdy shoes to avoid trips and slips.
  - Taking care with sharp objects such as kitchen knives.

Managing Bleeding

Minor cuts and scrapes should be cleaned and covered with an adhesive bandage or pad. Larger cuts should be covered with a clean pad and have pressure applied to help slow the bleeding (this may be in the form of a compression bandage or you may wish to apply the pressure using your hands) and be reported to your doctor.

Last Updated: 05 Oct 2009
Taking warfarin doesn't mean that you cannot do the things you enjoy, but when you're doing them you need to think about how you can protect yourself from injury.

Around the House

Around the house you can minimise your risk of bleeding by:

- Always wearing shoes outdoors.
- Wearing shoes or non-slip slippers indoors.
- Using a non-slip bath mat.
- Using a soft bristle toothbrush.
- Using an electric shaver.
- Wearing gloves while gardening.
- Being careful around pets.
- Taking care with sharp objects such as kitchen knives.
Travelling on long trips, make sure you have enough warfarin tablets with you and that you carry identification that indicates you take warfarin. It may be a good idea to wear a medic alert bracelet or carry a card in your wallet identifying that you take warfarin. (More information on MedicAlert® bracelets can be found at www.medicalert.com.au). A warfarin identification card for you to fill in is available here.

Because your diet and activity may vary on your trip you may need an INR check while you’re away. Always remember to take a letter with you from your healthcare professional detailing that you are taking warfarin, why you’re taking warfarin, and any other important information about your health. This may be useful if you need to see another doctor while you’re away. Taking your INR record book is also a great idea so that both your doctor at home, and any doctors you see while you’re away, can see how your warfarin has been working. A portable INR monitor may be another useful option for such a trip.
While taking warfarin means you need to be more careful, it doesn't mean you need to wrap yourself in cotton wool!

It is important to think about the activities you like doing and ask yourself “does this put me at risk of injury?” If the answer is yes, it may be best to try another activity. For example, contact sports, or any pastime that causes knocks, bumps or bruises, are usually best avoided.

There are many activities which you can still participate in safely, such as walking or swimming. Other activities, such as riding your bike, can still be safe. You may just need to remember to use protective gear, such as a helmet and gloves, while you are doing it.

The other important thing to note is that changes in the amount of exercise you do may change your INR. Discuss any plans to start a new activity with your doctor.
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Ella Claire van Tienen

Pregnancy

Warfarin has been shown to cause birth defects in the first trimester of pregnancy so must be avoided early in pregnancy. In some women, it may be used later in pregnancy, however alternate anti-clotting medication is usually prescribed during pregnancy, such as heparin injections. It is important that you do not become pregnant while taking warfarin. If you wish to become pregnant you should discuss this with your doctor first. There are other options available. They will decide what alternative option is best for your situation.

Should you become pregnant while taking warfarin you should notify your doctor as soon as possible.

Breastfeeding

Although warfarin must be avoided during pregnancy, it is safe to take warfarin while breastfeeding. This is because very little of the medication gets into the breast milk, and is unable to affect your baby.

Last Updated: 01 Sep 2009
Self-monitoring of INR is the process whereby someone tests their own INR in the comfort of their own home using a portable INR monitor. One of the benefits of testing the INR with a portable monitor is that instead of needing to have a blood test taken, the INR result can be measured using a finger prick of blood. The monitors look and operate very much like the type of monitor you may have seen people use to test their blood sugar levels.

When an INR measurement is obtained this result is communicated to the doctor. The doctor is then able to advise on any necessary changes in warfarin dose.

Studies have shown that about one quarter of people taking warfarin may be able and interested in self-monitoring of their INR.

Remember that everyone is different! Self-monitoring is definitely not for everyone! Just as everyone will need different doses of warfarin, everyone will find a way of INR monitoring that is best for them. Discuss your options with your doctor or your pharmacist if you're interested in trying something different. They can help find the best management option for you.
There are many benefits to be found through self-monitoring. People have greater control over their own therapy and are given more involvement in managing their health. They find they have more independence and that the self-monitoring method is more convenient.

- **Tighter INR control**
  Self-monitoring has been shown to help people achieve better control of their INR, meaning they spend more time in the target range.

- **Improved safety**
  More time in the target range means a lower likelihood of complications from warfarin therapy, both bleeding and clotting complications.

- **Convenience**
  By testing the INR with a simple finger-prick test, the test can be done at a time that suits and fits around a person’s daily schedule.

- **Greater independence**
  Self-monitoring means enables people to do the testing and to know the results. It enables people to monitor the changes in their INR alongside any changes in their diet or exercise, helping them to better understand the way the body and warfarin work together.

- **Only a finger prick!**
  Unlike regular INR testing which involves taking a full sample of blood from the arm to send to a pathology laboratory, self-monitoring involves just a finger prick sample of blood. Some people may find this more comfortable and convenient for them.

- **Working in a team**
  Self-monitoring has the potential to greatly improve the relationship with the doctor and pharmacist as everyone works together to manage anticoagulation therapy.

Training programs are now available for people wishing to self-monitor their anticoagulation therapy. This training helps to improve people’s knowledge of all aspects of warfarin therapy as well as train them on accurate use of point-of-care monitors. This may lead to increased independence and better health care outcomes.

It is important to remember that self-monitoring is not for everyone. It is thought that about one quarter of all people taking warfarin may be able to monitor their INR. Speak to your doctor if you are interested, and they will help decide the best management option for you.
Some patients who undertake self-monitoring of their INR may, in certain circumstances, be able to take the next step to self-management of their warfarin therapy.

Self-management involves measuring the INR, as for self-monitoring, but instead of communicating the dose to the doctor, the person adjusts their warfarin dose themselves.

The dose adjustment is made using a special dosing scale individualised for them by their doctor. The scale tells the person what changes to make depending on what the INR result is. If the INR is too far from the target INR range, the doctor needs to be contacted for advice on where to go from there.

This management option is especially useful for people travelling for long periods of times on big trips or overseas.

INR self-management is a big step and not everyone is suitable for this management option. Just as everyone needs different doses of warfarin, everyone will find a way of INR monitoring that is best for them. Discuss your options with your doctor or pharmacist if you're interested in trying something different.
There are now a number of different monitors available to enable consumers to monitor their INR in the home. These devices are portable, easy to use, and provide accurate readings quickly and easily.

There are two point-of-care monitors available for consumer use in Australia. The features of these devices are described below.

<table>
<thead>
<tr>
<th>INRiO™</th>
<th>CoaguChek™ XS</th>
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<tr>
<td>Manufacturer of monitor</td>
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All of the devices above have Therapeutic Goods Administration (TGA) approval.
Using a Portable Monitor

Each portable INR monitor works slightly differently, but they are all quite simple to use.

The basic testing procedure is:

1. Insert a test strip into the machine.
2. Apply a fresh drop of blood from a finger prick to the test strip.
3. The machine will perform the INR test.
4. The INR result is displayed on the screen.

For example, click here for a diagram of how to use the CoaguChek XS®.

Each manufacturer provides information on their monitors and the benefits each offers.

Roche have provided an animated demonstration of the self-monitoring procedure using the CoaguChek XS® device here:
http://coagucheck.com/nflash/animation/coaguChek_XS_patient.html

You can find information on the Hemosense INRatio® device here:
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The following checklist may be useful when considering if a consumer is a potential candidate for self-monitoring:

- Do they have a long-term indication for warfarin?
- Are they interested in learning more about warfarin and monitoring their INR?
- Do they have sufficient manual dexterity and eyesight to operate an INR monitor (or have a carer who is willing to do so for them)?

If the answer to the above questions is ‘yes’ then the consumer may be a potential candidate for self-monitoring.

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

Consumer Training

The following resources are available and may be useful in assisting to train a consumer to self-monitor:

- A checklist for points to cover during the training session.
- A training manual for consumers.
- An assessment form to ensure the consumer is appropriately trained and safe to commence self-monitoring.

* The training manual for consumer self-monitoring is available to INR trained accredited pharmacists to assist them to train consumers in self-monitoring. If you have completed the appropriate training and require a copy of this resource, please email info@anticoagulation.com.au

Last Updated: 14 Oct 2009

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Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen
Having a short and relatively severe course of symptoms with a sudden onset.

Acute Myocardial Infarction (AMI)
Also known as a heart attack. Where there is insufficient blood supply to the heart muscle that causes chest pain and death or damage of heart muscle.

Adverse effect
An unwanted action of a drug; a side effect.

Aetiology
The cause of the disease or disorder. Also spelt etiology (US).

Anticoagulant
A substance (such as a medicine) that is able to prevent coagulation, or clotting, of the blood.

Angina
Attacks of chest pain caused by low oxygen in the heart muscles. Also called Angina Pectoris.

Antibody
A substance produced by the body to act against substances foreign to the body, usually as part of an immune response to an infection or allergy. In some situations they are produced inappropriately and act against body tissues instead of foreign substances, resulting in an autoimmune condition.

Antiphospholipid Antibody
An antibody associated with some autoimmune conditions. This antibody causes increased and unwanted blood clot formation.

Antiplatelet
A substance that inhibits platelets in the blood sticking together.

Antithrombin III deficiency
A genetic deficiency of a substance that inhibits blood clotting. This deficiency causes increased blood clot formation.

Aorta
The large artery that carries blood from the heart to be supplied to the body.

Aortic valve
The heart valve that separates the aorta and the left side of the heart. It stops blood flowing back into the heart from the aorta.

Artificial Heart Valve
A valve that has been used to replace one of the heart's natural valves when it stopped working properly. May be a biological valve or a mechanical valve.

Asensio®
The brand name of a medicine used to reduce the risk of strokes through antiplatelet actions. Contains aspirin and dipiridamole.

Aspirin
An antiplatelet medicine used in low doses (between 75 and 150mg) to stop platelets sticking together and to reduce the risk of stroke and heart attack.

Asymptomatic
Producing no symptoms or without symptoms.

Atrial Fibrillation (AF)
Rapid uncoordinated contractions of the top chambers of the heart.

Atrium
One of the top chambers of the heart. Plural: atria
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Biological Heart Valve
An artificial heart valve made from tissues, traditionally from pig heart valves. This has the advantage of improved blood flow (compared to mechanical heart valves) as it does not require the lifelong use of warfarin. The disadvantage of these valves is that they last about 15 years before they need replacing.

Bivalirudin
An anticoagulant medicine belonging to the direct thrombin inhibitors group.

Cardiac
Relating to the heart.

Cardiologist
A doctor who specialises in the heart and its actions and diseases.

Cerebral infarct
A stroke causing an area of tissue death in the brain, resulting from the obstruction of a blood vessel in the brain due to a clot or embolus.

Clopidogrel
An antplatelet medicine used to reduce the risk of stroke, heart attack and blood clots.

Clot
A mass of solidified blood.

Clotting factor
Any substance that is involved in the clotting of blood.

CoaguChek XP®
One of the portable INR monitors available in Australia.
http://coaguchek.com/learn/aarchivepatients

Coumadin®
One of the brands of warfarin available in Australia. Produced in 1mg, 2mg and 3mg tablets.

Coumarin
A chemical derived from plants that has an anticoagulant action. It is the chemical that warfarin is produced from.

Dabigatran
An anticoagulant medicine that belongs to the direct thrombin inhibitors group.

D-dimer
A small protein present in the blood after a blood clot is broken up. Testing the blood for the presence of D-dimer is used when it is thought there may be a blood clot, such as in deep vein thrombosis (DVT) or pulmonary embolism (PE).

Deep vein thrombosis (DVT)
The formation of a blood clot (thrombus) in a deep vein; most commonly affects the veins in the leg.

Dipyridamole
An antplatelet medicine used to reduce the risk of stroke. Available alone or in combination with aspirin.

Direct thrombin inhibitors
A class of medicines that acts to directly inhibit the enzyme thrombin which is involved in blood clotting.

Doppler ultrasound
An ultrasound that utilises the Doppler effect to measure movement or flow in the body. This method is often used to detect blood clots.

Dosette
A product to help people manage their medicines, especially when they take many different tablets, or take them at lots of different times during the day. It can be filled by the person themselves, or can be filled by the pharmacist. Usually contain a week of medicines.
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Ella Claire van Tienen
Appendix 1a: General Patient Online INR Platform
Optimising warfarin management: An exploration of pharmacist-delivered models of care

### September 2011

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**Printable version of calendar**

**Next Test Date**

Your next testing day is Sunday, 4-Sep-2011 (2 Days)

Log an INR result

Ella Claire van Tienen
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Log INR test result

Date: 01/09/2011
INR: 2.7
Test Type: Home Test × Pathology Laboratory
Notes: All good

Other information that may be useful for your test history
- Illnesses such as the flu, vomiting or diarrhoea
- Big changes in your diet or exercise habits
- Other changes in your lifestyle such as changes in smoking or alcohol consumption

Consent to Collect Health Information
I consent to the collection use and disclosure of my health information by the University of Tasmania for the primary purpose for which it is collected. I understand that the information may be disclosed without my consent where it is reasonably necessary to lessen or prevent a serious threat to my life, health, safety or welfare, or where required by Law.

I understand and consent to the use of my health information on these terms.

Save Result
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen
Appendix 1b: Supervised Patient Online INR Platform
### Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen

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**Next Test Date**

Your next testing day is Friday, 9-Sep-2011 (7 Days)

Enter a home INR test result to be sent to your supervisor and reviewed

Log an INR result
Test Entry
There are 3 steps to recording a test result:

Step 1: Questions - You will need to answer some questions about your treatment and side-effects.

Step 2: Performing test - You will need to perform an INR test, and enter the result as well as any information that may be useful to your doctor when deciding your next warfarin dose.

Step 3: Results - The online INR monitoring system will record your result and notify your doctor that you have completed a test so they can review your dose.

Start
Step 1. Questions

Have you forgotten to take your treatment at any time since your last test?
- Yes  
- No

Have you had any bleeding or bruising since your last test?
- Yes  
- No

Many people on warfarin have minor bleeds such as gum bleeding and spotting from the nose, and some have easy bruising. Please describe the bleeding or bruising in the comments section on the next page.

Have you started or stopped any medications since your last test?
- Yes  
- No

Continue
Step 2. Test

Please perform your INR test with your CoaguChek device. For more help on this click here. After a short time you will be given a result on your device. Enter that INR result below.

**Record INR test result**

- **Date:** 02-Sep-2011 (format dd/mn/yyyy)
- **INR:** 3.2
- **Notes:** You indicated that you experienced bruising/bleeding. Please record the details.
  - Please record any other relevant information.
  - I have been experiencing a few bleeding noses.

Other information that may be useful to your doctor may include:
- Illnesses such as the flu, vomiting or diarrhoea
- Big changes in your diet or exercise habits
- Other changes in your lifestyle such as changes in smoking or alcohol consumption

**Consent to Collect Health Information**

I consent to the collection use and disclosure of my health information by the University of Tasmania for the primary purpose for which it is collected, I understand that the information may be disclosed without my consent where it is reasonably necessary to lessen or prevent a serious threat to my life, health, safety or welfare, or where required by Law.

I understand and consent to the use of my health information on these terms.

Continue
Step 3. Results

Your INR Result: 3.2

Your INR value is too high

Your Treatment supervisor will review your result and make any change if needed.

Your doctor has been notified that you have entered a new INR result. You will receive an email once your doctor has reviewed your result and made dose recommendations.

Your Next INR Test is due Monday, 12-Sep-2011
Optimising warfarin management: An exploration of pharmacist-delivered models of care

<table>
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<tr>
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<tr>
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<tr>
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</tr>
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<tr>
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</tr>
<tr>
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<tr>
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<tr>
<td>15-Aug-2011</td>
<td>2.5</td>
<td>Home</td>
<td>Seems ok</td>
</tr>
<tr>
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<td>3.2</td>
<td>Home</td>
<td>You indicated that you experienced bruising/bleeding. Please record the details. Please record any other relevant information.</td>
</tr>
<tr>
<td>09-Sep-2011</td>
<td>2.5</td>
<td>Home</td>
<td>You indicated that you experienced bruising/bleeding. Please record the details. Please record any other relevant information.</td>
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### Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen

#### Table of Warfarin Management:

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<tr>
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<td>2.5</td>
<td>Seems ok</td>
</tr>
<tr>
<td>01-Aug-2011</td>
<td>2.8</td>
<td>No problems at the moment</td>
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<tr>
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<td>View</td>
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</tbody>
</table>
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen
Appendix 1c: Supervised Online INR Platform Emails

INR Test result for Bruce Utas
info@anticoagulation.com.au
Sent: Fri 2/09/2011 2:17 PM
To: elaj@utas.edu.au

Hello,

Your patient, Bruce Utas has completed a home INR test and the results are available on the website.

Please log on to www.anticoagulation.com.au to view the test result and provide feedback to your patient.

Regards,

anticoagulation.com.au Team.

Anticoagulation.com.au - Feedback from your Treatment Supervisor
info@anticoagulation.com.au
Sent: Fri 2/09/2011 3:30 PM
To: elaj@utas.edu.au

Hello Bruce Utas,

Your Treatment Supervisor has provided feedback on your INR monitoring.

It is important that you log on to www.anticoagulation.com.au to view the feedback as your supervisor may have recommended a change in dosage or request that you perform an INR test on a particular date.

Regards,

anticoagulation.com.au Team.

Anticoagulation.com.au - A Patient has Acknowledged your feedback
info@anticoagulation.com.au
Sent: Fri 2/09/2011 3:34 PM
To: elaj@utas.edu.au

Hello,

This is an automated message to confirm that Bruce Utas has acknowledged your review of their INR test.

Regards,

anticoagulation.com.au Team.
Appendix 1d: Supervised Patient Online INR Platform – GP View

<table>
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<td>You indicated that you experienced bruising/bleeding. Please record the details. Please record any other relevant information. I have been experiencing a few small bruises.</td>
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<td>You indicated that you started new medication. Please record the details. Please record any other relevant information. I have recently been experiencing very severe indigestion so I bought some new tablets at the pharmacy, but I didn’t tell the pharmacist that I was taking the regular dose of warfarin (2mg daily).</td>
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Optimising warfarin management: An exploration of pharmacist-delivered models of care

Select a Patient: Bruce Utas


Set Dosages
Set all Dosages: 

---

September 2011

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Ella Claire van Tienen
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen
Appendix 15: Train the Trainer Manual
Preface

In recent years, the use of warfarin has increased, particularly in the elderly population. With an aging population, many more Australians will be started on warfarin therapy in the future. Unfortunately, due to a number of factors warfarin tends to be under-prescribed for some conditions for which it is useful, particularly for atrial fibrillation - a commonly occurring heart rhythm disturbance that affects 1/3 of the general population and 1/6 of people over the age of 80.

One of the limitations of warfarin therapy is that frequent pathology testing of the International Normalised Ratio (INR) is required. Therefore, one of the ways to improve the use of warfarin is to make INR testing more accessible to people taking warfarin. To this end, point of care INR monitors were developed in the mid-1980s, but were difficult to use, especially for elderly people. More recently, these monitors were made more user friendly and only require a single drop of blood from the user. Extensive research has gone into demonstrating the accuracy of these monitors compared to the pathology method. For a number of monitors, including the CoaguChek® XS developed by Roche Diagnostics, the accuracy data is particularly strong. The CoaguChek® XS is used routinely in Germany and The Netherlands, and use is growing in the UK and USA. The CoaguChek® XS has been evaluated in Australia by the authors, in collaboration with the Royal Hobart Hospital, and other organisations in a number of settings. These have included an outpatient hospital anticoagulation clinic, general practices and community pharmacies. The accuracy and usability of the CoaguChek® XS device was recently demonstrated by the authors in a study involving patient self-monitoring of warfarin.

Self-monitoring of warfarin therapy has developed into a very promising model of care whereby people on warfarin monitor their INR at home and contact their doctor for dosage adjustment. It is important to note that self-monitoring is not a suitable option for all people taking warfarin. About one-quarter of people on warfarin want to self-monitor, with about three-quarters of these people able to complete the necessary training to enable self-monitoring. The CoaguChek® XS has been evaluated in a number of settings. These have included an outpatient hospital anticoagulation clinic, general practices and community pharmacies. The accuracy and usability of the CoaguChek® XS device was recently demonstrated by the authors in a study involving patient self-monitoring of warfarin.

This training booklet has been developed with the intention to train accredited pharmacists to provide suitable persons who are taking warfarin with the knowledge and resources to monitor their own warfarin therapy. The booklet is only intended to be used as a part of a training package that includes practical demonstration of the CoaguChek® XS monitor and oral or electronic presentations. The booklet can be considered as support material for the presentations and as a reference for accredited pharmacists training patients to monitor their own warfarin therapy.

The authors would like to acknowledge the support of the National Safety and Quality Council for providing the necessary funding for the development of the training package. We acknowledge the initial support of Professor David Fitzmaurice and Dr. Ellen Murray from the University of Birmingham, England. We would also like to acknowledge the support of Roche Diagnostics Australia, the National Institute of Clinical Studies (NICS), and the Australian Association of Consultant Pharmacists (AACP).

Dr Luke Bereznicki, June 2008
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Accredited Pharmacist Training to Enable Patient Self-Monitoring of Warfarin

Ella Claire van Tienen
Introduction

Traditionally in Australia, warfarin therapy is managed in primary care or general practice. In some States, pathology centres manage warfarin therapy. In some parts of the UK and Netherlands, warfarinised patients attend primary care anticoagulation clinics, where point of care (POC) testing and computerised decision support software (CDSS) can be utilised to manage anticoagulated patients away from central pathology laboratories. Funding is provided for these centres to allow them to utilise POC devices and manage patients accordingly. This structure provides a natural pathway for patients to monitor their own therapy, also utilising POC devices. In Germany, it is estimated that around 500,000 patients currently manage their own anticoagulation and there is a nationally approved, formalised training program. The Association of Self-Management of Anticoagulation (ASA) has established a series of training centres across Germany. These centres organise seminars to train the trainers, namely doctors and nurses establishing home-monitoring with their patients, and also to train patients. An automatic process exists to transition appropriate patients from warfarin initiation to training for home-monitoring.

Some Australian general practitioners have endeavoured to incorporate POC into their practices, with mixed results. A lack of support at the funding level hampers these efforts, although general practices in Australia can be structured to run cost-effectively utilising existing Medicare rebates. However, a lack of Government support for POC in general practice at present makes it more difficult to implement more advanced forms of anticoagulation management such as patient self-monitoring (PSM) as general practices running anticoagulation clinics provide a natural platform for the assessment of appropriate patients for self-monitoring and training of these patients. It is important to acknowledge that patient self-monitoring and management represent the gold standard of care for warfarinised patients. While these forms of management may not be universally acceptable for all of the estimated 200,000 Australians taking warfarin, it is estimated that at least 50,000 would benefit significantly if they were implemented. Therefore it is appropriate for all patients taking warfarin to be assessed for their suitability for self-monitoring as the benefits are significant and include improved quality of life, reduced bleeding and thromboembolic complications and reduced mortality.

In Australia, pharmacists are in an ideal position to screen patients taking warfarin for their suitability to monitor their own therapy. Under existing funding structures, pharmacists could refer these patients to their general practitioner to discuss the concept, with a view to referral to an accredited pharmacist for specialised training, delivered as a Home Medicines Review (HMR). Implicit in this model, potential trainers must be trained to teach appropriate patients to monitor their own therapy. While POC devices are presently costly, private health insurers are now offering significant rebates on the cost of these devices on a case-by-case basis. Roche Diagnostics Australia also make their CoaguChek™ XS monitor available through pharmacy wholesalers so that community pharmacies can order in or stock the device for interested and suitable patients. With a critical mass of accredited pharmacists trained to train suitable patients, the Australian pharmacy profession can offer people taking warfarin a streamlined model of care that has the potential to greatly improve health outcomes.
Introduction

Improving the quality of anticoagulation

With the aim of improving the quality of anticoagulation, pharmacists can fulfil an important role together with patients, general practitioners and pathology providers (Figure 1). In particular, pharmacists can help to facilitate the transition of suitable patients from usual care to self-monitoring. However, an important role exists simply to better educate all warfarin patients, regardless of whether they go on to self-monitor. It is imperative that efforts to improve the quality of anticoagulation are not made by isolated professional groups. A collaborative and complimentary approach is far more likely to benefit patients and improve outcomes.

Figure 1: The professional interplay required to improve the quality of anticoagulation
Learning Objectives

Upon completion of this training package, the pharmacist should be able to:

- Understand the mechanism of action, indications, adverse drug reactions, main indications for warfarin, and recognise how these factors affect the therapeutic use of warfarin;
- Be aware of common food and drug interactions with warfarin;
- Understand the monitoring required with warfarin and its importance;
- Understand the principles of internal and external quality control procedures for point of care monitoring; and
- Possess the skills and knowledge necessary to identify and train suitable people taking warfarin to monitor their own warfarin therapy.

At the conclusion of training, the pharmacist will be assessed on the following:

- Practical ability to use the CoaguChek™ XS; and
- Theoretical knowledge (warfarin, point-of-care monitoring, quality assurance).
Anticoagulation Theory

Thrombosis

Two types of thrombi may be formed: arterial thrombi are composed primarily of platelets, bound together by fibrin strands. These thrombi are referred to as “white thrombi” because they have few red blood cells, and are usually relatively small. They generally occur in areas of rapid blood flow and are formed in response to an injured or abnormal vessel wall. Arterial thrombi usually occur in patients with pre-existing vascular disease, the most common of which is atherosclerosis. This produces clinical manifestations by inducing tissue ischaemia primarily through the obstruction of local blood flow.

Thrombi can occur in any part of the vascular system, including veins, arteries, the heart, and the microcirculation. A clot or fragment of a clot, which becomes dislodged from its site of origin, is known as an embolus. Emboli do not generally stop flowing of blood until they come to a narrowing of the circulatory system.

Unlike the arterial thrombi that form on arterial endothelium, venous thrombi are found primarily in areas of relative stasis, where dilution of activated clotting factors by blood flow is minimal. They are almost completely composed of fibrin and red blood cells, with a small number of platelets. The “red thrombi” are large and have only a weak attachment to the venous endothelium, usually at a valve or a bifurcation (splitting of the veins into smaller vessels) and may detach and embolise to occlude downstream vessels. Venous thrombi usually occur in the lower limbs, particularly the deep veins of the calf or thigh. They are usually silent but produce acute symptoms if they cause inflammation of the vessel wall or obstruction to blood flow, and if they damage the venous valves or if they embolise into the pulmonary circulation.

Mixed thrombi typically form in regions of slow to moderate blood flow such as those within the chambers of the heart or those on or around heart valves. These thrombi are composed of a mixture of red blood cells, platelets and fibrin and are known as mixed platelet-fibrin thrombi.
Warfarin; Mechanism of action

Warfarin is the most widely used anticoagulant in the western world. It exerts its anticoagulant effect by interfering with the interconversion of vitamin K quinol and its 2,3 epoxide (vitamin-K epoxide) (Figure 2). Vitamin K is a co-factor needed for the carboxylation of glutamate residues to γ-carboxyglutamates of vitamin K dependant proteins (clotting factors). These proteins, which include the coagulation factors II, VII, IX & X, require γ-carboxylation by vitamin K to exert a biological effect. By inhibiting the vitamin K conversion cycle, warfarin causes hepatic production of partially decarboxylated proteins with reduced coagulant activity, which in turn exerts an anticoagulant effect. Vitamin K antagonists also inhibit the carboxylation of the regulatory anticoagulants protein C & protein S.

Figure 2: Mechanism of action of warfarin

Warfarin has no direct effect on an established thrombus, nor does it reverse ischaemic tissue damage. However, once a thrombosis has occurred, the aim of oral anticoagulant treatment is to prevent further extension of the existing clot, and to prevent secondary thromboembolic complications.

Pharmacokinetics and pharmacodynamics

The relationship between the dose of warfarin and the response is influenced by genetic and environmental factors, including common mutations in the cytochrome P-450 enzyme (responsible for liver metabolism of warfarin). The optimal use of warfarin has been hampered by its greater than ten-fold inter-patient variability in the doses required to attain therapeutic responses. [5] Exaggerated responses to warfarin can occur in the elderly and reflects its reduced clearance with age, disease state interactions (such as congestive cardiac failure: CCF) and impaired clotting factor synthesis. [1] Hepatic dysfunction can potentiate the response to warfarin through impaired synthesis of coagulation factors and elimination of warfarin. [1] Hypermetabolic states produced by fever or hyperthyroidism can increase the response to warfarin, probably due to increased catabolism of vitamin-K dependant coagulation factors. [1]
Drug and Food interactions

Drug Interactions

The anticoagulant response to warfarin is influenced by pharmacokinetic factors; interacting drugs may influence the pharmacokinetics of warfarin by reducing gastrointestinal (GI) absorption or disrupting metabolic clearance. Drugs such as aspirin, clopidogrel, dipyridamole, and non-steroidal anti-inflammatory drugs (NSAIDs) increase the risk of warfarin associated bleeding by inhibiting platelet function. \[1\] Aspirin and NSAIDs can also produce gastric erosions that increase the risk of upper GI bleeding. The INR should be measured more regularly when any drug or herbal medicine is added, withdrawn or if dose adjustments of concomitantly used drugs are instituted in a patient treated with warfarin. \[1\]

Table 1 displays a list of important drug interactions with warfarin. \[3, 4\]
## Table 1: Clinically important drug-drug interactions with warfarin. Adapted from Hirsh et al. [5] and Myers. [6]

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<tr>
<td>Celecoxib</td>
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<tr>
<td>Co-trimoxazole</td>
</tr>
<tr>
<td>Erythromycin and other macrolides</td>
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<td>Metronidazole</td>
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<td>Dong quai</td>
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<tr>
<td>Prickly ash</td>
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<tr>
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<tr>
<td>Rifabutin</td>
</tr>
<tr>
<td><strong>Herbal medicines</strong></td>
</tr>
<tr>
<td>Ginseng</td>
</tr>
<tr>
<td>St John’s wort</td>
</tr>
<tr>
<td><strong>Increased bleeding risk because of effect on platelets</strong></td>
</tr>
<tr>
<td><strong>Medications</strong></td>
</tr>
<tr>
<td>Aspirin</td>
</tr>
<tr>
<td>NSAIDs</td>
</tr>
<tr>
<td>Feverfew</td>
</tr>
<tr>
<td>Liquorice</td>
</tr>
<tr>
<td><strong>Increased bleeding risk by effects on gastric mucosa</strong></td>
</tr>
<tr>
<td><strong>Medications</strong></td>
</tr>
<tr>
<td>Aspirin</td>
</tr>
<tr>
<td>NSAIDs/COX-2</td>
</tr>
</tbody>
</table>
Warfarin Theory

Food interactions

Patients receiving warfarin therapy are sensitive to fluctuating levels of dietary vitamin K. Therefore we should encourage adherence to the principle of consumption of a consistent intake of foods containing vitamin K, because dose requirements will be dependent on an individual’s vitamin K intake.

The literature suggests that most adults consume intakes of Vitamin K in the range of 60-200µg/day, [7] but vitamin K intakes of 600µg/day or more have been reported in some individuals. [7] Of all the fat-soluble vitamins, vitamin K has the highest individual daily variation in both dietary intake and corresponding plasma concentrations, [7] which increases the risk of complications through poor anticoagulant control.

Patients often ask what foods contain large amounts of vitamin K, and a general rule of thumb is that the greener the plant, the higher the vitamin K content. [7] Freezing, boiling, steaming, or microwaving vegetables does not significantly change the vitamin K content. [7] Fresh herbs are also rich sources of vitamin K, but their dietary contribution is not significant when consumed in small quantities. The other primary dietary sources of vitamin K are four plant oils: soybean, canola, cottonseed, and olive. Salad dressings, margarines, mayonnaise, cakes and pastries may be rich in phylloquinone if prepared with any of these four oils. [7] In contrast, peanut, corn, safflower, and sesame oils have very low vitamin K content. [7]

The vitamin K content of most other foods is very low. Root vegetables, such as potatoes, onions and squash are poor sources of vitamin K. As a general rule, animal products are also poor dietary sources of phylloquinone, including dairy products and liver. Table 2 displays common foods that have a vitamin-K content of 10µg or more per serve. [7]
Table 2: Vitamin K content of commonly consumed foods having >10 µg vitamin K per serve [7]

<table>
<thead>
<tr>
<th>Food</th>
<th>Serving Size</th>
<th>Mean vitamin K content per serve (µg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collards, fresh/frozen, boiled</td>
<td>½ Cup</td>
<td>374.0</td>
</tr>
<tr>
<td>Spinach, fresh/frozen, boiled</td>
<td>½ Cup</td>
<td>324.0</td>
</tr>
<tr>
<td>Brussels sprouts, fresh/frozen, boiled</td>
<td>¾ Cup</td>
<td>225.0</td>
</tr>
<tr>
<td>Coleslaw with dressing</td>
<td>1 Cup</td>
<td>119.0</td>
</tr>
<tr>
<td>Broccoli, fresh/frozen, boiled</td>
<td>½ Cup</td>
<td>88.0</td>
</tr>
<tr>
<td>Cabbage, fresh, boiled</td>
<td>½ Cup</td>
<td>73.0</td>
</tr>
<tr>
<td>Asparagus, fresh/frozen, boiled</td>
<td>½ Cup</td>
<td>72.0</td>
</tr>
<tr>
<td>Okra, fresh/frozen, boiled</td>
<td>½ Cup</td>
<td>32.0</td>
</tr>
<tr>
<td>Iceberg lettuce, raw</td>
<td>1/6 Medium head</td>
<td>28.0</td>
</tr>
<tr>
<td>Tuna canned in oil, drained</td>
<td>100 grams</td>
<td>25.0</td>
</tr>
<tr>
<td>Green peas, fresh/frozen, boiled</td>
<td>½ Cup</td>
<td>19.0</td>
</tr>
<tr>
<td>Celery, raw</td>
<td>1 Medium stalk</td>
<td>17.0</td>
</tr>
<tr>
<td>Mixed vegetables, frozen, boiled</td>
<td>½ Cup</td>
<td>15.0</td>
</tr>
<tr>
<td>Sauerkraut, canned</td>
<td>½ Cup</td>
<td>15.0</td>
</tr>
<tr>
<td>French salad dressing, regular</td>
<td>2 Tablespoons</td>
<td>15.0</td>
</tr>
<tr>
<td>Apple pie, fresh/frozen, commercial</td>
<td>1 Slice</td>
<td>14.0</td>
</tr>
<tr>
<td>Carrot, fresh, boiled</td>
<td>1 Medium</td>
<td>12.0</td>
</tr>
<tr>
<td>Cauliflower, fresh, boiled</td>
<td>½ Cup</td>
<td>12.0</td>
</tr>
<tr>
<td>Grapes, red/green, seedless, raw</td>
<td>½ Cup</td>
<td>12.0</td>
</tr>
<tr>
<td>Peppers, raw</td>
<td>3 Medium</td>
<td>11.0</td>
</tr>
<tr>
<td>Green beans, fresh/frozen, boiled</td>
<td>½ Cup</td>
<td>10.0</td>
</tr>
</tbody>
</table>
Managing warfarin

### Warfarin Initiation Protocols

The dosing of warfarin can be separated into initial and maintenance phases. An anticoagulant effect is seen within 2 to 7 days after initiating warfarin, according to the dose administered. When a rapid effect is required, heparin (unfractionated: UFH or low-molecular weight heparin: LMWH) should be given concomitantly with warfarin until the INR >2.0 for at least two days. This “cover” with heparin is needed because (1) the anticoagulant effect of heparins is almost immediate compared to warfarin and (2) if higher loading doses of warfarin are given (>10mg) there is a more rapid decrease in anticoagulant proteins (C & S) in relation to the procoagulant clotting factors. There is some debate surrounding the use of LMWH for “cover” when warfarin is initiated for stroke prevention in AF. There are a number of initiation protocols referred to in the literature and also a number of local institutional protocols exist (see below the Royal Hobart Hospital anticoagulation protocol), and it is suggested that local guidelines are followed when they exist. Starting doses of approximately 5mg daily usually result in an INR >2.0 after 4 or 5 days.

<table>
<thead>
<tr>
<th>Royal Hobart Hospital</th>
<th>Dose for age (mg)</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age and Disease State Adjusted Warfarin Initiation Protocol</td>
<td>INR</td>
<td>&lt;65 yrs</td>
</tr>
<tr>
<td><strong>1</strong></td>
<td>&lt;1.2</td>
<td>5</td>
</tr>
<tr>
<td><strong>2</strong></td>
<td>1.2</td>
<td>Requires specialist physician or haematologist advice prior to warfarin initiation</td>
</tr>
<tr>
<td><strong>3</strong></td>
<td>&lt;1.6</td>
<td>5</td>
</tr>
<tr>
<td><strong>4</strong></td>
<td>&lt;1.8</td>
<td>1.8-2.0</td>
</tr>
<tr>
<td><strong>5</strong></td>
<td>1.8-2.0</td>
<td>2.2-3.5</td>
</tr>
<tr>
<td><strong>6</strong></td>
<td>2.6-3.0</td>
<td>3.3-5.5</td>
</tr>
<tr>
<td><strong>7</strong></td>
<td>&gt;3.5</td>
<td>0</td>
</tr>
<tr>
<td><strong>8</strong></td>
<td>&gt;3.0</td>
<td>0</td>
</tr>
<tr>
<td><strong>9</strong></td>
<td>1.6-1.9</td>
<td>0.2-3.5</td>
</tr>
<tr>
<td><strong>10</strong></td>
<td>3.6-4.0</td>
<td>0</td>
</tr>
<tr>
<td><strong>11</strong></td>
<td>&gt;4.0</td>
<td>0</td>
</tr>
</tbody>
</table>

Ensure that the warfarin dose and INR are entered in the Warfarin Education Booklet and that education from a Pharmacist is acknowledged in medical notes.

<table>
<thead>
<tr>
<th>Use Day 4 Protocol as a Guide - Low INR (&lt;2.0) May Need Increased Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>INR (in am)</td>
</tr>
<tr>
<td>Daily INRs (in am)</td>
</tr>
<tr>
<td>INR is within the target range for 2 days consecutively.</td>
</tr>
<tr>
<td>If discharged monitoring may be performed by GP until day 7. GP</td>
</tr>
</tbody>
</table>

Warfarin Education Program: Accredited Pharmacist Training to Enable Patient Self-Monitoring of Warfarin

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*Ella Claire van Tienen*
Bleeding and warfarin therapy

The safety and efficacy of warfarin depend on maintaining the INR within the therapeutic range. Analysis of cohort studies have shown a sharp increase in the risk of bleeding when the INR is higher than the upper limit of the therapeutic range and the risk of thromboembolism is increased when the INR falls below 2.0 (Figure 3). [8-10][11, 12]

Contributing factors to the risk of bleeding are the underlying clinical disorders [13-17] and concomitant use of aspirin, NSAIDs or other drugs that impair platelet function, produce gastric erosions or impair synthesis of vitamin K dependent clotting factors.

Figure 3: The therapeutic window of anticoagulation

It is difficult to divide the contraindications to anticoagulation into absolute and relative. Each decision to anticoagulate an individual should be based on the risk/benefit ratio of bleeding and embolic recurrence.
Managing warfarin

Contraindications to Warfarin

Contraindications to anticoagulation could include:

- History of falls or tendency to fall.
- Dementia, unsupervised psychosis or other lack of patient cooperation.
- Chronic alcoholism or tendency to abuse alcohol.
- Chronic liver disease.
- Uncontrolled hypertension.
- Blood dyscrasias (platelet count <100x10^9/L) or documentation of any coagulation defects (congenital or induced).
- Bleeding tendencies that increase the risk of bleeding such as peptic ulcer, diverticular disease, genitourinary tract disease, sub-acute bacterial endocarditis, pericardial effusion or cerebral haemorrhage.
- Poor compliance to prescribed treatments.
- History of problems with warfarin in the past (e.g., poor control of INR, allergy).
- A comorbid condition with a poor prognosis such as malignancy.
- Pregnancy.

Managing Elevated INR or Warfarin Associated Bleeding

A number of approaches can be undertaken to lower an elevated INR (Table 3). The first step is to stop or withhold warfarin; the next step can be to administer vitamin K and the third and most effective way is to infuse fresh frozen plasma or prothrombin concentrate, which is highly expensive. After warfarin is withheld, the INR falls over several days (an INR between 2.0 to 3.0 falls to the normal range 4 to 5 days after warfarin is stopped. [18] The INR declines substantially within 24 hours after treatment with vitamin K. [19]
**Managing warfarin**

Table 3: Guidelines for the management of an elevated INR in adult patients with or without bleeding [16]

<table>
<thead>
<tr>
<th>Clinical setting</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>INR higher than the therapeutic range but &lt; 5.0; bleeding absent</td>
<td>Lower the dose or omit the next dose of warfarin. Resume therapy at a lower dose when the INR approaches therapeutic range. If the INR is only minimally above therapeutic range (up to 10.1), dose reduction may not be necessary.</td>
</tr>
<tr>
<td>INR 5.0–9.0; bleeding absent</td>
<td>Cease warfarin therapy; consider reasons for elevated INR and patient-specific factors. If bleeding risk is high, give vitamin K (1.0–2.0 mg orally or 0.5–1.0 mg IV). Measure INR within 24 hours; resume warfarin at a reduced dose once INR is in therapeutic range.</td>
</tr>
<tr>
<td>INR &lt; 9.0; bleeding absent</td>
<td>Where there is a low risk of bleeding, cease warfarin therapy, give 2.5–5.0 mg vitamin K orally or 1.0 mg intravenously. Measure INR in 6–12 hours, resume warfarin therapy at a reduced dose once INR &lt; 5.0. Where there is high risk of bleeding, cease warfarin therapy, give 1.0 mg vitamin K IV. Consider Prothrombinex-HT (25–50 IU/kg) and fresh frozen plasma (150–300 mL), measure INR in 6–12 hours, resume warfarin therapy at a reduced dose once INR &lt; 5.0.</td>
</tr>
<tr>
<td>Any clinically significant bleeding where warfarin-induced coagulopathy is considered a contributing factor</td>
<td>Cease warfarin therapy, give 5.0–10.0 mg vitamin K intravenously, as well as Prothrombinex-HT (25–50 IU/kg) and fresh frozen plasma (150–300 mL), assess patient continuously until INR &lt; 5.0, and bleeding stops. OR If fresh frozen plasma is unavailable, cease warfarin therapy, give 5.0–10.0 mg vitamin K IV, and Prothrombinex-HT (25–50 IU/kg), assess patient continuously until INR &lt; 5.0, and bleeding stops. OR If Prothrombinex-HT is unavailable, cease warfarin therapy, give 5.0–10.0 mg vitamin K IV, and 10–15 mL/kg of fresh frozen plasma, assess patient continuously until INR &lt; 5.0, and bleeding stops.</td>
</tr>
</tbody>
</table>

- Bleeding risk increases exponentially from INR 5 to 9; INR > 6 should be monitored closely.
- † Vitamin K effect on INR can be expected within 6–12 hours. In all situations carefully reassess the need for ongoing warfarin therapy.
Perioperative management of anticoagulation

The management of patients treated with warfarin that requires interruption of anticoagulation can be troublesome. This is because they have an increased risk of embolic events while ceasing warfarin, and the risk of these events needs to be weighed against the risk of bleeding whilst undergoing certain procedures. Most patients can undergo dental procedures (simple extractions), arthrocentesis, cataract surgery, and diagnostic endoscopy without alteration of their regimen. For other invasive and surgical procedures, oral anticoagulation needs to be withheld, and the decision whether to pursue an aggressive strategy of perioperative administration of intravenous heparin or subcutaneous low-molecular-weight heparin should be individualised as suggested in Table 4. After simple dental extractions, minor bleeding can be stopped with oral tranexamic acid mouthwash.

Table 4: Guidelines for the perioperative management of anticoagulation for procedures requiring discontinuation of oral anticoagulation (adapted from Dunn et al [21])

<table>
<thead>
<tr>
<th>Indication for anticoagulation</th>
<th>Examples</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indication with low annual risk of thromboembolic stroke (&lt;4%) without anticoagulation</td>
<td>Atrial fibrillation without history of thromboembolic stroke</td>
<td>Withhold oral anticoagulation</td>
</tr>
<tr>
<td>Indication with moderate annual risk of thromboembolic stroke (4%-7%) without anticoagulation</td>
<td>Mechanical aortic valve</td>
<td>Withhold oral anticoagulation. Optional administration of either treatment dose of IV heparin or SC LMWH whilst INR is sub-therapeutic</td>
</tr>
<tr>
<td>Indication with high annual risk of thromboembolic stroke (&gt;7%) without anticoagulation</td>
<td>Mechanical mitral valve; atrial fibrillation with history of thromboembolic stroke</td>
<td>Withhold oral anticoagulation and administer either treatment dose of IV heparin or treatment dose of SC LMWH whilst INR is sub-therapeutic</td>
</tr>
</tbody>
</table>
Overview of therapeutic uses of warfarin

Venous thromboembolism

Deep Vein Thrombosis (DVT) of the lower limb normally starts in the calf vein. About 10%-20% can extend to form proximal DVT, which are associated with a greater risk of pulmonary embolus (PE). A further 15%-25% can go on to develop into fatal PE. DVT commonly presents with pain, erythema, tenderness, warmth and swelling of the affected limb. Thus, in lower limb DVT, the affected leg is usually swollen with the circumference of the calf larger than the unaffected side.

Treatment strategies

Warfarin should be started at the same time as heparins and continued for at least 3 to 6 months. Heparins should be ceased when the INR has been therapeutic for at least two days (usually 5-7 days after initiation of warfarin). Standard heparin is usually given by IV infusion and requires hospital admission. Low Molecular Weight Heparins (LMWHs) such as enoxaparin are given in SC doses and permit outpatient treatment of uncomplicated proximal DVT. Symptomatic calf vein thrombosis should also be treated with anticoagulants.

The optimal duration of anticoagulation for VTE is dependent upon risk factors for recurrence (Table 5). The future clinical implications of new trials assessing long-term treatment for patients with idiopathic DVT are yet to be finalised.

Table 5: Duration of therapy for venous thromboembolism

(adapted from Turpie et al [22])

<table>
<thead>
<tr>
<th>Duration of therapy for venous thromboembolism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Three to six months</td>
</tr>
<tr>
<td>First event with a reversible (surgery, trauma, immobilisation, oestrogen use) or time limited risk factor</td>
</tr>
<tr>
<td>More than six months</td>
</tr>
<tr>
<td>Idiopathic venous thromboembolism, first event</td>
</tr>
<tr>
<td>A year to life time</td>
</tr>
<tr>
<td>First event with cancer (until resolved), anticardiolipin antibodies or antithrombin deficiency</td>
</tr>
<tr>
<td>Recurrent event, idiopathic or with thrombophilia</td>
</tr>
</tbody>
</table>

Warfarin Education Program: Accredited Pharmacist Training to Enable Patient Self-Monitoring of Warfarin
Therapeutic uses of warfarin

Atrial fibrillation

AF is the most common arrhythmia; the prevalence of AF is estimated to be 0.4%–1% of the general population and increases with age. [23, 24] The prevalence of AF is less than 1% in those under 60 years of age and reaches 10% in those over 80 years. The rapid and irregular atrial activity causes a loss of atrial contraction, in which the atria only quiver, leading to stasis of blood in the atria. [25] This promotes clot formation and the occurrence of thromboemboli, which can cause stroke. [25] The presence of AF confers a fivefold increase in the risk of stroke, with an absolute stroke risk of 4.5% per year that can range from <1% to >1% depending on risk factors for stroke (Table 6).

Table 6: Risk stratification for stroke prevention in AF. [26]

<table>
<thead>
<tr>
<th>Risk</th>
<th>High (warfarin) [6-12% per year]</th>
<th>Intermediate (warfarin or aspirin) [2-5% per year]</th>
<th>Low (aspirin) [&lt;1% per year]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hankey (2001)</td>
<td>• Age &gt; 65 years and hypertension or diabetes</td>
<td>• Age &lt; 65 years and hypertension or diabetes</td>
<td>• Age &lt; 65 years and no hypertension, diabetes, TIA, stroke or other clinical risk factors</td>
</tr>
<tr>
<td></td>
<td>• Previous TIA or stroke</td>
<td>• Recent myocardial infarction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Heart failure or impaired left ventricular dysfunction on echocardiography</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Thyroid disease or left atrial thrombus</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Maximum protection against stroke in AF is probably achieved with an INR range of 2.0 to 3.0, [9, 11, 12] whereas an INR range of 1.6 to 2.5 appears to be associated with incomplete efficacy, estimated at approximately 80% of that achieved with higher-intensity anticoagulation. [11]
Valvular heart disease

Mechanical valves are more thrombogenic than bioprosthetic valve and patients with mechanical valves require lifelong anticoagulant treatment. After mitral valve repair, oral anticoagulation (target INR 2.5) is needed for the first six weeks to three months, and thereafter treatment is guided by the presence or absence of risk factors such as AF, CCF, and an enlarged left atrium. Table 7 displays type of valves and recommended therapeutic ranges in Australia.

Table 7: Intensity of anticoagulation for prosthetic heart valves recommended in Australia. Recommendations from the Australasian Society of Thrombosis and Haemostasis. [27]

<table>
<thead>
<tr>
<th>Type of valve replacement</th>
<th>Target INR range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue heart valves (bioprosthetic [porcine] valves)</td>
<td>2.0-3.0 for the first 3 months then lifelong aspirin</td>
</tr>
<tr>
<td>Bileaflet mechanical heart valve (aortic)</td>
<td>2.5-3.5</td>
</tr>
<tr>
<td>Mechanical prosthetic heart valve-older first generation valves (high risk)</td>
<td>3.0-4.5</td>
</tr>
</tbody>
</table>
Checklist for patient counselling

- Discuss with the patient the reason for warfarin treatment, ensure they are clear of the reason they are taking it.
- Briefly explain warfarin’s mechanism of action.
- Explain the INR, the concept of a target range and emphasise the importance of regular testing.
- Emphasise the importance of compliance (discuss the maintenance of an INR diary, and recording doses—especially missed doses).
- Explain the possible effects of poor anticoagulation control:
  - Bleeding or severe bruising
  - Recurrence of thromboembolism
- Discuss the appropriate action if excessive bleeding or bruising occurs.
- Discuss the appropriate action if diarrhoea or vomiting occurs.
- Discuss starting new treatments or changing the dose of current treatment.
- Explain the existence of common OTC medication interactions, such as aspirin, NSAIDs, paracetamol, complementary therapies and laxatives. Emphasise the importance of discussing new treatments with your or another healthcare professional.
- Explain the role of vitamin K, and the importance of consistency in regards to vitamin K rich foods in the diet, rather than avoidance.
- Explain the importance of minimising their alcohol intake and why.
- Discuss ways to minimise high risk activities associated with an increased risk of physical trauma.
- Suggest wearing a MedicAlert® bracelet/necklace and carrying a warfarin ID card.
- Let them know about www.anticoagulation.com.au if they are interested in finding out more information.
One page guide to warfarin treatment

1. Warfarin belongs to a class of medications called anticoagulants ("anti-clotting medicines"). Warfarin keeps blood clots from forming or getting larger.
2. Many medications can change the way warfarin works. Ask your doctor or pharmacist about using any other medication, including over-the-counter medications, vitamins and herbal products.
3. Make sure your doctor or pharmacist knows if you are taking aspirin or aspirin-like medications, such as medications for pain relief and the common cold.
4. Avoid drinking large amounts of alcohol.
5. Certain foods will change the way warfarin works. Do not change your diet while taking warfarin. Foods that contain vitamin K (such as lettuce, spinach, broccoli, cabbage, cauliflower or liver) decrease the anti-clotting effect of warfarin. If you eat foods that have vitamin K, do not change the amount of these foods that you normally eat per week. The main point regarding diet is to eat a consistent amount of foods per week that contain vitamin K.
6. It is very important to have regular blood tests while taking warfarin. The test is called an INR, and it measures how fast your blood clots compared to normal.
7. You should carry an identification card that shows you are taking warfarin.
8. Make sure your doctor, dentist, or other health care provider knows you are taking warfarin before you have any surgery or dental work.
9. You should report the following to your doctor immediately:
   - Bleeding from the gums or nose.
   - Coughing up blood.
   - Red or black bowel motions.
   - Red or dark-brown coloured urine.
   - Unusually heavy menstrual bleeding.
   - Any bleeding from cuts or wounds that does not stop.
   - Easy bruising.
   - Severe headache.
10. **If you miss a dose**: Take the missed dose as soon as possible. If you do not remember until the next day, skip the missed dose. Only take your usual dose for the day. You should not take two doses at the same time.

*Adapted from the Institute for clinical systems improvement (www.icsi.org)
References


Optimising warfarin management: An exploration of pharmacist-delivered models of care

References


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Ella Claire van Tienen
Point of Care INR Testing

Thromboplastins

The prothrombin time (PT) test uses a tissue thromboplastin, an extract of tissue, to accelerate the clotting time of the blood. This simply initiates the clotting process, which is normally initiated when blood plasma is exposed to body tissue. This test is sensitive to changes in the vitamin K dependent factors (II, VII, IX and X) and is used to control warfarin therapy.

The tissue factor (TF) is usually prepared from a variety of sources, including human, rabbit and bovine brain, human placenta and more recently, recombinant human and rabbit preparations. A laboratory must then define the normal reference range for each reagent (TF) and technique used, using samples from 20 healthy adults. The average of these results is then calculated. This is known as the mean normal prothrombin time (MNPT) and is then used to calculate the prothrombin ratio (PR). The prothrombin ratio is expressed as:

\[ PR = \frac{\text{test PT}}{\text{MNPT}} \]

For a patient on warfarin, the PR is simply the ratio of their clotting time compared to a patient not on warfarin. That is, a PR of 2 means that the patient’s blood will take twice as long to clot compared to a ‘normal’ patient.

Each laboratory must standardise every batch of reagent for each testing method employed because it has been widely demonstrated that PRs performed on the same sample in different laboratories may not correlate well. This can be due to a number of pre-test and analytical variables, such as blood collection tube type, poor venipuncture technique and storage of samples, sample contamination, thromboplastin source, coagulometer effects and analysis temperature. The most important variable is the type of thromboplastin used. These variables can lead to inconsistencies in the PR and can lead to incorrect dosing and poor control of therapy.
The INR

The International Normalised Ratio (INR) was developed in the 1980s in an attempt to standardise the PT. To achieve this, each thromboplastin reagent is assigned an International Sensitivity Index (ISI) that reflects the sensitivity of the reagent to reduced levels of clotting factors. Thus the INR is merely a standardised form of the PR such that the same sample of plasma should give the same INR even if different thromboplastins are used that result in different PRs. The INR is expressed as:

\[ \text{INR} = \left( \frac{\text{test PT}}{\text{MNPT}} \right)^{\text{ISI}} \]

It is important that the ISI and MNPT are determined for each batch of thromboplastin and with each coagulometer used in order to assign the system ISI. For more detail on ISI calibration, a reference to the WHO Expert Committee on Biological Standardisation recommendations is provided (http://www.who.int/biologicals/index/Cardiovascular.htm).

Despite the INR theoretically being a standardised measure because of the ISI, thromboplastins with a low ISI (1.0-1.4) are preferred for INR determination as a high ISI essentially magnifies the PR, and any slight error may become a larger one. The use of high ISI reagents may give less dependable INR values during the initiation of oral anticoagulation with warfarin and in poorly stabilised patients.

Point of care INR measurement

INR testing is routinely conducted in centralised pathology laboratories or hospital centres in Australia. A number of possible models of care are now available for primary care health providers and patients. These include monitoring of INR in general practice clinics, patient self-testing and self-management of warfarin therapy. The new models of care rely heavily on point of care (POC) testing, broadly defined as testing performed in close proximity to the patient.

There are a number of POC INR devices that are available currently in Australia. These are generally of two types:

- Devices designed for professional use, primarily for hospital staff; or
- Devices intended for use by other healthcare personnel in anticoagulation clinics or primary care, or by patients themselves.

The former type of monitor generally is used for conducting the INR test in addition to others. They may permit the use of more than one type of sample; have large electronic memories and complex data management systems suitable for multi-user, multi-patient use. The latter type of device performs only the INR test, contains basic software and is focused on ease of use. Professional type devices are high cost and are not suitable for use in general practice. Devices for POC monitoring must meet certain requirements prior to their use in general practice.
Point of Care Testing

Available POC devices in Australia

At the time of writing, there are two portable INR monitors available commercially in Australia for consumer use: the CoaguChek™ XS and the INRatio™ (Hemosense).

Left: the CoaguChek™ XS monitor; right: INRatio™ device.

Both monitors measure the INR from capillary or venous samples; however, each monitor has a different means of achieving this. A comparison of monitor characteristics is shown in Table 8.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

The INRatio™

The INRatio™ uses an electrochemical detection method to determine changes in impedance in the sample. The monitor calculates the PT and INR from the measured impedance change and reports them on the display. The test strip features three channels, one of which tests the PT, while the other two provide a measure of internal quality control (low and high) for each sample. Because it has three channels, the monitor requires a larger blood sample, making it more problematic to use. If the test is not within quality control pre-set limits, the test result will not be displayed. The thromboplastin used has an ISI of 1.0 and the INRatio™ will deliver an INR result within two to three minutes. From manufacturer and published accuracy data, the INRatio™ correlates well with the laboratory method.[2, 3] However, there have been some reports of inaccuracy with the device in the UK.

The CoaguChek™ XS

The CoaguChek™ XS is a portable coagulometer that measures the INR using whole blood obtained by fingerprick. It has been designed specifically for use by non-health professionals. The procedure involves insertion of a test strip into the monitor and application of a drop of blood onto the test strip. The monitor uses an amperometric (electrochemical) method to determine the PT after activation of coagulation with thromboplastin on the test strip. Thrombin generated by the clotting process cleaves another substrate peptide in the test strip, which is oxidised, resulting in an increase in current flow. Based on the calibration of the device, at a certain current threshold the clotting time is measured and converted into the INR and displayed on the monitor. The PT is then converted to an INR using the ISI, determined for the batch of test strips, found on the control chip. The CoaguChek™ XS utilises a recombinant human thromboplastin with an ISI value close to 1.0. An INR result is provided within one minute of application of the blood sample to the test strip. An INR result is not displayed if internal quality control conditions are not met. The new model offers several improvements over the previous model (CoaguChek® S) including improved ease of use, reduced size, the use of a recombinant human thromboplastin with a lower ISI and internal quality control included on the test strip.
Table 8: Characteristics of the two POC monitors currently available in Australia

<table>
<thead>
<tr>
<th>Manufacturer of monitor</th>
<th>INRatio™</th>
<th>CoaguChek™ XS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology</td>
<td>HemoSense Inc.</td>
<td>Roche Diagnostics</td>
</tr>
<tr>
<td>Thromboplastin</td>
<td>Electrical impedance</td>
<td>Electrochemical</td>
</tr>
<tr>
<td>ISI</td>
<td>Recombinant human 1.0</td>
<td>Recombinant human 1.0</td>
</tr>
<tr>
<td>Sample type</td>
<td>Capillary</td>
<td>Capillary or venous</td>
</tr>
<tr>
<td>Sample size of blood required (microlitre)</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>Site on test strip where blood can be applied</td>
<td>Top</td>
<td>Top and side</td>
</tr>
<tr>
<td>INR range displayed (INR units)</td>
<td>0.7-7.5</td>
<td>0-8.0</td>
</tr>
<tr>
<td>Test time for results (mins)</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Strip shelf life</td>
<td>3 months</td>
<td>18 months</td>
</tr>
<tr>
<td>Memory (tests)</td>
<td>60</td>
<td>100</td>
</tr>
<tr>
<td>Power source</td>
<td>Batteries or adapter</td>
<td>Batteries</td>
</tr>
<tr>
<td>Weight of monitor (g)</td>
<td>335</td>
<td>175</td>
</tr>
</tbody>
</table>

POC Evaluation

All in vitro diagnostic equipment requires thorough evaluation before clinical implementation to ensure that results are reliable and consistently obtained. In Australia, the Therapeutic Goods Administration (TGA) reviews the available data from the manufacturer before a product is registered for use. While there are no specific guidelines for the calibration of POC devices, it is accepted that the manufacturers, using the same procedure as conventional laboratory systems, should perform INR calibration. For POC INR monitors, the user cannot alter the ISI and MNPT calibration provided by the manufacturer. The PT and INR from a POC INR system is compared with at least two other reference systems selected from instruments and reagents (usually one rabbit brain and one human recombinant thromboplastin) that have been validated previously.

POC INR systems have been widely evaluated in clinical practice, including testing by healthcare professionals in hospitals and general practices, as well as patient self-monitoring and self-management. On the basis of the available literature, POC INR monitors perform at a similar level with conventional laboratory testing.[5, 6]
Accuracy of POC INR devices

The accuracy of the INR measured with POC testing devices depends essentially on the calibration. Presently, the responsibility of calibration rests entirely with manufacturers because access to the software to change encoded parameters is not possible for the majority of commercial devices. Easier calibration procedures for POC testing devices are currently under investigation by the European Concerted Action on Anticoagulation (ECAA) and its working group.[6-19]

To check the performance of POC testing, comparing the INRs measured using the devices with those measured using conventional methods is a common method. By definition, the true INR of a given plasma sample should be the one measured with the primary international reference preparation (IRP) for thromboplastin, called 6/7/40, coupled with the manual (tilt-tube) technique to detect clot formation (defined as the standard method). However, the IRP 6/7/40 was discontinued many years ago and replaced by other IRPs, which were calibrated against their predecessors. Therefore, the true INR is not known. For practical purposes, it can be assumed that the INR measured with one of the established IRPs for thromboplastin coupled with the manual (tilt-tube) technique is a good approximation of the true value. The INR measured with other conventional systems may also be considered as a good approximation of the true value only if they have been calibrated against an IRP. The reproducibility assessed for one commercial POC testing device was acceptable (median CV = 4.883), but poorer than that of the conventional laboratory INR measurement (median CV < 1.533).[1]

The College of American Pathologists suggests if one method of monitoring anticoagulation is to be replaced or supplemented by another method, the new method should be calibrated against the old method.[20] Therefore, a correlation study of both methods is a crucial step prior to implementing the POC method.

Statistical and clinical agreement

The agreement between paired INR measurements (i.e., those obtained with the POC testing device and those obtained with the standard method) can be assessed by statistically or clinically relevant criteria. Statistically relevant criteria are concerned with the correlation analysis of paired INR measurements and/or comparison of mean values. Although they are widely used it should be realised that these statistical evaluations, if used alone, are not very informative. For instance, two methods might be highly correlated (high correlation coefficient) even though their results are systematically biased. It is more useful to plot the differences of paired measurements against the average value.[21] This enables an assessment of systematic differences over the whole range of measured INRs.

Clinically relevant criteria usually rely on the assumption that the INR values measured for the same patient by two systems are in agreement, if using either INR does not result in changes of dose prescription. Requirements for agreement of paired INR measurements have been developed [22, 23] and may form the basis for POC testing assessment. Being more closely related to decision making on dose prescription, the agreement based on clinically relevant criteria should be considered more meaningful than that based on statistically relevant criteria.

It is important to note that accuracy and precision need to be established for each device; the devices cannot be used interchangeably and the performance of one monitor cannot be transposed onto another. [2]
References


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References

Accuracy and Clinical Utility of the CoaguChek™ XS Portable International Normalised Ratio Monitor in a Pilot Study of Warfarin Home-Monitoring

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The effectiveness and safety of warfarin is maximised by the maintenance of a target international normalised ratio (INR) range, below which effectiveness is lost, and above which the bleeding risk is unacceptably high. The key objective of point-of-care testing is to provide a fast, accurate result so that appropriate treatment can be started or treatment modified, resulting in an improved clinical status and reduced bleeding and/or hospitalisation costs. In a previous study, we found that general practitioners suggested that the availability of portable INR monitors would assist in the management of their patients with anticoagulation and would perhaps increase their compliance with warfarin therapy.

The CoaguChek XS portable INR monitor (Roche Diagnostics, Basel, Switzerland) was released in October 2003 and, although the results of the majority of publications have been published, its accuracy has not been assessed in clinical practice to date. Particularly, it was found that the laboratory method used was not the same as the accuracy and stability of the CoaguChek XS monitor, which used by patients to perform safely self-testing in a pilot study involving communication with the general practitioner via the Internet.

Materials and Methods

Participants and point-of-care procedure

This study was undertaken as a component of a warfarin home-monitoring pilot study. The pilot study involved 22 patients recruited from western Tasmania, Australia who were both interested in home monitoring of anticoagulation and had access to the Internet at their home. In all, 17 of these patients were assigned two mailing packets to enable self-monitoring, the first involved theoretical aspects of anticoagulation monitoring and a practical demonstration of the CoaguChek XS, and the second involved revision and practical testing to ensure that the INR monitoring technique was adequate. In the time between the first and second sessions (usually 1 week), patients completed at least two comparator tests consisting of a morning test with the CoaguChek XS and a laboratory INR test at the patient's usual laboratory within 4 h of each other. These results were documented by the technician and if the CoaguChek XS INR differed by >5% compared with the laboratory INR, the patient was asked to perform another comparison test. If further tests were >15% discordant, the patient was excluded from the trial.

Once two comparison tests were completed and were within 15% of the corresponding laboratory value, the patient returned the pilot study and completed home monitoring once weekly. A morning INR was completed every morning in vivo and the laboratory method when the patient was admitted to the wards, or in the discretion of the patient's general practitioner. Patients continued in the pilot study for up to 6 months self-monitoring. The pilot study was granted ethics approval by the Tarrantia Human Research Ethics Committee and all patients and doctors provided written consent.

The CoaguChek XS is a portable comparator that measures the INR using whole blood obtained by fingerstick. It has been developed specifically for use by non-health professionals. The procedure involves insertion of a test strip into the monitor and aspiration of a drop of blood onto the test strip. The monitor uses an amperometric (electrochemical) method to determine the prothrombin time after activation of coagulation with thromboplastin within the test strip. The prothrombin time is then converted to an INR using the international sensitivity index (ISI), determined for the batch of test strips. Based on the control strips, the CoaguChek XS uses a recombinant human thromboplastin with an ISI value close to 1. An ISI result is provided within 1 min of application of the blood sample to the test strip.

Abbreviations: INR, international normalised ratio; ISI, international sensitivity index.
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Table 1: Comparison of CoagCheck XS and laboratory international normalised ratio results

<table>
<thead>
<tr>
<th>Parameter</th>
<th>CoagCheck XS</th>
<th>Laboratory</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>INR range</td>
<td>2.1–3.0</td>
<td>2.0–3.0</td>
<td>0.02</td>
</tr>
<tr>
<td>mean difference (SD)</td>
<td>0.07 (0.52)</td>
<td>0.38 (0.58)</td>
<td>0.007</td>
</tr>
<tr>
<td>INR values</td>
<td>100</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>INR values (INR)</td>
<td>1.64 (1.42)</td>
<td>1.69 (1.54)</td>
<td>0.03</td>
</tr>
<tr>
<td>Acceptable INR (INR)</td>
<td>1.5–2.5</td>
<td>1.5–2.5</td>
<td></td>
</tr>
<tr>
<td>Acceptable INR (INR)</td>
<td>90</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td>Acceptable INR (INR)</td>
<td>90</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td>Acceptable INR (INR)</td>
<td>90</td>
<td>90</td>
<td></td>
</tr>
</tbody>
</table>

In the study, INR was defined as the percentage of INR results from the CoagCheck XS that differed from the laboratory in the categorisation of the individual patient’s INR value. The INR categories were as follows: 1–1.9, 2–3, 3–1.9, and 4–6. The INR categories were determined on a trial-by-trial basis. INR results that did not differ from the laboratory INR were considered to be within the targeted range. Narrow agreement was achieved when both the CoagCheck XS and the laboratory were within the targeted range. Narrow agreement was achieved when both the CoagCheck XS and the laboratory were within the targeted range. Narrow agreement was achieved when both the CoagCheck XS and the laboratory were within the targeted range. Narrow agreement was achieved when both the CoagCheck XS and the laboratory were within the targeted range. Narrow agreement was achieved when both the CoagCheck XS and the laboratory were within the targeted range.
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References

Figure 2. Bland-Altman style bias plot for CoogaCheck X5 and laboratory INR values.

Table 2. Comparison of international normalised ratio categories for CoogaCheck X5 and laboratory results (indices given as a percentage of laboratory readings).

Discussion

In a study designed to test the accuracy of CoogaCheck X5 INR determination compared with laboratory-observed INR, we found the CoogaCheck X5 to be 100% accurate against expanded and narrow agreement criteria. This comparison favours the ability of other previously published studies by the authors, where the same INR range was found to be between 90% and 95% accurate against expanded agreement criteria, between 80% and 90% accurate against narrow agreement criteria. Previous studies by the investigators with the CoogaCheck S model found that INR was categorised in the same normal range on 69% and 85% of occasions. This study found that 80% of all INR results were in the same category.

The regression analysis is only a measure of association, not causation, a far superior measure in the Bland-Altman analysis. This plot provides a more accurate representation of disagreement for a given mean INR by both methods. Both of these analyses indicated a general under-estimation of the INR, which needs to be considered in the interpretation of INR results provided by the CoogaCheck X5 monitor. This was also shown in prior studies of the CoogaCheck S device. The CoogaCheck X5 was more accurate when the bounds of the parameters were within 8%. For CoogaCheck S, Failing haemorrhage was observed in patients with INR above 4.3.

The accuracy data for the CoogaCheck X5 in this study are particularly important in light of a number of potential variables. The use of the CoogaCheck X5 was not re-examined or even newly introduced, but is the strength that was generally achieved and had received few training sessions regarding the use of the monitor. Additionally, a range of INR results were used from the study. From these results, it could be expected that if the CoogaCheck X5 is implemented in community practice, it is appropriate for a monitored INR of 2.0 to 3.0. The CoogaCheck X5 could provide accurate and dependable results.

This accuracy comparison is limited by a small number of patient volunteers and patients, however, given the diversity of the user groups, the monitor performed extremely well and is a testament to the accuracy of the device. The previous study, CoogaCheck S, performed similarly well when used by a variety of users in general practice and community pharmacy.

The CoogaCheck X5 performed admirably in this pilot study. In addition to being highly accurate, participants found it simple to use, and both doctors and patients were highly satisfied with its performance. However, the device should have been used by 17 different patients, and blood had been drawn at different pathologies, and the CoogaCheck X5 was highly accurate compared with the laboratory method.
Quality Assurance

Quality assurance broadly describes any measures taken to ensure the reliability of testing and reporting. Thus, it encompasses the calibration of the monitor, taking the sample from the patient, analysis and accurate recording of the results.

Quality assurance is comprised by two equally important entities. These are internal quality control (IQC) and external quality control (EQC). These are distinct but complementary components of quality assurance (Figure 4). That is, both are essential in demonstrating that any monitoring system is providing precise and accurate INR results. IQC establishes the day-to-day consistency of results from one monitoring system. Therefore, IQC is a measure of precision only and variances may alert to problems with the storage of test strips or the workings of the monitor. EQC is used to identify the degree of agreement of measurements from one centre to those of another. Thus, EQC is a measure of the accuracy of the results obtained from a given system compared to a standard measure. For example, the accuracy of a POC monitor to the local laboratory.

Figure 4: Diagrammatical representation of accuracy (measured by EQC) and precision (measured by IQC)

Accurate and Precise

Accurate but Imprecise

Precise but Inaccurate

Inaccurate and Imprecise

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Accredited Pharmacist Training to Enable Patient Self-Monitoring of Warfarin

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Ella Claire van Tienen
Quality Assurance

Internal quality control

IQC is used to determine whether the INR monitor is performing on a consistent basis. Basically, IQC ensures that the results obtained from the system are reliable enough to make a decision regarding the next dose of warfarin. The quality of INR results may be influenced by a number of factors, including: appropriate sample collection and handling; selection of a suitable technique; maintenance of standard operating procedures; adequate recording of results and the appropriate selection and training of suitable personnel to conduct the test.

As previously mentioned, IQC is most useful for identifying the precision of a laboratory technique. That is, the degree of agreement between repeat measurements of the same sample. In the ‘target’ diagram above (Figure 4), precision is denoted as the closeness of the five triangles. Note that a technique may be very precise while remaining inaccurate compared to the true value (the center of the target) or ‘inaccurately precise.’ This phenomenon underlines the importance of conducting EQC in tandem with IQC.

Available methods of IQC

The INRatio™ and CoaguChek™ XS INR monitors all feature inbuilt IQC, while the CoaguChek™ XS also has liquid IQC vials available from the manufacturer. The test strips for the INRatio™ and CoaguChek™ XS monitors have extra capillaries (tubes) where the blood sample mixes with a control solution. The monitor will not display a result for the IQC tests, but an indication that they are within pre-set levels is given. The INR result is not provided if there is a problem with the IQC test or if they are out of range. This in-built IQC is not regarded as sufficient on its own to ensure quality control.

Liquid controls, such as those available for the CoaguChek™ XS are the preferred means of IQC because they behave in the same way as a blood sample provided by the patient. The control is made up of small flexible dropper units containing a sealed ampoule of diluted and lyophilized plasma. The inner ampoule is crushed, reconstituting the sample. This is left for a short period and then placed on a test strip in exactly the same way as a blood sample. These controls are simple to use and are suitable for use by healthcare professionals and patients alike. Each liquid control has a target reading, as well as a range within which the INR reading from the monitor should result. This range may be inappropriately wide (±1.0 INR units). For any sample, the variance from the target INR of the IQC should not exceed 0.5 INR units. If an INR is obtained that is outside of this range, a second test should be conducted. If this IQC is also out of range, testing should be suspended until the problem is rectified. For a practice, this may mean taking venous samples that day for analysis in a pathology laboratory. Storage conditions for the monitor, test strips and liquid quality control vials should be checked. The performance of the monitor may also need to be checked by the manufacturer.

External quality control

There are a number of possible approaches to EQC for POC INR monitors. The aim of EQC is to demonstrate the similarity of one method’s results to those of another method. EQC is a measure of accuracy, or the closeness of the measured value to the true value. However, if a centre is only comparing its results to one other centre, there is no guarantee that the value from the other centre is ‘true.’ The difference in results between a POC device and a laboratory may not necessarily exceed that of one laboratory to another laboratory. Despite efforts to standardise the PR with ISI, this problem arises because of many reasons, including different monitoring systems, operators, operating conditions and reagents. By definition, the original reference thromboplastin was assigned an ISI of 1.0. However, stocks of this reagent do not exist, so new reference thromboplastins are compared to their predecessors.
Quality Assurance

Any small errors in ISI can be transposed and magnified onto the INR reading. Despite these potential problems, it is acceptable for one method to be compared to another so long as that method is calibrated to a reference thromboplastin.

For newer monitors, such as the CoaguChek™ XS, there are formal external quality assurance programs, such as that provided by the Royal College of Pathologists of Australasia. This might be useful for organisations utilising a POC device, but relatively expensive for a patient self-monitoring. An acceptable approach is for the patient to periodically have a pathology INR measured, to compare with the home INR (as long as it is within four hours of the pathology INR). This comparison could be conducted on a regular basis to provide ongoing EQC. It is reasonable to expect good agreement (± 0.5 INR units) for patients stabilised on long-term warfarin therapy. If good agreement does not occur, the problem may lie with either comparator system. INR deviation of up to 15% is considered acceptable for clinical purposes.

Whatever approach is used, it is imperative that EQC is conducted at regular intervals and the results are documented to maintain the accuracy of the monitor. This is the case for pathology and hospital laboratories, so it is no different for a patient using a device at home or for a clinic operating a POC monitor.
Patient Self-Monitoring

Introduction

The therapeutic benefits of warfarin are highly dependent on maintaining the international normalised ratio (INR) within the therapeutic range.[3] Poor compliance, variable dietary intake, drug interactions, inadequate knowledge, and miscommunication between the patient and physician have all been cited in the literature as potential causes for fluctuations in the INR.[2-5]

Bleeding complications with warfarin occur more frequently in older patients than in younger individuals.[6-10] Anticoagulation in elderly patients poses unique challenges because they are simultaneously at higher risk for recurrent thromboembolism and major bleeding, including catastrophic intracranial haemorrhage. Older patients have characteristics that may place them at higher risk for anticoagulant-related bleeding, but they also have characteristics that make them more likely to benefit from the therapy.[6, 10] The dilemma is that the use of warfarin is now increasing at a steady rate (approximately 103 per year[11]) because of its proven benefits in atrial fibrillation (AF).[12] AF is a very common arrhythmia, with a prevalence of approximately 5% in people over 60 years of age and 10% in people over 75 years of age. It is recognised as a major public health problem associated with significant morbidity and mortality.[13, 14] The presence of AF has been confirmed in many studies as an important risk factor for ischaemic stroke and other thromboembolic events.[15, 16] Approximately 15% of all strokes are associated with AF, and the association increases steadily with age.[15] It has been conclusively demonstrated that long-term anticoagulation therapy can reduce the risk of stroke by approximately 68% in patients with non-valvular AF.[12, 14, 17-19]

Once stabilised on warfarin, more frequent monitoring may be required in older adults, because they may experience greater fluctuations in the INR, particularly during illness or with alterations in their medication regimens.[20] More frequent monitoring may ensure that the target INR does not rise above recommended levels in older patients.[21]

Practically, frequent laboratory testing represents a significant burden and may be unrealistic for many elderly patients who are initiating warfarin therapy. Compared to younger patients, older patients are more often dependent on others for transportation and may be challenged by physical limitations to mobility. These impediments to frequent testing are especially relevant for those patients who live in rural areas or in less developed countries.[22]

The Australian Patient Safety Foundation has previously recommended that there be an assessment of home monitoring of anticoagulant therapy.[23] Patient self-management and self-testing of warfarin have great potential to maximise the safety of anticoagulant therapy. As noted by Gallus,[24] the best opportunity for patients to assume the fullest responsibility for safe and effective warfarin therapy would be home-testing of the INR. Self-testing and adjustment of warfarin dosages by patients is an evolving strategy worldwide for the management of oral anticoagulation.[25-29] Self-management of oral anticoagulation therapy is a model of care that allows patients to monitor their INR with a portable device, and make limited adjustments to their dose of warfarin in a similar way to diabetic patients with insulin dosage. Patients measure most or all of their INRs, interpreting the results themselves, and translating these into dosage adjustments of warfarin (Table 9), as opposed to simply measuring their results and referring to a health care practitioner for guidance on all dosage changes (self-monitoring).
Table 9: Sample dosage adjustment scale for self-management for stable patients (assuming the target INR range is 1 – 3)

<table>
<thead>
<tr>
<th>INR result</th>
<th>Warfarin dose</th>
<th>Next test due</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1.1</td>
<td></td>
<td>Contact doctor</td>
</tr>
<tr>
<td>1.1-1.4</td>
<td>Increase by .....mg each day</td>
<td>1 week</td>
</tr>
<tr>
<td>1.5-1.9</td>
<td>Increase by .....mg every second day</td>
<td>1 week</td>
</tr>
<tr>
<td>2.0-3.0</td>
<td>Same dose each day</td>
<td>2 weeks</td>
</tr>
<tr>
<td>3.1-3.4</td>
<td>Decrease by .....mg every second day</td>
<td>1 week</td>
</tr>
<tr>
<td>3.5-3.9</td>
<td>Decrease by .....mg each day</td>
<td>1 week</td>
</tr>
</tbody>
</table>

Current warfarin dose

| 1-2 mg | 1/1 0.5 mg |
| 3-5 mg | 1/1 1 mg |
| 6-9 mg | 1/1 1.5 mg |
| 9 mg or over | 1/1 2 mg |


Rationale

Self-management and self-monitoring of anticoagulation are partly based on the premise that more frequent testing will lead to tighter anticoagulation control and thus improved clinical outcomes. Data indicate that the mortality of warfarinised patients is related to the INR; that is, an INR range of 2–3 is associated with the lowest rate of mortality. Increasing rates of mortality are equally associated with both under- and over-anticoagulation neither is acceptable for the patient on warfarin. It has also been shown that the time in the therapeutic range correlates strongly with clinical outcomes (bleeding and embolic) and that more frequent testing seems to increase the time in the therapeutic range. Studies have shown that the anticoagulation status of self-monitored patients is better than, or at least equivalent, to that of patients monitored by a general practitioner or specialist clinician.

“In comparison with routine care by general practitioners, self-management was found to be better.”

Interestingly, one study demonstrated that self-management of warfarin therapy improved thromboembolic and haemorrhagic outcomes, with only a slight increase in the percentage of INR tests in the therapeutic range compared to control patients (anticoagulation clinic) and no difference in the percentage of time in INR range between the groups. It was noteworthy that the improvement of clinical outcomes was achieved without an improvement in INR control; thus, the benefits of self-management extended beyond improved INR control to patient empowerment, improved adherence and an improved awareness of health status by the patient.
Studies have generally shown an inverse relationship between patient knowledge and adverse outcomes of warfarin therapy. Good outcomes have been recorded where patients have had increased participation in their care and were encouraged to communicate more effectively with doctors and other health professionals about drug interactions and changes in lifestyle or diet.\[25\]

Ultimately, self-monitoring by patients has the greatest potential to maximise the safety of anticoagulant therapy. It allows patients to assume significant responsibility for their own therapy, which can lead to improvements in patients' self-worth, closer adherence to treatment, and increased control of treatment with warfarin.\[36, 37\] It has been shown that self-monitoring patients are less anxious about their therapy.\[33\] Other advantages of self-management include patients having the ability to conduct testing at home, saving travel and time to visit a clinic/doctor, and that they are less dependent on the health care system to manage their therapy.

In summary, studies have shown self-management and self-monitoring to be feasible, accurate, associated with a greater time in the therapeutic range, and improved outcomes for patients. A recent systematic review and meta-analysis of published trials concluded that self-management improves the quality of oral anticoagulation (improved control of INR, reduced thromboembolic and bleeding complications and reduced mortality)\[38\]. Patients capable of self-monitoring and self-adjusting therapy have fewer thromboembolic events and lower mortality than those who self-monitor alone. It may not be a unanimously appealing option as self-management and self-monitoring require special training to implement\[39\] and there are still many variables, such as patient selection criteria and testing frequency, that need optimisation.\[40\]. However, self-management and self-monitoring of oral anticoagulation are now widely practiced in Germany and the Netherlands and are becoming more popular in the UK and USA\[26, 39, 41\].\[42, 43\] This trend will inevitably be followed in Australia.

**Selection of patients for self-monitoring of warfarin**

Recently, the International Self-Monitoring Association for Oral Anticoagulation released guidelines for the implementation of self-management and self-monitoring of oral anticoagulation.\[44\] Self-monitoring can be considered for patients who are on long-term warfarin (artificial valve prosthesis, recurrent VTE, chronic atrial fibrillation and post myocardial infarction with impaired left ventricular pump function).
Patient Self-Monitoring

A number of criteria have been identified common to many self-monitoring or self-management studies relating to patient selection and potential capability in the literature:

- They should have a long-term indication for warfarin (AF, artificial valves, long-term prevention of DVT) [43].
- They must be over 18, or be supervised by someone who is over 18 [46, 47].
- The patient must be willing to learn the testing procedure and perform self-testing [40].
- They need to have a basic understanding of their condition, their treatment, the potential for side effects, and the importance of regular treatment, or be capable of learning this [40, 45, 48, 49].
- They must have adequate reading and writing skills – they need to be capable of maintaining documentation [40, 50, 51].
- They should have no symptoms of dementia, that is they must have sufficient memory and mentation/cognitive ability to follow simple/home-monitoring instructions [40, 51-53].
- They must have sufficient visual acuity to operate the testing device [40, 48-52, 54-57].
- They must have sufficient manual dexterity/adequate motor skills to manage the testing device [40, 46, 48-52, 56-58].
- They should have no physical limitations, especially affecting the hands such as Parkinson's Disease, residual damage from a stroke, or disabling arthritis [47, 49, 53, 57].
- They must not be considered too anxious about their health to monitor their own therapy [52].
- They should have no history of liver disease [47].
- They should have no diagnosis of antiphospholipid syndrome [53].
- They should have no coagulopathies such as antithrombin III deficiency [47].
- They should exhibit no evidence of drug or alcohol abuse [47, 50].

The main determinant of a patient monitoring their own warfarin therapy is a willingness to do so; most patients who are able to lead an independent and self-supporting life are capable of self-monitoring, irrespective of education and social status. [33, 60] The only intellectual requirement is the ability to understand the concept of warfarin therapy and its particular risks and benefits. Necessary physical requirements include sufficient manual dexterity and acuity of vision; although carers of patients unable to operate an INR monitor can be trained to do so.

Once the patient has expressed willingness to self-monitor, they must be appropriately trained to do so. It is important to recognise that it is difficult to separate the benefits of utilising point of care INR monitors and structured educational programs for patients taking warfarin. All studies involving point of care INR monitoring have involved educational programs which not only train patients to use the monitor, but also provide detailed education regarding anticoagulation itself. In one recent study [35], patient self-management did not result in a significant increase in the time that patients spent in the therapeutic range compared to controls. However, there were significant reductions in bleeding and thromboembolic complications. The ability to learn to self-monitor is not dependent on age, although age and co-morbidity play an important role in the decision to participate. [61]
Willingness to participate

In a study of self-management of warfarin, approximately 25% of patients from primary care anticoagulation clinics in the UK who were invited to participate provided their consent to be involved. Of these patients, approximately 75% were able to complete training requirements. Of the patients that were excluded, the majority (79%) excluded themselves because they found it difficult to use the monitor. This may have reflected problems with the training provided to these patients or the use of the CoaguChek™ S monitor, which has now been superseded by the CoaguChek™ XS.

In a survey of Southern Tasmanian people taking warfarin, 243/289 (84%) people expressed a willingness to participate in a trial of warfarin self-monitoring. Of the people that enrolled in the Warfarin home-Monitoring Pilot Study, no patients failed to complete the training requirements.

Outside of trial conditions, cost is a major factor for people willing to self-monitor. Although a small proportion of people that take warfarin will be able to afford the required equipment, the majority are not able to bear the costs without some form of subsidy. For patients with private health insurance, funding bodies are currently offering 60–80% rebates on the cost of purchasing a home INR monitor, on a case-by-case basis. For example, a CoaguChek™ XS, retailing at approximately $1000 AUD will be reduced to $200 to $400 AUD.
Training of suitable patients

Provision of an education program is an integral part of self-monitoring. The main goal is to teach patients practical skills, which enable them to determine accurate INR results. Theoretical training is also essential to realise the full benefits of self-monitoring.

The key components of a self-monitoring training program include:

- Basic information on blood coagulation;
- Theoretical principles of drug interactions with oral anticoagulants;
- Dietary information;
- Disease-specific information related to the risks and benefits of anticoagulation;
- Practical information on self-monitoring with coagulometers;
- Signs of bleeding and thromboembolic events;
- Information on the frequency of INR monitoring; and
- Documentation of results and reporting of adverse events.

The accompanying training manual for consumers (see Appendix) was developed with a grant from the Safety and Quality Council and was based on packages used in the UK and Germany. As part of its development it was piloted with patients, pharmacists and doctors. It was also used in the Warfarin Home-Monitoring Pilot Study. In this trial it was used in both the group environment (three to five patients) and in the home setting (one on one). In the home setting, the theoretical component can be delivered in 45-75 minutes, depending on the patient. Practical training with the monitor then follows for approximately 30 minutes. At the end of the session, a test should be provided for the patient to complete to ensure that they have understood the basic theory behind anticoagulation (Figure 5). This can be completed on-the-spot or mailed to the community pharmacy if the patient prefers to revise the training manual before completing it.

It is useful to gauge the knowledge of the patient prior to the training session. A copy of a warfarin knowledge questionnaire used by the authors follows. The advantage of having the patient complete this prior to the session is that it allows the trainer to target specific areas of knowledge during the session. It can also be used following the session to document the improvement in knowledge due to the training session as a means of quality control.
Figure 5: Sample theoretical assessment

Warfarin Home-Monitoring
Theoretical Assessment

Name: ........................................

Please answer in the space provided below:

1. How does warfarin work?

2. How often should you test your INR?

3. What is your target INR, and what does this mean?

4. What are the signs of too much warfarin?

5. What are the signs of too little warfarin?

6. Why is quality control important if using a portable INR monitor?
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Warfarin Knowledge Questionnaire

© Zeolla MM, Brodeur MP, Dominelli A, Haines ST, Allie N

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

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

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

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

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

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

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

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

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

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

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

12. Skipping even one dose of warfarin can:
- Cause your INR to be above the ‘target range’
- Increase your risk of bleeding
- Cause your INR to be below the ‘target range’
- Decrease your risk of having a clot

13. Drinking alcohol while taking warfarin:
- Is safe as long as you separate your dose of warfarin and the alcohol consumption
- May affect your INR
- Does not affect your INR
- Is safe as long as you are on a low dose
Warfarin Knowledge Questionnaire

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

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

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

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

18. Each time you get your INR checked, you should:
   - Skip your dose of warfarin on the day of the test
   - Avoid eating high fat meals on the day of the test
   - Avoid foods high in vitamin K on the day of the test
   - Let your doctor know if you missed any doses of warfarin

19. Which of the following over-the-counter products is most likely to interact with warfarin?
   - Nicotine replacement therapies
   - Herbal/dietary supplements
   - Allergy medications
   - Calcium supplements

20. A patient with an INR value above the 'target range':
   - Is at an increased risk of having a clot
   - Is more likely to have drowsiness and fatigue from warfarin
   - Is at an increased risk of bleeding
   - Is less likely to experience side effects from warfarin
Scoring the questionnaire

Correct answers are as follows:

- One: B
- Two: A
- Three: D
- Four: B
- Five: D
- Six: B
- Seven: A
- Eight: A
- Nine: B
- Ten: B
- Eleven: B
- Twelve: C
- Thirteen: B
- Fourteen: B
- Fifteen: B
- Sixteen: B
- Seventeen: C
- Eighteen: D
- Nineteen: B
- Twenty: C
Quality assurance of practical training for self-monitoring

There is a possibility that some patients, either due to poor technique or for unknown reasons will not get accurate results using portable INR monitors. This has been recognised by the authors in a trial involving outpatients at the Royal Hobart Hospital. Therefore, to ensure that the patient (or carer) is using the monitor appropriately, it is essential that the pharmacist training the patient completes a non-in phase using the monitor. This involves, on two separate occasions, the patient completing a test on the home-monitor and having blood drawn for a pathology test within 4 hours of each other. Once the results of these comparison tests are compared, the home-test should be within 15% of the pathology test. The reasons for this discrepancy are outlined in the Quality Assurance chapter of this manual. Comparison tests within 15% are considered the same for monitoring purposes.

Once two comparison tests are completed and within 15% the patient may continue to monitor at home and report the results to the general practitioner either by telephone or e-mail. If comparison tests are not well correlated, further training may be warranted. If the patient or carer continues to fail to get accurate results with the home-monitor, they should not continue self-monitoring. In the Home-Monitoring Pilot Study this did not occur; however the study only involved a small number of patients. A copy of a manuscript of the accuracy of the CoaguChek® XS in the Pilot Study is present in the supporting information of this manual.

Given that the CoaguChek® XS performs IQC every time a test is conducted, comparison pathology testing should be completed every three-months as a means of EQC. General practitioners may wish to do this more frequently and this is at their discretion.

Frequency of testing

In studies of self-monitoring, patients often test their INR once weekly. One of the advantages of self-monitoring is that it enables more frequent testing compared to conventional management. While a patient is self-monitoring, the frequency of testing is at the discretion of the general practitioner. It is certainly not recommended to test more frequently than once weekly; either once weekly or once fortnightly is considered optimal for patients that are self-monitoring when their INR is relatively stable. If changes are made to the patient’s medication regimen or significant changes are made in dietary consumption of vitamin K, an INR should be completed 3-7 days following the change and then weekly until stabilised.

Documentation

Each step in the self-monitoring training process should be documented and signed off by the relevant health care professional, or by the patient where appropriate. This is particularly important as the ongoing responsibility for the patient remains with the GP and the accredited pharmacist is not in the position to follow-up the patient unless further medication reviews are required. Once completed, the general practitioner should retain the documentation of the training as a part of their patient records.

The patient should continue to document their INR as normal and make note of any adverse events.
References


References


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Accredited Pharmacist Training to Enable Patient Self-Monitoring of Warfarin

Ella Claire van Tienen
Optimising warfarin management: An exploration of pharmacist-delivered models of care

References

References


Using the CoaguChek™ XS

A detailed description of the CoaguChek™ XS (Figure 6) and how to use it is available on the training DVD supplied to you as a part of the training package. Please refer to this for more detail on how to perform a test.

Figure 6: The CoaguChek™ XS INR Monitor
Using the CoaguChek XS

Tips on how to obtain a good capillary sample:

- Warm hands by running under warm running water to ensure good blood flow to the fingers.
- Avoid calloused areas. Try pricking the side of the finger pad.
- Do not use the same finger twice, try a different finger if the first does not produce a good sample (the clotting process will be occurring in the first finger and may cause an altered reading if used again straight away).
- Do not prick the finger until you are ready to apply the drop of blood immediately to the strip (within 15 seconds).
- Hold the elbow up to promote blood flow to the finger tips.
- Touch the drop of blood to the test strip, not the finger to the test strip.
- “Milk” the finger – avoid squeezing (this can damage small blood vessels and start the clotting process).

Health and safety:

- Wash hands thoroughly with soap and warm water before and after performing the INR test.
- Equipment should be stored in its case and out of reach of children.
- Place all needle ends, used test strips and used quality control vials in a sharps (yellow) container.
Basic Business Model of Pharmacist Conducted Training of Patients to Self-Monitor

Patient suitability:
- Willingness to participate in self-monitoring
- Understand the concept of oral anticoagulation
- Sufficient manual dexterity and acuity of vision (or suitable family member/carer)
- No previous experience necessary

Patient selection:
- Self-identification
- General practitioners
- Pharmacists
- Other health professionals
- Family members

Referral Process:
- Patients can be identified by community pharmacists
- Patients should be referred to their GP to discuss self-monitoring
- Patients could be provided with information about self-testing to discuss with GPs
  - www.coagucheck.com
  - www.anticoagulation.com
- Community pharmacies will organise patient training by accredited pharmacist

HMR Referral:
- GP agrees that patient may be appropriate for self-monitoring
- Discuss self-testing with the patient
- Referral to community pharmacy (for training for self-testing)
  - Currently patients need to purchase INR monitor
  - Pharmacy or medical supplier
  - Contact may be made with a community pharmacy and discussion about the use of an anticoagulant-trained pharmacist

Training and the HMR:
- All patients undergoing self-monitoring should complete a structured training course and must be willing to accept responsibility for testing
- Regular and ongoing consultation with the prescriber is necessary
- Education should comprise theoretical component, practical training, theoretical test, regular (annual) follow-up
- Training should be the primary focus of this particular review
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Business Model

Reporting:
- Knowledge assessment
- Observations on the ability to self-monitor
- If concerned regarding the ability to self-monitor appropriately, patients should receive an unsatisfactory assessment and may require a further training session.
- Training should take between 1 and 2 hours
- Reporting and follow-up 1 hour
- Overall 2 to 3 hours

How to make contact with suitable trainers:
- Roche
- AACP
- Promotion of services to community pharmacists
- Register of anticoagulant trained pharmacists on website www.anticoagulation.com.au (in development)

Monitor distribution:
- Community pharmacies (wholesalers will stock monitors)
- Community pharmacies can be affiliated with an anticoagulant trained accredited pharmacist

Promotion:
- AACP
- Roche
- UMORE
- www.anticoagulation.com.au
- Medical practitioners

Numbers:
- 200,000 Australians taking warfarin
- 20-25% eligible for self-monitoring
- 40 – 50,000 patients interested and able to self-monitor
- Need a system for training and ongoing assessment
- Annual HMRs

Roche:
- Maintain a database of anticoagulant trained accredited pharmacists
- Place patients in contact with a pharmacy who is affiliated with a suitable accredited pharmacist
- Also provide information for GPs

A flowchart for the assessment and training of patients for self-monitoring follows on the next page (Figure 7).
Figure 7: Clinical pathway to improve the quality use of warfarin therapy using pharmacists

Identification
Community Pharmacist, Consumer
Referral to GP

Suitable for Training
GP

PSM Education HMR
Accredited Pharmacist

Yes, Referral via Community Pharmacy

PSM
Accredited Pharmacist

Support
Community Pharmacy, ongoing care

Warfarin Education
Community Pharmacist

Annual HMR
Accredited Pharmacist

GP

Suitability for patient self-monitoring
- Patients may be deemed unsuitable for patient self-monitoring for the following reasons
  - Results comparing the CoaguChek™ and pathology monitoring are >15% discrepant
  - Assessment of the ability to be able to use the monitor is deemed “not yet competent”
  - Knowledge assessment is not to the level deemed satisfactory to use the monitor

---

Warfarin Education Program:
Accredited Pharmacist Training to Enable Patient Self-Monitoring of Warfarin
Audit Parameters for Patients Undertaking Home-Monitoring

Once the INR has been appropriately determined it is important to confirm that the appropriate dose of anticoagulant is being given. It is important to verify that a safe and therapeutic INR is being achieved. One endpoint that can be used is the incidence of adverse events. However there are drawbacks associated with using this as an audit parameter, as there is some risk associated with simply using warfarin at all (although this risk is increased by poor control).

The level of therapeutic control can be expressed in terms of the proportion of all INRs within the therapeutic range. For individual patients, methods of expressing this include:

- The proportion of tests performed which are within the therapeutic range; and
- The proportion of time spent by individuals in the therapeutic range.

Proportion of tests within range

This method considers a number of INR measurements within the target range expressed as a percentage of the total number of values obtained.

Proportion of time spent in range

The linear change method is generally accepted as the best way to estimate time spent in the therapeutic range. It recognises that a patient who is below the therapeutic range at the first test but above at the second test must have spent some time within the therapeutic range. Spreadsheets are available to easily calculate time spent within the target range. Typically, warfarinised patients managed in the community are within the target range only 50-60% of the time. Self-monitoring has the potential to improve this figure and subsequently improve clinical outcomes.
Resources

For Professionals
www.anticoagulation.com.au
www.anticoagulation.org.uk
www.anticoagulationeurope.com
www.cloccare.com
www.coaguchek.com

For Patients
www.anticoagulation.com.au
www.ismap.org
www.medhelp.org/HealthTopics/Anticoagulation.html

Further Reading for Pharmacists
ABC of antithrombotics series in the British Medical Journal (www.bmj.com)
Seventh American College of Chest Physicians (ACCP) Conference on Antithrombotic Therapy (www.chestjournal.org)
Appendices

Appendices

Warfarin Education Program: Self-Monitoring Education Manual for Consumers
The contents of the Warfarin Education Program: Self-Monitoring Education Manual for Consumers is shown in Appendix 16: Train the Patient Manual


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Abstract

This document provides health care professionals involved in initiating and monitoring oral anticoagulation therapy with guidelines for the provision of safe and effective patient self-testing/patient self-management of oral anticoagulation.

Methods and results: The consensus group has critically reviewed the literature and compared the results of usual care (UC) vs. anticoagulation clinic and patient self-management/patient self-testing (PSMT/PSST). The education and training of patients for warfarin monitoring are described, together with the satisfaction of patients, the efficacy of quality of life and cost-effectiveness. The consensus across that patient self-testing and patient self-management are effective methods of motivating and anticoagulation therapy, resulting in outcomes at least as good as, and possibly better than, those achieved with an anticoagulation clinic. All patients must be appropriately selected and treated. Currently available self-testing self-management devices give INR results which are comparable with those obtained in laboratory testing. The most frequent testing frequency is weekly but lower frequency of testing may be justified based on institutional or patient conditions.

Conclusions: The consensus group agree that there are several points in favour of PSMT/PSST, for example, a higher degree of medical safety, increased patient education, improved resistance to changes in lifestyle, increased independence for the patient and improved outcomes. © 2004 Elsevier Ireland Ltd. All rights reserved.

Keywords: Patient self-management; Oral anticoagulant therapy; International Normalized Ratio; Complement; International consensus guidelines

1. Introduction

Oral anticoagulation with coumarin derivatives is performed to a steadily increasing number of patients as lifelong therapy for indications such as mechanical heart valves, atrial fibrillation or inherited or acquired thrombophilic disorders. In addition, oral anticoagulation therapy has been shown to effectively prevent arterial embolism in a wide variety of clinical conditions [1–3].

The ability to maintain patients within a desired therapeutic range required for oral anticoagulation therapy is a challenge due to two main factors. These are the narrow pharmacologically therapeutic range of the coumarin derivatives, and the variability of their biological effect [4]. This variable dose response results in difficulties in initial dose selection and stabilisation, as well as long-term difficulties in maintaining stability.

It has been shown that improved anticoagulant control results in improved outcomes, with a decrease in the incidence of bleeding complications and thromboembolic events [5]. It is, therefore, essential to maintain close control of the intensity of anticoagulation in order to minimise the
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen

Additional Resources

Table 1

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<th>Study</th>
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<th>Number of patient years</th>
<th>Years of data collection</th>
<th>New or established anticoagulation</th>
<th>Indicators</th>
<th>Major bleed risk</th>
<th>Fatal bleed risk</th>
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NA = not available. Rate = percentage of patients experiencing major bleed. V = vitamin K antagonist. E = event. E. coli = Escherichia coli.

Table 2

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<td>2.0</td>
<td>0.45</td>
<td>81%</td>
</tr>
<tr>
<td>Sneddon [18]</td>
<td>60</td>
<td>0.15</td>
<td>1978-1986</td>
<td>N.E.</td>
<td>V &amp; &amp;</td>
<td>1.2</td>
<td>0.8</td>
<td>75%</td>
</tr>
<tr>
<td>Fosse [19]</td>
<td>925</td>
<td>1.90</td>
<td>1980-1986</td>
<td>N.E.</td>
<td>V &amp; &amp;</td>
<td>1.2</td>
<td>0.8</td>
<td>75%</td>
</tr>
<tr>
<td>Win et al [20]</td>
<td>1851</td>
<td>6.68</td>
<td>1988</td>
<td>N.E.</td>
<td>V &amp; &amp;</td>
<td>2.4</td>
<td>0.44</td>
<td>81%</td>
</tr>
<tr>
<td>Emmerson [21]</td>
<td>1645</td>
<td>6.68</td>
<td>1988</td>
<td>N.E.</td>
<td>V &amp; &amp;</td>
<td>2.3</td>
<td>0.44</td>
<td>81%</td>
</tr>
<tr>
<td>Various patients [22]</td>
<td>4758</td>
<td>10.40</td>
<td>1980-1986</td>
<td>N.E.</td>
<td>V &amp; &amp;</td>
<td>2.0</td>
<td>0.45</td>
<td>81%</td>
</tr>
</tbody>
</table>

NA = not available. Rate = percentage of patients experiencing major bleed. V = vitamin K antagonist. E = event. E. coli = Escherichia coli.

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Table 1: Frequency of acute haemorrhagic events in patients on warfarin management as reported in observational management studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Model of care</th>
<th>Number of patients</th>
<th>Number of patient years</th>
<th>Years of data</th>
<th>Indications</th>
<th>Target</th>
<th>MI</th>
<th>MACE</th>
<th>Major</th>
<th>Fatal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cacolice et al. [5]</td>
<td>UC</td>
<td>26</td>
<td>6,3</td>
<td>1970-1980</td>
<td>Yes &amp; anticoagulation</td>
<td>1.3-2.1</td>
<td>1.2-0.8</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Cacolice et al. [6]</td>
<td>AMS</td>
<td>26</td>
<td>6,3</td>
<td>1970-1980</td>
<td>Yes &amp; anticoagulation</td>
<td>1.3-2.1</td>
<td>1.2-0.8</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Cacolice et al. [7]</td>
<td>UC</td>
<td>278</td>
<td>6,3</td>
<td>1970-1980</td>
<td>Yes &amp; anticoagulation</td>
<td>1.3-2.1</td>
<td>1.2-0.8</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Wilcox et al. [8]</td>
<td>UC</td>
<td>44</td>
<td>6,3</td>
<td>1970-1980</td>
<td>Yes &amp; anticoagulation</td>
<td>1.3-2.1</td>
<td>1.2-0.8</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>O'Brien et al. [9]</td>
<td>UC</td>
<td>82</td>
<td>6,3</td>
<td>1970-1980</td>
<td>Yes &amp; anticoagulation</td>
<td>1.3-2.1</td>
<td>1.2-0.8</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td></td>
</tr>
</tbody>
</table>

UC—unclear, AMS—anticoagulation management service, TE—thromboembolism, PPR—prospective trial registry, INR—International Normalised Ratio. 3 Major and fatal haemorrhagic, thromboembolic, and cost savings rates expressed as percent per year per year of therapy, final haemorrhagic events included with more harm outcomes. The use of anticoagulation.

A co-ordinated and focused approach to the management of therapy by pharmacist programme (anticoagulation clinic care, ACC) significantly improves clinical outcomes by improving therapeutic control and time-in-therapeutic range (TTR), increasing the frequency of haemorrhage or thromboembolism and shortening the time of hospital stay.

Table 2: Capillary whole blood (point-of-care) PT instruments

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Coagulation methodology</th>
<th>Sample type</th>
<th>Home use approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prothrombin 1000</td>
<td>Clot initiation: Thrombin</td>
<td>Capillary WB</td>
<td>No</td>
</tr>
<tr>
<td>Citochrom 112 Coagulation</td>
<td>Clot initiation: Thrombin</td>
<td>Capillary WB</td>
<td>Yes</td>
</tr>
<tr>
<td>ThromboDex Coagulation</td>
<td>Clot initiation: Thrombin</td>
<td>Venous WB</td>
<td>Yes</td>
</tr>
<tr>
<td>Organon</td>
<td>Clot initiation: Thrombin</td>
<td>Venous WB</td>
<td>Yes</td>
</tr>
<tr>
<td>ThromboDex</td>
<td>Clot initiation: Thrombin</td>
<td>Venous WB</td>
<td>Yes</td>
</tr>
</tbody>
</table>

All instruments in this category are based on the original Prothrombin 1000 and similar and different devices. The latest version available in the US is Prothrombin 1000 and the device analysed in the current study is the Organon．

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Table 4: Summary of studies measuring time in therapeutic range or adverse events using patient self-testing or patient self-management stratified according to whether computer group was used (EUC) or not (UC).

<table>
<thead>
<tr>
<th>Study</th>
<th>Study group</th>
<th>Number of patients</th>
<th>Time in range (%)</th>
<th>Major bleed (%)</th>
<th>TI (%)</th>
<th>Infections (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study 1</td>
<td>EUC</td>
<td>50</td>
<td>80</td>
<td>0.5</td>
<td>0.1</td>
<td>0.3</td>
</tr>
<tr>
<td>Study 2</td>
<td>UC</td>
<td>40</td>
<td>70</td>
<td>1.2</td>
<td>0.3</td>
<td>0.2</td>
</tr>
<tr>
<td>Study 3</td>
<td>EUC</td>
<td>60</td>
<td>90</td>
<td>0.8</td>
<td>0.5</td>
<td>0.4</td>
</tr>
<tr>
<td>Study 4</td>
<td>UC</td>
<td>50</td>
<td>70</td>
<td>1.5</td>
<td>0.4</td>
<td>0.3</td>
</tr>
</tbody>
</table>

RCT = randomised controlled trial; EUC = enhanced usual care; UC = usual care; TI = time in range; EUC = enhanced usual care; UC = usual care; TI = time in range.
None of these PST/PSM studies were adequately designed to clearly answer the important question of what might account for better therapeutic control. The major variables not adequately controlled included the level of patient education, the subtle impact on compliance, the frequency of monitoring and the consistency of regent and instrumentation. Further studies are needed to outline the importance of these parameters.

A strong relationship between TTR and bleeding rates has been observed across a large number of studies with different patient populations, different target ranges, different scores for measuring intensity of anticoagulation (i.e. PT, PT ratio and INR) and different models of dosage management. A similar relationship holds for TTR and rates of thromboembolism. Many studies indicate that an increased frequency of testing leads to more results within the therapeutic range (31,39). The frequency of testing is dependent on many factors including patient stability, compliance, fluctuations in co-morbid conditions, the addition or discontinuation of other medications, changes in diet, the quality of dose-adjustment decisions and the stage of treatment (46). The increased frequency of monitoring of the INR may be a factor for improved outcomes with PST/PSM.

Recently, a German study (48,51) with over 2800 patients followed for a total of 8061 follow-up years after mechanical heart valve replacement suggested that significant fluctuations in consecutive INR measurements were the strongest predictors for both thromboembolic and bleeding events rather than over or under anticoagulation. Other factors may however also be important in this regard. For example, patient education regarding anticoagulation therapy and patient empowerment are important elements in improving quality of treatment and patient awareness and could also be a major factor for improving patient compliance. Based on the above factors, NOC PT scores offer the potential to lower the risk/benefit profile of anticoagulant therapy, improve patient satisfaction and possibly improve patient compliance. By reducing the labour intensity of physician management, PST/PSM can also encourage more widespread use of oral anticoagulants.

4. Quality of life

As well as improving TTR and reducing the number of potential complications associated with oral anticoagulant therapy, improvement in quality of life is an important benefit which has been observed with PSM (48,49,52).

5. Cost-effectiveness

It has been shown that PSM can be cost-effective in the long-term. While the initial costs of PSM are higher than those for laboratory monitoring of INR due to the cost of training and personnel, unless the anticoagulation team is reduced, several studies (53–55) suggest that PSM is the most cost-effective method of monitoring patients on oral anticoagulation therapy. In a usual primary care setting (55), the reduction in costs associated with the 30% reduction in severe complications and the 20% reduction in minor events due to treatment observed with PSM was $22,000 per life year gained. However, it must be noted that cost savings may differ between various countries and different institutions, depending on the costs of the actual system of anticoagulant control.

6. Suitable patients

Patient self-testing/self-management should be considered in patients who are on long-term oral anticoagulation with artificial heart valve prostheses, chronic atrial fibrillation, thorobembolism (e.g., after recent deep vein thrombosis in the leg and pulmonary embolism) and post-myocardial infarction with impaired left ventricular pump function, including advanced congestive concomitanty.

Various studies have found that, as with self-testing and self-management of insulin-dependent diabetics, most patients who are able to lead an independent and self-supporting life are, in principle, capable of self-testing/self-management of oral anticoagulants, irrespective of education and social status (45,57). The only requirement in terms of intellectual ability is that the patient (or care giver) is able to understand the concept of oral anticoagulant therapy and its potential risks. Other factors may however also be important in this regard. For example, patient education regarding anticoagulant therapy and patient empowerment are important elements in improving quality of treatment and patient awareness and could also be a major factor for improving patient compliance. Based on the above factors, NOC PT scores offer the potential to lower the risk/benefit profile of anticoagulant therapy, improve patient satisfaction and possibly improve patient compliance. By reducing the labour intensity of physician management, PST/PSM can also encourage more widespread use of oral anticoagulants.

7. Suitable coagulometers

The coagulometers currently available differ in their physical methods of measurement and in their degree of automation (Table 4). Easy, portable, fully automated coagulometers have now become available which allow the reliable determination of the PT expressed as INR, from one drop of capillary whole blood from a fingerstick (28).
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8. Education and training

Education on the theoretical and pharmacological aspects of anticoagulation is a fundamental requirement for all patients on anticoagulant therapy, training on point-of-care INR testing is essential for those patients in IST/PFSM.

Education and training interventions will develop differently in each country, depending on local circumstances. However, it will require the development of resources to train the trainers, as well as the patients.

9. Training the trainers

In order that patient training can be successfully achieved, health care professionals who train patients must themselves be trained in the management of anticoagulant therapy and have practical knowledge of IST/PFSM devices. There is a considerable amount of material already available for training. This material should be used as a module within a teaching session that is separate from the structured training programme. The training of trainers should be performed in a structured manner, using a review of the anticoagulant devices, followed by a practical session, and then a written examination. The training should be conducted by experts, who have completed the IST/PFSM training course, and who are approved by the local authorities.

10. Training the patients

Providing an appropriate education programme is an important part of IST/PFSM. For self-training, the main goal of training is to teach patients practical skills that enable them to achieve accurate INR results. This may include practical advice on the monitoring device and finger-pricking technique.

For self-measurement, the main goal is to help patients be able to keep their INR in the target range when necessary. This may include practical advice on the monitoring device and finger-pricking technique. It is important to ensure that patients are trained in the use of the device and understand the implications of their INR results.

The contents of the AHA-PMG training course include:

- basic information on blood coagulation;
- theoretical principles of individual anticoagulation interactions with oral anticoagulants;
- practical information on monitoring with coagulometers;
- evaluation of measurements and, if necessary, dose adjustment;
- signs of bleeding events (overdose) and thromboembolic events (underdose);
- information on the frequency of INR determination;
- keeping a patient diary/myocardial control record keeping;
- travel, radiation, unstable prophylaxis, intermittent injections, etc.

11. Monitoring of IST/PFSM

Despite the flexibility of patients to self-test and manage, adequate clinical support remains essential. On-going education, advice in cases of uncontrolled bleeding, or the need to incorporate an invasive procedure are, amongst others, all issues which must be considered.
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References of guidelines which have already been published from various National Societies

J. Ameli et al., International Journal of Cardiology, 10 (2003) 35-43


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Self-monitoring of oral anticoagulation: a systematic review and meta-analysis

Summary
Background Non-patient testing has made self-monitoring of anticoagulation with warfarin feasible, and several trials have suggested that such monitoring might be equal to or better than standard monitoring. We did a systematic review and meta-analysis of all randomised controlled trials that assessed the effects of self-monitoring or self-management (self-testing and self-dosage) of anticoagulation compared with standard monitoring.

Methods We searched the Cochrane Register of Controlled Trials, MEDLINE, EMBASE in April 2009, and contacted manufacturers and authors of relevant studies. Outcomes assessed were major haemorrhage, thromboembolic events, death, costs in range, minor haemorrhage, frequency of testing, and feasibility of self-monitoring.

Findings We identified 14 randomised trials of self-monitoring; pooled estimates showed significant reductions in thromboembolic events (RR 0.45, 95% CI 0.30-0.68), all-cause mortality (0.61, 0.38-0.90), and major haemorrhage (0.63, 0.42-0.93). Trials of combined self-monitoring and self-adjusted therapy showed significant reductions in thromboembolic events (0.47, 0.20-0.70) and death (0.37, 0.16-0.87), but not major haemorrhage (0.99, 0.42-2.04). No difference was noted in minor haemorrhage. 11 trials reported improvements in the mean proportion of international normalisation ratios in range.

Interpretation Self-management improves the outcomes of oral anticoagulation. Patients capable of self-monitoring and self-adjusting therapy have fewer thromboembolic events and have mortality and major haemorrhage rates that are less than those who self-monitor alone. However, self-monitoring is not feasible for all patients, and requires identification and selection of suitable candidates.

Introduction
Oral anticoagulants with vitamin K antagonists clearly reduce thromboembolic events. In particular, well controlled anticoagulation with warfarin could potentially prevent more than half of the strokes related to atrial fibrillation and to brachiocephalic replacements, with a low risk of major bleeding complications. However, much of this potential benefit is not realised because anticoagulation is either not done or done well.

The therapeutic range for anticoagulation is narrow; an international normalised ratio (INR) of less than 2 increases the risk of thromboembolism, and an INR of more than 4.5 increases the risk of major bleeding.

To maximise patient safety and maximise target range requires frequent testing and appropriate adjustment. When monitored monthly, around 20% of patients remain within target range, compared with 50% when monitored weekly. Numerous functions in the use of warfarin rules, including the complex pharmacokinetics of warfarin, the need for continuous monitoring and dose adjustments, meeting events, non-compliance, drug interactions, and increased costs of monitoring and therapy.

One way to improve anticoagulation management is the use of home monitoring devices that allow the patient to measure INR with a dropper of white blood. Such handheld devices have proved sufficiently reliable. When self-monitoring, the patient can either self-test and self-adjust treatment according to a predetermined dose schedule, or self-test and call a clinic to receive the appropriate dose adjustments. Potential advantages of self-monitoring include improved convenience for patients, better treatment compliance, more frequent monitoring, and fewer thromboembolic and haemorrhagic complications.

Self-monitoring of anticoagulation seems a more attractive option in existing mode of care, although published guidelines state that there are no reliable clinical outcome data to support its use.

We aimed to assess the current evidence for the effectiveness of self-monitoring and self-adjustment by patients on treatment with oral anticoagulants.

Methods
Eligibility and search strategy
We included all published and unpublished controlled trials that randomly assigned patients compared the effects of self-monitoring (self-testing and self-management) of anticoagulation with control and dosage by personal physician, anticoagulation management clinics, or home services or reported the clinical outcomes of thromboembolic events and major bleeding episodes.

We included studies of patients on anticoagulant therapy irrespective of the indication for treatment (i.e., valve replacement, venous thromboembolism, or atrial fibrillation). There were no language restrictions.

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We searched Medline, Embase, CINAHL, PsycINFO, and AMED databases using a range of relevant keywords. We excluded studies that did not involve patient education or self-management strategies. We included studies that involved patient education or self-management strategies. We excluded studies that did not involve patient education or self-management strategies. We included studies that involved patient education or self-management strategies. We excluded studies that did not involve patient education or self-management strategies. We included studies that involved patient education or self-management strategies.

Data analysis
We used RevMan software to perform a meta-analysis. We used the Mantel-Haenszel method to calculate the pooled odds ratio. We used fixed effects models to estimate the effect size. We used random effects models to account for heterogeneity between studies. We performed sensitivity analyses to assess the robustness of our findings.

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In which patients had mechanical valves there was a non-significant effect on thromboembolic events (p=0.30, OR 0.71, 95% CI 0.44-1.15). The meta-analysis subgroup analysis suggested a greater reduction in strokes when compared with studies in the low-dose range (OR 0.27, 95% CI 0.08-0.88) than when compared with studies in the high-dose range (OR 0.56, 95% CI 0.35-0.88, p=0.02).

I from reported major hemorrhage outcomes were provided in one of the six trials. The effect of self-monitoring was not associated with a significant one-third reduction in major hemorrhage in the subgroup analysis. Excluding the four studies with a low quality of evidence increased the sensitivity of the effect (OR 0.44, 95% CI 0.15, p=0.03).
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Fig. 3: Self-monitoring of warfarin dosage from fixed-dose model

Table 3: Test frequency

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Monitoring group compared with the control groups showed a significant reduction in
the mean age of 75 years. Of these, 12 were either excluded or withdrawn from the study,
with a range of 1.6 to 1.9. The exclusion rate was higher in trials that included older
participants (mean age 75 years). Of the patients assigned to the intervention, 28%
(range 9-49%) were able to complete self-monitoring. The main reasons for the
dropouts were problems with the monitoring device, physical limitations in performing
self-monitoring, patients attending training, or failing to maintain treatment.

Discussion
Although no trial above was significant, the combined trials suggested that self-monitoring
in real-world conditions leads to a significant one-third reduction in
the mean age of 75 years. Of these, 12 were either excluded or withdrawn from the study,
with a range of 1.6 to 1.9. The exclusion rate was higher in trials that included older
participants (mean age 75 years). Of the patients assigned to the intervention, 28%
(range 9-49%) were able to complete self-monitoring. The main reasons for the
dropouts were problems with the monitoring device, physical limitations in performing
self-monitoring, patients attending training, or failing to maintain treatment.

This systematic review adds to three previous reviews of self-monitoring and self-anticoagulation.
One previous review, which included eight trials, identified a significant reduction in major clinical events (HR 0.64, 95% CI 0.43-0.90; p=0.01), and another review of four randomised trials concluded that self-management
by patients in self and was associated with a significantly lower risk of anticoagulation control. A review identifying 12 trials
between randomised controlled trials and five quasi-experimental trials concluded that patients undertaking
self-management remained in the therapeutic range for the same time as or longer than patients under usual care,
and that the evidence of adverse events was the same or less than patients under usual care.

Our review has some potential limitations. First, although our search was comprehensive, the potential
for missing both published and unpublished studies cannot be excluded. Second, variation in the quality of care in the
central groups can affect the rate of testing and hence the interpretation of findings, which may limit the
assessing the quality of anticoagulation control. A review identifying 12 trials
between randomised controlled trials and five quasi-experimental trials concluded that patients undertaking
self-management remained in the therapeutic range for the same time as or longer than patients under usual care,
and that the evidence of adverse events was the same or less than patients under usual care.

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Appendix 16: Train the Patient Manual
Preface

In recent years, the use of warfarin has increased, particularly in the elderly population. With an aging population, many more Australians will be started on warfarin therapy in the future. Unfortunately, due to a number of factors warfarin tends to be under-prescribed for some conditions for which it is useful, particularly for atrial fibrillation - a commonly occurring heart rhythm disturbance that affects 1% of the general population and 10% of people over the age of 80.

One of the limitations of warfarin therapy is that frequent pathology testing of the International Normalised Ratio (INR) is required. Therefore, one of the ways to improve the use of warfarin is to make INR testing more accessible to people taking warfarin. To this end, point of care INR monitors were developed in the mid-1980’s, but were difficult to use, especially for elderly people. More recently, these monitors were made more user friendly and only require a single drop of blood from the user. Extensive research has gone into demonstrating the accuracy of these monitors compared to the pathology method. For a number of monitors, including the CoaguChek™ XS developed by Roche Diagnostics, the accuracy data is particularly strong. The CoaguChek™ XS is used routinely in the United Kingdom and Germany. The CoaguChek™ XS has been evaluated in Australia by the authors in collaboration with the Royal Hobart Hospital and other organisations, in a number of settings. These have included an outpatient hospital anticoagulation clinic, in general practices and community pharmacies.

Self-monitoring of warfarin therapy has developed as a very promising model of care whereby people on warfarin monitor their INR at home and communicate the result to their general practitioner for dosage adjustment. It is important to note that self-monitoring is not a suitable option for all people taking warfarin. About one-quarter of people on warfarin want to self-monitor, with about three-quarters of these people able to complete the necessary training to enable self-monitoring. In clinical studies, self-monitoring has resulted in improved control of INR, reduced clotting and bleeding complications and improved quality of life compared to usual management.

This training manual has been developed with the intention of providing suitable persons who are taking warfarin with the knowledge and resources to monitor their own warfarin therapy. The booklet is intended to be used as a part of a training package that includes practical demonstration of the CoaguChek™ XS monitor in a one-on-one education session with a trained pharmacist. The booklet can also be considered as a reference for people monitoring their own warfarin therapy.

The authors would like to acknowledge the support of the National Safety and Quality Council for providing the necessary funding for the development of the package. We also acknowledge the initial support of Professor David Fitzmaurice and Dr. Ellen Murray from the University of Birmingham, England, the Royal Hobart Hospital and the National Institute of Clinical Studies (NICS).
Learning Objectives

The learning outcomes of this training package are that the consumer will:

- Have a basic understanding of blood coagulation and management of warfarin;
- Have a basic understanding of the International Normalised Ratio (INR) test;
- Understand their condition requiring warfarin and the target range for the INR;
- Understand the effects of over and under anticoagulation;
- Understand the effects of diet, lifestyle and drug interactions on the INR;
- Have an understanding of the point-of-care (POC) INR system and finger pricking device;
- Have an understanding of the internal quality control procedures for the POC INR monitoring system;
- Have an understanding of external quality control procedures for the POC INR monitoring system; and
- Understand the importance of documentation of INR results and other complications.

At the conclusion of training, the consumer will be assessed for the following:

- Practical ability to use point-of-care INR monitors; and
- Ability to document all results from the INR monitors and adverse effects.

Each person will be individually assessed to satisfy the trainer that they are able to undertake warfarin self-monitoring.
Section 1

Objectives:
- To develop a basic understanding of treatment with anticoagulants;
- To understand why anticoagulant treatment is important;
- To develop an understanding of the INR and why it can vary; and
- To understand how to conduct an INR test with a POC INR monitor, including
  - How to prick the finger; and
  - How to apply blood to the machine.

What is covered in the first section:
- Blood clotting;
- Need for treatment;
- How warfarin works;
- Things that vary response to warfarin;
- The target INR; and
- Practical demonstration of the CoaguChek® XS INR monitor.
Blood Coagulation

Blood is a fluid that is pumped around the body by the heart. The body depends on blood circulating all the time to provide organs such as the brain and heart with oxygen and other nutrients. Blood coagulation plays a crucial role to ensure that thrombosis (clotting) and haemostasis (bleeding) is in balance. If damage occurs to blood vessels, these blood vessels constrict and release substances that attract platelets. Platelets are cells which when activated accumulate around the edges of a wound and attract other platelets, forming a platelet plug.

![Components of a Blood Clot](image)

- This is not a permanent plug, slight changes in pressure in the blood vessels or abrupt movements of the body can be enough to dislodge this plug and allow bleeding to start again. Therefore a mechanism is required which stabilises the plug of platelets and attaches it firmly to the edges of the wound.
- Only coagulation permits secure closure of the wound. Normally coagulation takes place quickly so that as little as possible of the valuable blood is lost either externally, (for example, after a cut), or internally if the blood enters the tissues (for example, internal bleeding occurs).
- The body has a dozen or so clotting factors which are proteins and are produced in the liver. The clotting factors are sequentially activated by damage to blood vessels and result in the formation of a blood clot. Some of these clotting factors require vitamin K in order to be properly made.
- It is vital that bleeding and clotting are fully functional and in balance. Even slight changes in clotting factors can lead to excessive blood coagulation and to the formation of a blood clot.
- Thrombosis is a blood clot in a blood vessel, which often blocks the entire vessel. Thromboses are also more likely to form when blood flow is slower, e.g. through prolonged bed rest or sitting for many hours in an airplane.
Blood coagulation

With some diseases or medical conditions blood clots are produced more easily and frequently than normal. This can be because of blood pooling or changes in blood vessels. These conditions include:

- Deep vein thrombosis (DVT) or pulmonary embolus (PE);
- Atrial fibrillation (AF); and
- Artificial heart valves.

**Key Message:** The body normally balances bleeding and clotting activity. Damage to blood vessels results in the activation of clotting factors and formation of a blood clot. Some diseases can also result in increased clotting activity.
How Does Warfarin Work?

- Warfarin is the most commonly used anticoagulant; a drug to prevent and treat unwanted and dangerous blood clots. Unwanted blood clots may cause strokes, heart attacks, and other very serious (and possibly deadly) events such as blood clots in the legs or lungs. If it is used correctly, warfarin can be one of the most valuable drugs we have. If warfarin therapy is not managed very carefully, it can be harmful because of the potential to cause bleeding.
- In order for your blood to form a clot, you need certain proteins (clotting factors) in your blood. Normally, your liver makes these proteins and it requires vitamin K to do so. You get vitamin K from many of the foods you eat (especially green vegetables and certain oils) and the bacteria in your bowel also produce it. Warfarin reduces your liver’s ability to use vitamin K to make these blood clotting factors and this makes it harder for your blood to clot.

The Liver: Manufacturing Clotting Factors and Warfarin

Key Message: Warfarin reduces the ability of the blood to clot and this reduces the risk of stroke and blood clots. If too much warfarin is taken, the risk of bleeding increases dramatically.
Taking warfarin

- Vitamin K and warfarin tend to work against each other. If your intake of vitamin K increases, you will need more warfarin to keep your blood from clotting. If your intake of vitamin K is reduced, your dose of warfarin will also have to be reduced in order to keep you from bleeding.
- The amounts of vitamin K and warfarin in your body tend to rise and fall quite slowly. One way to think about this balance between warfarin and vitamin K is that it is the WEEKLY (rather than the daily) intake that is being balanced against each other.

The Effect of Vitamin K on the INR for People Taking Warfarin

- Because the level of warfarin rises or falls rather slowly, any change in dose may take several days or even a couple of weeks to reach a new stable level. Similarly, if you miss a dose of warfarin (or take an extra dose) the level of warfarin (and therefore its effect) may be altered for several days.
- In order to maintain a consistent intake of vitamin K, you need to know something about the vitamin K content of the foods you eat. As a "rule of thumb", green vegetables, especially leafy green vegetables (spinach, alfalfa, broccoli, lettuce, cabbage, coriander, parsley etc.), and certain oils (canola and olive) have a high content of vitamin K. Most fruits, meats, dairy products, and grains are low in vitamin K.

Key Message: Vitamin K opposes the effect of warfarin. It is not important how much or how little vitamin K is in your diet. Rather, it is important to understand that vitamin K will affect your INR - a BALANCED diet is required. You DO NOT need to cut foods containing vitamin K out of your diet.
### Vitamin K Content of Commonly Consumed Foods

(average daily intake 60-200 micrograms per day)

<table>
<thead>
<tr>
<th>Food</th>
<th>Serving Size</th>
<th>Mean vitamin K content per serve (microgram)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collards, fresh/frozen, boiled</td>
<td>⅛ Cup</td>
<td>374.0</td>
</tr>
<tr>
<td>Spinach, fresh/frozen, boiled</td>
<td>⅛ Cup</td>
<td>324.0</td>
</tr>
<tr>
<td>Brussels sprouts, fresh/frozen, boiled</td>
<td>⅛ Cup</td>
<td>225.0</td>
</tr>
<tr>
<td>Coleslaw with dressing</td>
<td>1 Cup</td>
<td>119.0</td>
</tr>
<tr>
<td>Broccoli, fresh/frozen, boiled</td>
<td>⅛ Cup</td>
<td>88.0</td>
</tr>
<tr>
<td>Cabbage, fresh, boiled</td>
<td>⅛ Cup</td>
<td>73.0</td>
</tr>
<tr>
<td>Asparagus, fresh/frozen, boiled</td>
<td>⅛ Cup</td>
<td>72.0</td>
</tr>
<tr>
<td>Okra, fresh/frozen, boiled</td>
<td>⅛ Cup</td>
<td>32.0</td>
</tr>
<tr>
<td>Iceberg lettuce, raw</td>
<td>⅛ Medium head</td>
<td>28.0</td>
</tr>
<tr>
<td>Tuna canned in oil, drained</td>
<td>100 grams</td>
<td>25.0</td>
</tr>
<tr>
<td>Green peas, fresh/frozen, boiled</td>
<td>⅛ Cup</td>
<td>19.0</td>
</tr>
<tr>
<td>Celery, raw</td>
<td>1 Medium stalk</td>
<td>17.0</td>
</tr>
<tr>
<td>Mixed vegetables, frozen, boiled</td>
<td>⅛ Cup</td>
<td>15.0</td>
</tr>
<tr>
<td>Sauerkraut, canned</td>
<td>⅛ Cup</td>
<td>15.0</td>
</tr>
<tr>
<td>French salad dressing, regular</td>
<td>2 Tablespoons</td>
<td>15.0</td>
</tr>
<tr>
<td>Apple pie, fresh/frozen, commercial</td>
<td>1 Slice</td>
<td>14.0</td>
</tr>
<tr>
<td>Carrot, fresh, boiled</td>
<td>1 Medium</td>
<td>12.0</td>
</tr>
<tr>
<td>Cauliflower, fresh, boiled</td>
<td>⅛ Cup</td>
<td>12.0</td>
</tr>
<tr>
<td>Grapes, red/green, seedless, raw</td>
<td>⅛ Cup</td>
<td>12.0</td>
</tr>
<tr>
<td>Plums, raw</td>
<td>2 Medium</td>
<td>11.0</td>
</tr>
<tr>
<td>Green beans, fresh/frozen, boiled</td>
<td>⅛ Cup</td>
<td>10.0</td>
</tr>
</tbody>
</table>
Factors that affect warfarin

When to take warfarin

- The time of day when you take your dose of warfarin does not affect how it works. However, it is a good idea to take it at about the same time every day to reduce the chances that you might forget to take it. It may also help if you take it at the same time that you do something else that is routine to you - such as take it when you eat your dinner.
- Doctors may prefer that you take your warfarin in the evening. This is done so that on those days when your blood test is checked, the dose can be adjusted that day, if needed, rather than having to wait until the next day’s dose.

What to do if you miss a dose:

- If you miss only ONE dose of warfarin, what you should do depends on when you realise you’ve missed the dose. As a general rule, you should take the dose as soon as you remember if you remember on the same day you missed the dose. However, if you don’t realise until the day after the missed dose, do not take it.
- Do NOT take double doses of warfarin (unless directed to do so by your doctor). Also, it is very important to make a note of any missed doses so that you can tell your doctor the date that you missed any doses.
- If you miss more than one dose of warfarin contact your doctor for advice.

Factors that affect warfarin

- Many things can alter the INR if you are taking warfarin. Such factors include:
  - Changes in your diet;
  - Introduction of vitamins, food supplements or herbal preparations;
  - Other medications (either prescription or those bought “over the counter”);
  - Changes in your level of exercise;
  - Getting sick;
  - Smoking; and
  - Consuming alcohol.
- A change in the INR may cause a big change in your risk of bleeding or blood clot formation. Therefore, you should keep your doctor informed of any of these types of changes and discuss in advance any changes you are planning in any of the above factors (such as going on a trip, starting an exercise program, trying to stop smoking, going on a new diet, taking a herbal preparation, etc.).
Alcohol and warfarin

- Alcohol can have a number of effects on people taking warfarin. It can change how fast your body breaks down warfarin. Whether it increases or decreases how your body handles warfarin may depend on how much alcohol you drink, how often you drink, and whether the alcohol has damaged your liver.
- Also, alcohol irritates the lining of your stomach and this may cause your stomach to bleed (known as ‘internal bleeding’).
- It is best not to drink alcohol, but if you do, you should limit your consumption to only 1 or 2 standard drinks per day (see following Australian Standard Drinks Guide) with 2 alcohol free days per week. It is very important to keep your doctor informed of any change in the amount, or how often, you drink alcohol.

Australian Standard Drinks Guide

![Australian Standard Drinks Guide Image]

*Note: BAC = Blood Alcohol Concentration. **Wine: 10% alcohol by volume; **LC: Light Cider; **HC: Hard Cider; **CI: Cider; **BMI: 4.0% alcohol by volume; **BC: 10% alcohol by volume; **BEW: 4.0% alcohol by volume; **BE: 5.0% alcohol by volume; **TEW: 1.1% alcohol by volume; **TE: 4.0% alcohol by volume; **T: 10% alcohol by volume.
Other medications and warfarin

- Assume that any medicine can affect warfarin unless proven otherwise.
- Any medicine that you purchase at your pharmacy or supermarket may affect your INR. For example, some pain relievers can increase the risk of bleeding.
- Before starting any new medicine, vitamin or herbal supplement, or before changing your diet significantly, you should check with your pharmacist or doctor. Tell them that you are taking warfarin and ask if this could be a problem with the new medicine or diet you want to try.
- For example, vitamin E, paracetamol, and some multivitamins can affect the INR. Anti-inflammatory tablets (e.g. Nurofen® or Voltaren®) can increase the risk of bleeding.
- There are 2 different brands of warfarin available in Australia. They are called Marevan and Coumadin. These brands are not the same and should not be swapped. For example, 3mg of Marevan is the same as 3mg of Coumadin. Changing brands may affect your INR. You should not swap brands without talking to your doctor first.

Key Message: A balanced and consistent approach to warfarin therapy is the best way to avoid complications. Avoiding sudden changes in lifestyle (diet, exercise, alcohol intake) will reduce changes in the INR. Check with health care professionals before taking new medicines/herbal products. Often problems with warfarin can be avoided by using a different medication or being aware of potential problems and planning around them in advance.
Atrial Fibrillation

Why Do I Need Warfarin?

Atrial Fibrillation, or AF, is an irregular heart beat which causes the top chambers of the heart (the atria) to beat in an uncoordinated rhythm. AF is the most common irregular heart beat and 1 in 35 people aged over 65 have AF. This increases to 1 in 10 over the age of 80 years. The irregular heart rhythm in the atria causes the atria to fill with blood in an inefficient way. This results in pooling of blood in the atria, increasing the risk that clots will develop in the chambers. If a piece of a blood clot in the atria leaves the heart and becomes lodged in an artery in the brain, a stroke results. About 15 percent of strokes occur in people with AF.

Medicines are used to help reduce stroke risk in people with AF. Long-term use of warfarin in people with AF and other stroke risk factors can reduce the chances of having a stroke by two-thirds.
### Atrial Fibrillation

#### Risk classification for people with atrial fibrillation:

<table>
<thead>
<tr>
<th>Risk category and risk of stroke (% of people who will suffer a stroke per year)</th>
<th>Very High (8-12%)</th>
<th>High (5-8%)</th>
<th>Moderate (3-4%)</th>
<th>Low (&lt;2%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk Factors in addition to AF</td>
<td>Previous mini stroke</td>
<td>Age more than 65 years and hypertension or diabetes</td>
<td>Age less than 65 years and hypertension or diabetes</td>
<td>Age less than 65 years</td>
</tr>
<tr>
<td></td>
<td>(transient ischaemic attack) or stroke</td>
<td>Recent heart attack</td>
<td>Heart failure</td>
<td></td>
</tr>
</tbody>
</table>

#### Recommended Treatment

- Warfarin
- Warfarin
- Warfarin or Aspirin
- Aspirin
Visualisation of the number of strokes that will occur in people that are at very high risk of stroke (how many people out of 100 per year would have a stroke):

- Untreated (12 out of 100)
- Treated with warfarin (3 out of 100)
- Treated with aspirin (9 out of 100)
Visualization of the number of strokes that will occur in people that are at high risk of stroke (how many people out of 100 per year would have a stroke)

- Untreated (7 out of 100)
- Treated with warfarin (2 out of 100)
- Treated with aspirin (3 out of 100)
Mechanical Heart Valves

Heart Valve Surgery

In Australia, many prosthetic (artificial) heart valve replacements are performed each year. There is a major difference between mechanical and biological prosthetic valves. Mechanical valves are long-lived but require people to take life-long anticoagulation. Biological valves save the need for long-term anticoagulation but wear out sooner and need replacing after only 10-15 years.

Anticoagulation is needed with artificial heart valves because exposure of the blood to a foreign surface (the metal valve) initiates the clotting response. This means that warfarin is required for as long as the valve is in place. In the case of biological heart valves, warfarin is needed only for a short time (6-weeks to 3-months). This is because clotting can occur while the heart is healing around the new valve. Once healing has occurred, the replacement valve does not usually cause clotting to occur because the valve is made up of biological tissue (not artificial).

Level of anticoagulation for prosthetic heart valves recommended in Australia

<table>
<thead>
<tr>
<th>Type of valve replacement</th>
<th>Target INR range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue heart valves (bioprosthetic [porcine] valves) &quot;Pig valves&quot;</td>
<td>2.0-3.0 for the first 3 months then lifelong aspirin</td>
</tr>
<tr>
<td>Bileaflet mechanical heart valve (aortic)</td>
<td>2.5-3.5</td>
</tr>
<tr>
<td>Mechanical prosthetic heart valve- older first generation valves (high risk)</td>
<td>3.0-4.5</td>
</tr>
</tbody>
</table>
Deep Vein Thrombosis

Deep Vein Thrombosis and Pulmonary Embolus

A deep vein thrombosis (DVT) is a potentially deadly condition caused by a blood clot that forms in a vein - most commonly the deep veins in the legs. This clot formation can happen if the vein is damaged or if the blood flow in the vein is slow or stops. DVT can cause pain and swelling in the leg, but many times it produces no symptoms. If the clot breaks off it can travel via the bloodstream to the lungs. When a blood clot travels to the lungs, it is called a pulmonary embolism (PE). A PE often causes shortness of breath and chest pain.

Swollen Leg Due to DVT

Who gets a DVT?
Some people are more prone to getting blood clots in the leg. The chance of getting a DVT increases as we age and doubles with each decade of life over the age of 40. People who have had a DVT in the past are at a much higher risk of getting another DVT. Some people can inherit conditions that make them more prone to forming blood clots.
Symptoms of a DVT
When a clot forms, it can either partially or totally block the flow of blood in the vein. Smaller blood clots that partially block blood flow may cause only mild symptoms or none at all. Larger blood clots that block blood flow usually cause:

- Leg swelling.
- Leg pain - often worse when standing or walking.
- Leg warmth and redness.

Treating a DVT
Once a DVT is suspected and diagnosed, prompt treatment is required. The purpose of treatment is to prevent:

- The clot from getting bigger.
- The clot from travelling to the lungs.
- New clots from forming.

Development of a DVT
**INR testing**

**Understanding the INR Test**

INR stands for International Normalised Ratio. As its name suggests, the test is standardised and one INR result can be compared to another INR result regardless of how or where the result was obtained. So, the INR is really just the standard unit used to report the result of the level of anticoagulation. There are a few things worth mentioning about the INR:

- An individual whose blood clots normally and who is not on anticoagulation therapy should have an INR of approximately 1.0.
- The higher your INR is, the longer it takes your blood to clot and the higher the risk of bleeding.
- As the INR decreases below the target range, the risk of clotting events increases.

**Understanding the 'Target INR Range' and the Risk of Complications**

- **Clotting**
- **Target range (INR 2.0-3.5)**
- **Bleeding**

**Key Message:** Your target INR is the best balance between bleeding and clotting complications for you. The more time that you spend within the target range the fewer complications that will occur.
INR testing

- The ideal target INR range will vary from person to person depending on a variety of factors such as the reason for taking anticoagulants, other medical conditions, and a number of other issues. The most common INR target range for people taking warfarin is somewhere between 2.0 and 4.0. Target INR ranges of more than 4 are avoided because of the risk of bleeding.
- The target INR, in general, for conditions such as atrial fibrillation, deep-vein thrombosis and pulmonary embolism is 2.5, with a target INR range of 2 to 3.
- The target INR for people with a replacement heart valve depends on the type of valve used and the position that it is placed in the heart. This target INR range can vary from 1.5 up to 4.0, but is often 2.5-3.5.
- The target range for a condition is the ‘best balance’ between clotting events and bleeding events for that condition. While the clotting and bleeding risks are lowest within that target range, it is important to remember that clotting and bleeding can still occur when you are within the target INR range.
- It is very important for people taking warfarin to be aware of the signs of bleeding or clotting and to talk to their doctor straight away if they notice any of these signs.

**Signs of a high INR (bleeding)**

- Bleeding gums.
- Menstrual bleeding that is heavier than normal.
- Bruises for no reason or more bruises than normal.
- Nosebleeds.
- Blood in the urine.
- “Coffee ground” vomit or the passing of black “tarry” stools.

**Signs of a low INR (clotting)**

- Pain in the legs or chest.
- Swelling, warmth, or redness of the legs.
- Breathlessness.
- Signs of stroke (unable to move or talk).

**Key Message**: Any signs of bleeding or clotting should be reported immediately to either your doctor or to a hospital doctor (via emergency room). Bleeding and clotting can still occur at your target INR because of other medications that you take or other problems you might experience (e.g. a fall or knock).
INR testing

Frequency of INR Testing

Generally, the INR is measured daily at the beginning of warfarin therapy, then weekly and then once every 2 to 4 weeks depending on how stable the INR is. One of the advantages of warfarin self-monitoring is that it enables people taking warfarin to monitor their INR more frequently. This results in an improvement in the control of the INR and fewer bleeding and clotting complications.

While monitoring your warfarin therapy, you will need to monitor your INR at least once a fortnight and communicate the result to your doctor. If you need to change the amount of warfarin that you take, the INR test should be repeated a week later.

To allow for some freedom with regard to testing times, we can normally allow a 5-day window (2-3 days either side of the due date) for the test. This will allow you to be at home when you perform the test rather than take the monitor to work.

Key Message: Test your INR as often as directed by your doctor. Generally, this will be once a fortnight, or weekly following a dosage change.
Warfarin Self-Monitoring or Management with a POC Device

This is the active involvement of the person taking warfarin in his/her treatment. After being suitably trained the person assumes responsibility for monitoring the intensity of anticoagulation and may adjust the dose of warfarin based on the INR reading.

Warfarin self-monitoring

This is where the person assumes the job of measuring the INR, while the treating doctor decides what dose of warfarin is to be taken.

Benefits:

Studies show that warfarin self-monitoring makes anticoagulation more effective, with positive results such as:

- Reduction of clotting events and bleeding complications;
- Reduction in the number and duration of periods spent in hospital;
- Greater safety when living conditions change;
- Significant improvement of quality of life; and
- Significant increase in the number of INR results within the therapeutic range and fewer INR fluctuations.

Warfarin self-management

This is where the person assumes responsibility for measuring their INR and can adjust the dose of warfarin according to the INR, provided it is within a pre-set range, based on pre-arranged guidelines. Self-management allows a high level of control over warfarin therapy and these people may also benefit from extensive education regarding their warfarin therapy in addition to the above benefits.

Key Message: Monitoring your own warfarin therapy allows you to be more responsible for your own health.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Point of Care INR monitoring

Accuracy of POC Monitors

- To use point of care devices, a single drop of blood from your finger is required. A test strip is fed into the device, the drop of blood applied and the device reports the INR. These devices typically are easy to use and report accurate results. Additionally, if an INR result is not what was expected, another test can be conducted straight away to either confirm or refute the result.
- Evaluation studies have shown the CoaguChek™ XS device to be extremely reliable in terms of precision and accuracy.
- The INR test itself relies on an extract of tissue (artificial human tissue) inside the test strip to initiate the clotting process when it and blood come together on the test strip. The time to form a clot is measured and this is called the prothrombin time. This time is then converted to the INR.
- It is because of small differences in the tissue extract in the strip that the clotting time can vary from test to test, depending on which tissue sample is used.
- Variations of up to ±15% are found in INR values and are acceptable when comparing one laboratory to another or the CoaguChek™ XS to a laboratory or another portable device.

As a rule of thumb:

- The greater the INR, the greater the possible variations, e.g.:
  - Pathology INR of 3.5; acceptable variation between 2.1 - 2.9.
  - Pathology INR of 3.0; acceptable variation between 2.5 - 3.5.
  - Pathology INR of 4.0; acceptable variation between 3.4 - 4.6.

These are all generally acceptable variations from a pathology result for a portable monitor or another pathology laboratory.

- While this variation is not ideal, the point must be made that variation occurs not just from a portable device to laboratory, but also from one laboratory to another.
- The view of the experts is that when checking and adjusting their dose of warfarin, people should always use the same measuring system.
- Consistency is the key, this means that if a change in the INR occurs you and your doctor can be confident that the difference is not related to the testing device, but to changes in your clotting time.

Key Message: The CoaguChek™ XS is highly accurate and reliable when used in the correct way. It is normal for some variation to occur between CoaguChek™ XS INR results and pathology results. Comparisons between different pathology laboratories shows that the same variation can occur in this setting. Consistency of monitoring method is the key.
Using the CoaguChek™ XS Monitor

A detailed description of the CoaguChek™ XS and how to use it is available in the User’s Manual that accompanies your CoaguChek™ XS. Please refer to this for more detail on how to perform a test.

The CoaguChek™ XS INR Monitor
Point of Care INR monitoring

Tips on how to obtain a good blood sample

- Warm hands by running under warm running water to ensure good blood flow to the fingers.
- Avoid calloused areas. Try pricking the side of the finger pad.
- Do not use the same finger twice, try a different finger if the first does not produce a good sample (the clotting process will be occurring in the first finger and may cause an altered reading if used again straight away).
- Do not prick the finger until you are ready to apply the drop of blood immediately to the strip (within 15 seconds).
- Hold the elbow up to promote blood flow to the finger tips.
- Touch the drop of blood to the test strip, not the finger to the test strip.
- “Milk” the finger – avoid squeezing (this can damage small blood vessels and start the clotting process).

Health and safety

- Wash hands thoroughly with soap and warm water before and after performing the INR test.
- Equipment should be stored in the case provided and out of reach of children.
- Place all needle ends and used test strips in a sharps (yellow) container or another suitable container.

Key Message: Using correct technique will ensure accurate results. Always wash your hands with warm water and dry them before a test. Never squeeze your fingers to get a drop of blood. If gentle ‘milking’ is not enough, try a different finger.
Section 2

Objectives:
- To review the theory that was covered in the first section;
- To review your INR results obtained between sessions and technique;
- To develop an understanding of quality control measures and why they are important; and
- Assessment of theory and demonstration of competency with the CoaguChek™ XS.

What is covered in the second section:
- Review of theory;
- Quality control;
- Adjusting the warfarin dose; and
- Assessment of theoretical knowledge and practical competency.
Review of Section 1

Review of First Section

Indications for warfarin:
- Thrombosis.
- Atrial fibrillation.
- Heart valve replacement.

How warfarin works:
- Works by slowing down the clotting process.
- Takes a little longer to stop bleeding.
- INR tests the effectiveness of warfarin.

Target INR:
- To keep your blood at the right level.
- Atrial fibrillation/thrombosis (generally between 2 and 3).
- Heart valve replacement (generally between 2 and 3.5 depending on type of valve used).
- Best balance of bleeding and clotting risk.

Adverse events:
- Too much warfarin makes you bleed and increases the INR.
- Too little warfarin causes clot and lowers the INR.

Frequency of blood tests:
- Every two weeks but after one week if a change in warfarin dose has occurred.

The effect of diet and other medications on warfarin:
- Vitamin K opposes the effect of warfarin.
- Too much will lower the INR.
- Found mainly in green leafy vegetables.
- A balanced intake is required.
- Check with a doctor or pharmacist before starting any new medication, even herbal and over the counter products.
Quality Assurance

Quality assurance broadly describes any measures taken to ensure the reliability of testing and reporting. It covers the calibration of the monitor, taking the sample, and accurate recording of the results.

- Quality assurance is comprised of 2 equally important parts. These are internal quality control (IQC) and external quality control (EQC).
- These are separate but equally important components of quality assurance. That is, both are essential in demonstrating that any monitoring system is providing precise and accurate INR results.
- IQC ensures that if you measured your INR five times in a few minutes that the results would be very similar to each other. This is called precision (or consistency).
- EQC is a measure of the accuracy of the results obtained from the CoaguChek™ XS compared to a laboratory. If the laboratory INR is the ‘true’ INR, EQC checks that the INR results from your CoaguChek™ XS monitor are close to it and can be relied upon to alter your dose (if required). This refers to the accuracy of the CoaguChek™ XS.

Key Message: Quality assurance = insurance and confidence. If quality assurance procedures are conducted regularly, you and your doctor can be confident that you are using the CoaguChek™ XS correctly and that the results can be relied upon.
Quality Assurance

Internal Quality Control

Internal quality control is conducted automatically every time you use the CoaguChek™ XS. If there are any problems detected by the monitor, the result will not be displayed and the test will need to be repeated.

External Quality Control

EQC is a measure of accuracy, or the closeness of the measured value to the true value. Inaccuracy can occur because of many reasons, including different monitoring systems, operators, operating conditions and testing solutions.

It is important that EQC is conducted at regular intervals and the results documented to maintain the accuracy of your monitor. It is important for both you and your doctor that adequate quality control measures are taken while you are using the monitor as this will mean that you can feel confident in the accuracy of your monitor.

For example, having a comparison INR test done by your GP every three months is sufficient to check on the accuracy of your monitor.
Assessment

Theoretical assessment:
1. How does warfarin work?
2. How often should you test your blood?
3. What is meant by target INR?
4. What are the signs of too much warfarin?
5. What are the signs of too little warfarin?
6. What is QC and when do you need to do it?

Practical assessment:
1. Finger pricking technique.
2. POC monitoring competency.
   a. Placing of sample.
   b. Two tests recorded with a discrepancy of not more than 15%.
3. Maintenance of POC monitor and test strips.
Additional Resources

Speak to your health care professional if you are unsure about anything in this manual. If you have access to the internet you might like to visit some of the web sites listed below to find more information.

Online resources

- www.anticoagulation.com.au
- www.anticoagulation.org.uk
- www.clotcare.com
- www.ismaap.org
- www.medhelp.org/HealthTopics/Anticoagulation.html
**WARFARIN AND YOU**

**Consumer Information Leaflet**

Warfarin is a medicine that is used to increase the time it takes for your blood to clot. It belongs to a class of medicines called anticoagulants. These medicines help to prevent unwanted blood clots which may cause a stroke, heart attack or venous blockages.

In Australia there are two brands of warfarin. They are called MAREVAN® and COUMADIN®.

<table>
<thead>
<tr>
<th>MAREVAN® brand warfarin tablets</th>
<th>COUMADIN® brand warfarin tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 mg tablet (brown)</td>
<td>1 mg tablet (light tan)</td>
</tr>
<tr>
<td>3 mg tablet (blue)</td>
<td>2 mg tablet (lavender)</td>
</tr>
<tr>
<td>5 mg tablet (pink)</td>
<td>5 mg tablet (green)</td>
</tr>
</tbody>
</table>

These two brands of warfarin are not the same and should not be swapped or changed unless advised to do so by your doctor.

**How does warfarin work and how much should I take?**

Normally the body balances bleeding and clotting activities, but some conditions can alter this balance and increase the risk of an unwanted blood clot.

Warfarin works by reducing the formation of certain blood clotting factors produced by your liver. To produce these clotting factors the liver needs vitamin K and warfarin interferes with the liver's ability to use vitamin K.

Because everybody is different it makes sense that everybody reacts differently to warfarin. This also means that the dose of warfarin that works best is different for everybody. Your doctor will find the best dose for you based on the results of your blood tests.

The dose of warfarin needed is that which prevents clots but doesn’t cause unwanted bleeding.
What is the INR?
A blood test is needed to determine the effect of warfarin for each person and this is measured as the International Normalised Ratio or INR. The INR is a measure of how long it takes for blood to clot.

The INR for a person not taking warfarin is 1. The higher the INR, the longer it takes for blood to clot. The desired INR for you will depend on the reason for which you are taking warfarin.

Your doctors will try and keep your INR within a range – called the target INR range.

The target INR range is different for different conditions. For example, for people with atrial fibrillation - an irregular heart beat in the top chambers of the heart - the target INR range is 2 to 3. Higher INR ranges are recommended for people who have a mechanical heart valve or for those with some irregular clotting conditions.

Clotting is necessary to stop bleeding when you cut yourself. When taking warfarin your clotting time is increased so it takes longer for a clot to form. Having your INR in the correct range reduces the risk of potentially dangerous bleeding.

Generally regular blood tests are essential to check that your INR is within the correct range. Your doctor will tell you the correct range for your condition.

Your doctor will also tell you how often you will need to have a blood test. When you first start taking warfarin these tests will be frequent, often every one or two days for the first week. Once your warfarin levels have stabilised, testing is usually only repeated every 4 weeks, or as often as your doctor tells you. Your dose of warfarin may be changed based on the blood test results.

How do I take warfarin?
Warfarin is usually taken once a day, with or without food. Some doctors prefer that their patients take their dose in the evening. This allows the dose to be changed if necessary on the day that the INR results are obtained.

After each blood test you should contact your doctor for instructions and write down any dosage changes for your records. One suggested option is to use an INR record form (a sample is attached at the back of this leaflet) writing the dose you need to take in the appropriate day and then circling this dose when you have taken it (see below). This will help to both remind you of the correct dose and indicate to you that you have taken that day’s dose.

Example of an INR record form:

<table>
<thead>
<tr>
<th>Week beginning (date)</th>
<th>Recommended Warfarin Dose</th>
<th>Date of test</th>
<th>INR result</th>
<th>Next appointment/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/02/09</td>
<td>X X X X X X</td>
<td>12/02/09</td>
<td>2.3</td>
<td>26/02/09</td>
</tr>
<tr>
<td>18/02/09</td>
<td>X X X X X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
When should I take warfarin?
You should take your dose exactly as your doctor tells you and not miss any doses.
If you do forget to take a dose and then remember within a few hours, take your dose. If it is more than a few hours - for example the next day - just take your next dose at the usual time and make a note of the missed dose to tell your doctor.
You should not take a double dose.
In the event you miss more than one dose contact your doctor for advice.

Why is my diet important?
Because vitamin K and warfarin tend to work against each other, it is important to be aware that changes in diet can have an impact on warfarin activity within the liver.

As vitamin K is essential for a healthy diet you should not try and eliminate vitamin K from your food intake. In fact the recommended daily intake of vitamin K remains the same for people taking warfarin and for those who don’t.
Aim to balance your vitamin K intake by being consistent with the foods that you eat.

You don’t have to eat the same types of food everyday!
Having a diet with a variety of foods is important. Remember vitamin K is needed for a healthy diet and foods containing vitamin K should be included.

Foods high in vitamin K include broccoli, brussels sprouts and leafy green vegetables like spinach, cabbage and kale. Generally the greener the vegetable the higher the vitamin K content. Canola and soybean oil also have high vitamin K content. Most fruits, meats, dairy and grains products have low vitamin K content.

Dietary supplements such as Sustagen® and Resource® which may be recommended by your doctor for extra calories or nutrients are quite low in vitamin K.
From time to time you may wish to eat something not usually in your diet. A list of foods and their vitamin K content is provided on the next page.
Additional Resources

Vitamin K

This is NOT a list of foods to avoid or a complete list of all foods containing vitamin K, it provides an idea of those foods with high and moderate vitamin K content as an aid to helping you maintain a consistent dietary intake.

<table>
<thead>
<tr>
<th>Foods with low Vitamin K content</th>
<th>Foods with moderate Vitamin K content</th>
<th>Foods with high Vitamin K content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfalfa</td>
<td>Asparagus</td>
<td>Broccoli (cooked)</td>
</tr>
<tr>
<td>Beans (green)</td>
<td>Avocado</td>
<td>Brussels sprouts</td>
</tr>
<tr>
<td>Carrots &amp; Cauliflower</td>
<td>Red Cabbage</td>
<td>Cabbage (raw)</td>
</tr>
<tr>
<td>Celery, Corn &amp; Potato</td>
<td>Green Peas</td>
<td>Endive (raw)</td>
</tr>
<tr>
<td>Breads Cereal</td>
<td>Lettuce (iceberg)</td>
<td>Lettuce (gourmet)</td>
</tr>
<tr>
<td>Rice</td>
<td>Pickle, dill</td>
<td>Parsley</td>
</tr>
<tr>
<td>Fruit &amp; juices (mostly)*</td>
<td>Beans (snap)</td>
<td>Silver beet (cooked)</td>
</tr>
<tr>
<td>Cheese (cheddar) Milk</td>
<td>Cheese (blue)</td>
<td>Spinach (cooked &amp; raw)</td>
</tr>
<tr>
<td>Eggs &amp; Butter</td>
<td>Margarine</td>
<td>Mayonnaise</td>
</tr>
<tr>
<td>Sunflower Sesame oil</td>
<td>Olive oil</td>
<td>Canola &amp; Soybean oil</td>
</tr>
<tr>
<td>Fish, Meat, Pork, Chicken</td>
<td>Abalone</td>
<td>Liver</td>
</tr>
</tbody>
</table>

* Cranberry juice consumption has been linked with increased bleeding with warfarin

What about other medicines?

Many medications may change the anti-coagulant action of warfarin. This includes medicines prescribed by your doctor and items you can buy without prescription from your pharmacy, supermarket or health food store.

Assume that any medicine can affect warfarin unless advised otherwise.

To minimise the risk of having a problem with your warfarin:

- Check with your doctor or pharmacist before starting or stopping any medicines
- Tell the pharmacist you are taking warfarin before purchasing any Over The Counter medicines (OTC medicines)
- Ask your pharmacist before buying any vitamins, herbal or natural therapies
- If you visit a different doctor, or see a dentist, be sure to tell them you are taking warfarin
- Wear a MedicAlert® bracelet identifying that you take warfarin (for more information, ask your pharmacist, call 1800 882 222, or visit www.medicalert.com.au)

The following Tables list some of the common medicines and complementary products which can interfere with warfarin.
Warfarin and other medications

There are many medicines that can affect warfarin that are not listed here. Check with your doctor or pharmacist before starting any new medication including complementary products purchased from health food stores.

These are examples of medicines and complementary products which may INCREASE your clotting risk. This is not a complete list – if you are concerned about a medicine you are taking, please talk to your healthcare professional.

<table>
<thead>
<tr>
<th>Medicine type</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription</td>
<td>Anti-epileptics like carbamazepine (Telegro®) and phenytoin (Dilantin®) and antithyroid processes like carbimazole (Neo-Mercazole®) and propylthiouracil</td>
</tr>
<tr>
<td>Complementary products</td>
<td>Ginseng, Green Tea, St. John's Wort, Vitamin K (in some multivitamins)</td>
</tr>
</tbody>
</table>

These are examples of medicines and complementary products which may INCREASE your bleeding risk. This is not a complete list – if you are concerned about a medicine you are taking, please talk to your healthcare professional.

<table>
<thead>
<tr>
<th>Medicine type</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription</td>
<td>Antibiotics like cotrimoxazole (Bactrim®) and erythromycin (Eryc®) and anti-inflammatory drugs like indomethacin (Indocid®) and celecoxib (Celebrex®) and ulcer and reflux medicines like omeprazole (Losec®) and cinetidine (Tagamet®) and heart and cholesterol medicines like amiodarone (Cordaron®) and simvastatin (Zocor®)</td>
</tr>
<tr>
<td>OTC medicine</td>
<td>Aspirin and Pain relievers</td>
</tr>
<tr>
<td></td>
<td>Cough and cold medicines</td>
</tr>
<tr>
<td></td>
<td>Oral anti-fungals like miconazole (Daktarin gel®) and fluconazole (Diflucan®)</td>
</tr>
<tr>
<td>Vitamins and herbal products</td>
<td>Vitamin E, Co-enzyme Q10, Garlic supplements, Ginger supplements, Ginkgo Biloba, Glucosamine</td>
</tr>
</tbody>
</table>
Other Factors that can affect warfarin and your INR

ALCOHOL

Generally it is best not to drink alcohol whilst taking warfarin but if you do, you should restrict your daily intake to no more than one or two standard drinks a day, with two alcohol free days a week.

One standard drink is equal to:
• One small glass of wine (100ml)
• One nip of spirits (30ml)
• One middy of normal strength beer (285ml)

Alcohol in excess can affect liver function which can affect the way warfarin works. Alcohol also iritates the lining of your stomach, which may increase the likelihood of a stomach bleed.

ILLNESS

Any new illness especially involving:
• Diarrhoea or vomiting
• Fever or infection
• Loss of appetite
• Jaundice
• Medicines you may use to treat your illness

Contact your doctor if you become sick with a fever, the flu, or an infection. Also call if you have diarrhoea or vomiting that lasts for more than one day.

LIFESTYLE

Other considerations that should be discussed with your doctor include:
• Changes in your level of exercise
• Trying to stop smoking
• Changes in your diet - fasting or crash diets
• Travelling on long trips – make sure you have enough warfarin tablets and carry identification that indicates that you take warfarin. Because your diet and activity may vary you may need an INR check whilst away.

Pregnancy must be avoided as warfarin can seriously affect an unborn baby in early pregnancy. All women who may become pregnant should discuss with their doctor the risks and means of reducing those risks. Should you become pregnant whilst taking warfarin you must notify you doctor at the earliest opportunity.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

**Signs and Symptoms of unusual bleeding**

Sometimes, if your INR is too high you may experience some unusual bleeding. These are the signs:

- Severe bruising that gets worse
- Any bleeding that takes a long time to stop
- Unexplained bleeding or bruising
- Menstrual bleeding that is much heavier than usual
- Red or dark urine
- Red or black bowel motions
- Coughing up blood, or anything red
- Bloody or dark stained vomit
- Severe headache or dizziness
- Weakness or lethargy
- Unusual pain or swelling

If any of the above symptoms occur, and they are concerning you, you should contact your doctor. If your doctor is unavailable, go to your nearest hospital emergency department.

**Living safely with warfarin**

While you can perform all your normal daily activities whilst taking warfarin it would be a good idea to avoid contact sports. Any falls, blows or injures should be reported to your doctor. You might not always see visible signs of bleeding.

Minor cuts and scrapes should be cleaned and covered with an adhesive bandage or pad. Larger cuts should be covered with a clean pad and have pressure applied to help slow the bleeding (this may be in the form of a compression bandage or you may wish to apply the pressure using your hands) and be reported to your doctor.

Around the home:

- Use a non-slip bath mat.
- Use a soft bristle toothbrush.
- Use an electric shaver.
- Wear gloves while gardening.
- Be careful around pets.
- Wear non-slip footwear/sturdy shoes to avoid trips and slips.
- Take care with sharp objects such as kitchen knives.

**Options for monitoring your INR**

Aside from laboratory monitoring of INR, portable devices are available for home monitoring. While these devices are remarkably accurate and provide results similar to laboratory monitoring, they do require proper training in their use along with periodic comparisons to INR measurements obtained by an external laboratory. Ask your doctor or pharmacist if you are interested in this option and they can help you figure out the best management option for you.
Additional Resources

INR Record Form

Name
Referring doctor
Warfarin brand
INR range required

<table>
<thead>
<tr>
<th>Week beginning (date)</th>
<th>Recommended Warfarin Dose</th>
<th>Date of test</th>
<th>INR result</th>
<th>Next appointment/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mon</td>
<td></td>
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<td></td>
<td></td>
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<td>Tue</td>
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<td>Sat</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Sun</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Warfarin Education Program - Self-Monitoring Education Manual for Consumers

Page 40
Appendix 17: Implementation Toolkit
This resource was developed using funding from the Australian Government Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement through the Fourth Community Pharmacy Agreement Small Rural Grants Program managed by the Pharmacy Guild of Australia.

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Cover photo by pekto.
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Note: this document has been prepared using the details of the CoaguChek XS POC INR device. It will be modified as required in the future for other devices.
Preface

This toolkit has been designed to provide community pharmacies in Australia with the resources they require to implement a standardised and clinically effective anticoagulation monitoring service in their practice.

An anticoagulation monitoring service should strive to ensure patients have equitable access to a convenient, community based monitoring service tailored to local needs. It should aim to provide comprehensive and ongoing education and support to patients so they gain a better understanding of their therapy. Improve compliance and optimise the outcomes of treatment.

This document aims to provide liaison strategies to assist pharmacies to work with other healthcare professionals in their community to determine the most appropriate service to meet the community’s, and more specifically the individual patient’s, needs. It contains basic business models so that the proposed services can be incorporated into current practice in such a way that they are sustainable.

The toolkit also includes a set of standard operating procedures to guide pharmacies on the recommended ways to conduct an anticoagulation service. These cover areas such as quality assurance, record keeping and procedures for each different type of service.

Additionally, a wide range of tools are provided to ensure the service is as easy to implement as possible.

This toolkit has been contributed to and commented on by a wide range of stakeholder organisations including:

- Royal Australian College of General Practice
- Royal College of Pathologists of Australasia
- National Stroke Foundation
- Pharmacy Guild of Australia
- Pharmaceutical Society of Australia
- Australian Association of Consultant Pharmacy
- Society of Hospital Pharmacists of Australia
- Australian General Practice Network
- Roche Diagnostics Australia

This is the first version of this toolkit. Any comments or suggestions would be welcomed to enable us to refine these resources for future use.

If you have any feedback, questions, or require additional support, please contact the Unit for Medication Outcomes Research and Education at the School of Pharmacy, University of Tasmania on 1800 998 504 or email info@anticoagulation.com.au

Implementation Toolkit for Point of Care INR Monitoring Services in Community Pharmacy
## Abbreviations

**Abbreviations used in this document**

- AACP: Australian Association of Consultant Pharmacy
- AF: Atrial Fibrillation
- CV: Coefficient of Variation
- DVT: Deep Vein Thrombosis
- EQC: External Quality Control
- GP: General Practitioner
- HMR: Home Medicines Review
- INR: International Normalised Ratio
- IQC: Internal Quality Control
- IRP: Internal Reference Preparation
- ISI: International Sensitivity Index
- MNPT: Mean Normal Prothrombin Time
- NPT: Near Patient Testing
- PE: Pulmonary Embolism
- POC: Point Of Care
- PR: Prothrombin Ratio
- PSM: Patient Self-Monitoring
- PT: Prothrombin Time
- QA: Quality Assurance
- QAP: Quality Assurance Program
- QCPP: Quality Care Pharmacy Program
- RCPath: Royal College of Pathologists of Australasia
- SOP: Standard Operating Procedures
- TF: Tissue Factor
- TGA: Therapeutic Goods Administration
- VTE: Venous Thromboembolism
- WHO: World Health Organisation
Introduction

The role of anticoagulation in the primary and secondary prevention of ischaemic stroke and other conditions is well established. There are a number of groups of patients who benefit from warfarin therapy, including those with heart valves, recurrent thrombosis or atrial fibrillation (AF) and they all need ongoing monitoring to maintain the optimum effect and to reduce the risk of adverse events and complications.

In simple terms, managing warfarin therapy effectively requires a means of measuring the international normalised ratio (INR) accurately, interpretation of the result obtained, advice on the warfarin dose and management of the complications associated with warfarin therapy. There are a number of models available to facilitate this process.

Traditionally services have been provided by general practice, pathology laboratories, or by hospital clinics, but the increase in the number of people taking warfarin, and the increasing awareness of the challenges that exist in managing anticoagulation, has prompted a move to providing monitoring in other settings.

A diagnostic test, particularly a point of care (POC) test, is only clinically relevant if it influences the disease diagnosis, management or prognosis. The ability to perform an INR test with the patient facilitates and improves clinical management and overcomes concerns relating to delays between testing and dosing advice being received by the patient. This can be particularly advantageous in rural and remote areas where access to a laboratory can be limited.

Several publications have shown that frequent INR monitoring, such as that achieved through POC testing, leads to an increase in the time spent in the therapeutic INR range and a decrease in the incidence of adverse events.

Point of care INR testing can also be used in the context of patient self-monitoring (PSM) where a patient tests their own INR and liaises with their doctor to obtain dosing advice. This method of management gives patients a greater involvement in their own health care, which in turn has been demonstrated to improve the outcomes of therapy.

The purpose of this document is to clarify common standards for the provision of anticoagulation monitoring services in primary care, and to provide the necessary tools and suits for implementation of a safe, effective and sustainable service in community pharmacies.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Point of Care INR Theory

Overview

The therapeutic benefits of warfarin are highly dependent on maintaining the INR within the therapeutic range. Poor compliance, variable dietary intake, drug interactions, inadequate knowledge, and miscommunication between the patient and physician have all been cited in the literature as potential causes for fluctuations in the INR.

Bleeding complications with warfarin occur more frequently in older patients than in younger individuals. Anticoagulation in elderly patients poses unique challenges because they are simultaneously at higher risk for recurrent thromboembolism and major bleeding, including catastrophic intracranial haemorrhage. Older patients have characteristics that may place them at higher risk for anticoagulant-related bleeding, but they also have characteristics that make them more likely to benefit from the therapy. The dilemma is that the use of warfarin is now increasing at a steady rate (approximately 10% per year) because of its proven benefits in AF. AF is a common arrhythmia, with a prevalence of approximately 5% in people over 60 years of age and 10% in people over 75 years of age. It is recognised as a major public health problem associated with significant morbidity and mortality. The presence of AF has been confirmed in many studies as an important risk factor for ischaemic stroke and other thromboembolic events. Approximately 15% of all strokes are associated with AF, and the association increases steadily with age. It has been conclusively demonstrated that long-term anticoagulation therapy can reduce the risk of stroke by approximately 63% in patients with non-valvular AF.

Once stabilised on warfarin, more frequent monitoring may be required in older adults, because they may experience greater fluctuations in the INR, particularly during illness or with alterations in their medication regimen. More frequent monitoring may ensure that the target INR does not rise above recommended levels in older patients.

Practically, frequent laboratory testing represents a significant burden and may be unrealistic for many elderly patients who are initiating warfarin therapy. Compared to younger patients, older patients are more often dependent on others for transportation and may be challenged by physical limitations to mobility. These impediments to frequent testing are especially relevant for those patients who live in rural areas or in less developed countries.

Point of care monitoring may be performed in a number of settings, and can be conducted by a suitably trained person or the patient themselves. This document refers to POC INR monitoring in three main settings: pharmacy-based monitoring services, outreach services to patients, and patient self-monitoring.

Pharmacy-based services: cover services where INR monitoring is conducted in a pharmacy setting by the pharmacist. It involves testing the patient’s INR with a portable monitor and relaying the result to the patient’s doctor. A pharmacy service should be governed by a set of standard operating procedures which cover topics such as quality assurance, training, record keeping, and health and safety, as well as how to perform the test.

Outreach services: cover INR testing services offered outside the pharmacy environment by a pharmacist. These may include INR tests as part of an HMR or at a residential care facility. They are ideally offered in conjunction with a pharmacy-based service to ensure the monitor...
undergoes the necessary quality assurance procedures and recommended training is completed.

**Patient self-monitoring:** involves a patient testing their own INR with a portable device and adjusting their warfarin dose in consultation with their doctor. Patient’s wishing to undertake PSM will ideally receive a comprehensive education and training session coordinated by the pharmacy who supplies the device. This method of monitoring, and the selection and training of patients for self-monitoring, is discussed in more detail later in this section.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Point of Care INR Theory

Clotting Time Measurement

Thromboplastins

The prothrombin time (PT) test uses a tissue thromboplastin, an extract of tissue, to accelerate the clotting time of the blood. This simply initiates the clotting process, which is normally initiated when blood plasma is exposed to body tissue. This test is sensitive to changes in the vitamin K dependent factors (II, VII and X) and is used to control warfarin therapy.

The tissue factor (TF) is usually prepared from a variety of sources, including human, rabbit and bovine brain, human placenta and more recently, recombinant human and rabbit preparations. A laboratory must then define the normal reference range for each reagent (TF) and technique used, using samples from 20 healthy adults. The average of these results is then calculated. This is known as the mean normal prothrombin time (MNPT) and is then used to calculate the prothrombin ratio (PR). The prothrombin ratio is expressed as:

\[ PR = \frac{\text{test PT}}{\text{MNPT}} \]

For a patient on warfarin, the PR is simply the ratio of their clotting time compared to a patient not on warfarin. That is, a PR of 1 means that the patient's blood will take twice as long to clot compared to a 'normal' patient.

Each laboratory must standardize every batch of reagent for each testing method employed because it has been widely demonstrated that PRs performed on the same sample in different laboratories may not correlate well.2 This can be due to a number of pre-test and analytical variables, such as: blood collection tube type, poor venipuncture technique and storage of samples, sample contamination, thromboplastin source, coagulometer effects and analysis temperature. The most important variable is the type of thromboplastin used. These variables can lead to inconsistencies in the PR and can lead to incorrect dosing and poor control of therapy.

The INR

The International Normalised Ratio (INR) was developed in the 1980s in an attempt to standardise the PT. To achieve this, each thromboplastin reagent is assigned an International Sensitivity Index (ISI) that reflects the sensitivity of the reagent to reduced levels of clotting factors. Thus the INR is merely a standardised form of the PR such that the same sample of plasma should give the same INR even if different thromboplastins are used that result in different PRs. The INR is expressed as:

\[ \text{INR} = (\text{test PT} / \text{MNPT})^{0.2} \]

It is important that the ISI and MNPT are determined for each batch of thromboplastin and with each coagulometer used in order to assign the system ISI. For more detail on ISI calibration, a reference to the WHO Expert Committee on Biological Standardisation recommendations is provided (http://www.who.int/biologicals/index/Cardiovascular.htm). Despite the INR theoretically being a standardised measure because of the ISI, thromboplastins with a low ISI (1.0-1.4) are preferred for INR determination as a high ISI essentially magnifies the PR, and any slight error may become a larger one. The use of high ISI reagents may give less dependable INR values during the initiation of oral anticoagulation with warfarin and in poorly stabilised patients.
Point of Care INR Measurement

INR testing is routinely conducted in hospital centres and primary care settings. The INR test is a common test used to monitor the effectiveness of anticoagulant therapy. A number of models for monitoring and management of anticoagulant therapy care are now available. These include self-monitoring by patients and primary care staff, and centralised monitoring systems. The two models of care rely heavily on point of care (POC) testing, broadly defined as testing performed in close proximity to the patient.

There are a number of POC INR devices that are available currently in Australia. These are generally of 2 types:

- Devices designed for professional use, primarily for hospital staff;
- Devices intended for use by other healthcare personnel in anticoagulation clinics or primary care, or by patients themselves.

The former type of monitor is generally used for conducting INR tests in addition to other blood tests. They may permit the use of more than 1 type of sample; have large electronic memories and complex data management systems suitable for multi-user, multi-patient use. The latter type of device performs only the INR test, contains basic software and is focussed on ease of use.

POC monitoring must meet certain Therapeutic Goods Administration requirements prior to use in general practice.

POC Evaluation

All in vitro diagnostic equipment requires thorough evaluation before clinical implementation to ensure that results are reliable and consistently obtained. In Australia, the Therapeutic Goods Administration (TGA) reviews the available data from the manufacturer before a product is registered for use. While there are no specific guidelines for the calibration of POC devices, it is accepted that the manufacturer, using the same procedure as conventional laboratory systems, should perform INR calibration. For POC INR monitors, the user cannot alter the ISI and MNPT calibration provided by the manufacturer. The PT and INR from a POC INR system is compared with at least 2 other reference systems selected from instruments and reagents (usually one rabbit brain and one human recombinant thromboplastin) that have been validated previously.

POC INR systems have been widely evaluated in clinical practice, including testing by healthcare professionals in hospitals and general practices, as well as patient self-testing and self-management. On the basis of the available literature, POC INR monitors have similar levels of performance to conventional laboratory testing.
Point of Care INR Theory

Accuracy of POC INR Devices

The accuracy of the INR measured with POC testing devices depends essentially on the calibration. Presently, the responsibility of calibration rests entirely with manufacturers because access to the software to change encoded parameters is not possible for the majority of commercial devices.

A technique often employed to check the accuracy of a POC INR device is to perform a direct comparison with conventional methods. By definition, the true INR of a given plasma sample should be the one measured with the primary international reference preparation (IRP) for thromboplastin, called 67/40, coupled with the manual (tilt-tube) technique to detect clot formation (defined as the standard method). However, the IRP 67/40 was discontinued many years ago and replaced by other IRPs, which were calibrated against their predecessors. Therefore, the true INR is not known. For practical purposes, it can be assumed that the INR measured with one of the established IRPs for thromboplastin coupled with the manual (tilt-tube) technique is a good approximation of the true value. The INR measured with other conventional systems may also be considered as a good approximation of the true value only if they have been calibrated against an IRP. The reproducibility assessed for one commercial POC testing device was acceptable (median CV = 4.18%), but poorer than that of the conventional laboratory INR measurement (median CV < 1.5%).

The College of American Pathologists suggests if one method of monitoring anticoagulation is to be replaced or supplemented by another method, the new method should be calibrated against the old method. Therefore, a correlation study of both methods is a crucial step prior to implementing the POC method.

Statistical and clinical agreement

The agreement between paired INR measurements (i.e. those obtained with the POC testing device and those obtained with the standard method) can be assessed by statistically or clinically relevant criteria. Statistically relevant criteria are concerned with the correlation analysis of paired INR measurements and/or comparison of mean values. Although they are widely used, it should be understood that these statistical evaluations, if used alone, are not very informative. For instance, two methods might be highly correlated (high correlation coefficient) even though their results are systematically biased. It is more useful to plot the differences of paired measurements against the average value. This enables an assessment of systematic differences over the whole range of measured INRs.

Clinically relevant criteria usually rely on the assumption that the INR values measured for the same patient by two systems are in agreement, if using either INR does not result in changes of dose prescription. Requirements for agreement of paired INR measurements have been developed and may form the basis for POC testing assessment. Being more closely related to decision making on dose prescription, the agreement based on clinically relevant criteria should be considered more meaningful than that based on statistically relevant criteria.
Introduction to Patient Self-Monitoring

Patient self-monitoring of warfarin, with or without self-adjustment, has great potential to maximise the safety of anticoagulant therapy. As noted by Gallus, the best opportunity for patients to assume the fullest responsibility for safe and effective warfarin therapy would be home-testing of the INR. Self-monitoring and adjustment of warfarin dosages by patients is an evolving strategy worldwide for the management of oral anticoagulation. Self-management of oral anticoagulation therapy is a model of care that allows patients to monitor their INR with a portable device, and make limited adjustments to their dose of warfarin in a similar way to diabetics patients with insulin dosage. Patients measure most or all of their INRs, interpreting the results themselves, and translating these into dosage adjustments of warfarin, as opposed to simply measuring their results and referring to a health care practitioner for guidance on all dosage changes (self-monitoring).
Rationale for Self-Monitoring

Self-management and self-monitoring of anticoagulation are partly based on the premise that more frequent testing will lead to tighter anticoagulation control and thus improved clinical outcomes. Data indicate that the mortality of patients on warfarin is related to the INR; that is, an INR range of 2-3 is associated with the lowest rate of mortality. Increasing rates of mortality are equally associated with both under- and over-anticoagulation. It has also been shown that the time in the therapeutic range correlates strongly with clinical outcomes and that more frequent testing seems to increase the time in the therapeutic range. Studies have shown that the anticoagulation status of self-monitored patients is better than, or at least equivalent, to that of patients monitored by a GP or specialist clinic.

Interestingly, one study demonstrated that self-management of warfarin therapy improved thromboembolic and haemorrhagic outcomes, with only a slight increase in the percentage of INR tests in the therapeutic range compared to control patients (anticoagulation clinic) and no difference in the percentage of time in INR range between the groups. It was noteworthy that the improvement of clinical outcomes was achieved without an improvement in INR control; thus, the benefits of self-management extended beyond INR control to patient empowerment, improved adherence and an improved awareness of health status by the patient.

Generally studies have shown an inverse relationship between patient knowledge and adverse outcomes of warfarin therapy. Good outcomes have been recorded where patients have had increased participation in their care and were encouraged to communicate more effectively with doctors and other health professionals about drug interactions and changes in lifestyle or diet.

Ultimately, self-monitoring by patients has the greatest potential to maximise the safety of anticoagulant therapy. It allows patients to assume significant responsibility for their own therapy, which can lead to improvements in patients’ self-worth, closer adherence to treatment, and increased control of treatment with warfarin. It has been shown that self-monitoring patients are less anxious about their therapy. Other advantages of self-monitoring include patients being able to conduct testing at home, saving travel and time to visit a clinic/doctor, and that they are less dependent on the health care system to manage their therapy.

Studies have shown self-monitoring to be feasible, accurate, associated with a greater time in the therapeutic range, and improved outcomes for patients. A recent systematic review and meta-analysis of published trials concluded that self-monitoring improves the quality of oral anticoagulation (improved control of INR, reduced thromboembolic and bleeding complications and reduced mortality). Patients capable of self-monitoring and self-adjusting therapy have fewer thromboembolic events and lower mortality than those who self-monitor alone. It may not be a unanimously appealing option as self-monitoring requires special training to implement, and there are still many variables, such as patient selection criteria and testing frequency that need optimisation. However, self-monitoring of oral anticoagulation is now widely practised in Germany and the Netherlands and is becoming more popular in the UK and USA. This trend will inevitably be followed in Australia.
Selection of Patients for Self-Monitoring

Self-monitoring can be considered for patients who are prescribed long-term warfarin (artificial valve prosthesis, recurrent venous thromboembolism (VTE), chronic AF and post myocardial infarction with impaired left ventricular pump function).48

A review of self-monitoring studies has identified the following patient criteria to assist appropriate patient selection:

- They should have a long-term indication for warfarin (AF, artificial valves, long-term prevention of DVT)49
- They must be over 18, or be supervised by someone who is over 1850, 51
- The patient must be willing to learn the testing procedure and perform self-monitoring48
- They need to have a basic understanding of their condition, their treatment, the potential for side effects, and the importance of regular testing, or be capable of learning this49, 50, 52, 53
- They must have adequate reading and writing skills – they need to be capable of maintaining documentation49, 54, 55
- They should have no symptoms of dementia, that is they must have sufficient memory and mentation/cognitive ability to follow simple home-monitoring instructions50, 55-57
- They must have sufficient visual acuity to operate the testing device51, 52, 53, 62-64
- They must have sufficient manual dexterity/adequate motor skills to manage the testing device49, 50, 52-53, 55-60
- They should have no physical limitations, especially affecting the hands such as Parkinson’s disease, residual damage from a stroke, or disabling arthritis51, 53, 57, 60
- They must not be considered too anxious about their health to monitor their own therapy52
- They should have no history of liver disease52
- They should have no diagnosis of antiphospholipid syndrome53
- They should have no coagulopathies51 such as antithrombin III deficiency
- They should exhibit no evidence of drug or alcohol abuse51, 52

The main determinant of a patient monitoring their own warfarin therapy is a willingness to do so; most patients who are able to lead an independent and self-supporting life are capable of self-monitoring, irrespective of education and social status.50-53. The most essential requirements are the ability to understand the concept of warfarin therapy and its particular risks and benefits, and sufficient manual dexterity and acuity of vision; although carers of patients unable to operate an INR monitor can be trained to do so.

Once the patient has expressed willingness to self-monitor, they must be appropriately trained to do so. All studies involving point of care INR monitoring have involved educational programs which not only train patients to use the monitor, but also provide detailed education regarding anticoagulation itself. In one recent study,54 patient self-monitoring did not result in a significant increase in the time that patients spent in the therapeutic range compared to controls. However, there were significant reductions in bleeding and thromboembolic complications which may be attributed to the training program. The ability to learn to self-monitor is not dependent on age, although age and co-morbidity also play an important role in the decision to participate.44
Training for Self-Monitoring

Provision of an education program is an integral part of self-monitoring. The main goal is to teach patients practical skills, which enable them to determine accurate INR results. Theoretical training is also essential to realise the full benefits of self-monitoring.

The key components of a self-monitoring training program include:

- Basic information on blood coagulation;
- Theoretical principles of drug interactions with oral anticoagulants;
- Dietary information;
- Disease specific information relating to the risks and benefits of anticoagulation;
- Practical information on self-monitoring with coagulometers;
- Signs of bleeding and thromboembolic events;
- Information on the frequency of INR monitoring and;
- Documentation of results and reporting of adverse events.

A training manual for patients was developed with a grant from the Australian Safety and Quality Council and was based on packages used in the UK and Germany. As a part of its development it was piloted with patients, pharmacists and doctors. It was also used in the Warfarin Home-Monitoring Pilot Study. In this trial it was used in both the group environment (three to five patients) and in the home setting (one on one). In the home setting, the theoretical component can be delivered in 45-75 minutes, depending on the patient. Practical training with the monitor then follows for approximately 30 minutes. At the end of the session, a test should be provided for the patient to complete to ensure that they have understood the basic theory behind anticoagulation (a Pre Self-Monitoring Assessment is provided in the Toolkit Templates). This can be completed on-the-spot or mailed to the community pharmacy if the patient prefers to revise the training manual before completing it.

It is useful to gauge the knowledge of the patient prior to the training session. A copy of a warfarin knowledge questionnaire is included in the Toolkit Templates. The advantage of having the patient complete this prior to the session is that it allows the trainer to target specific areas of knowledge during the session. It can also be used following the session to document the improvement in knowledge due to the training session as a means of quality control.
Liaison Strategies

Strategies and Suggestions

Deciding on the best anticoagulation service for your community

Every community is unique. Each community has different needs and a skill base comprising a variety of different talents and personalities. For these reasons it is not possible to provide a ‘one size fits all’ strategy for deciding what service is best for your community. This is something you must do, in consultation with the various stakeholders in your area.

The first step in deciding on a service is to look at the attributes of your practice and the potential users of your service. One way of doing this is to perform a SWOT analysis.

**SWOT Analysis**

```
Strengths
Weaknesses
Opportunities
Threats
```

A SWOT analysis enables you to identify:

- **Strengths**: attributes of your business that may facilitate offering an anticoagulation service
- **Weaknesses**: attributes of your business that may make it harder to offer a service
- **Opportunities**: external factors that may help your business offer an anticoagulation service
- **Threats**: external factors that may make it harder for your service to succeed
Liaison Strategies

SWOT analysis is an extremely valuable process that allows you to identify the subsequent steps in the planning of your service. It will help you determine what service is achievable for your business, and the factors which may assist or impede the success of this service.

Some points that may be useful to consider include:

Strengths and Weaknesses

☐ Do you have a personal interest in the anticoagulation area?
☐ Do you need to up skill to offer this service?
☐ How many staff do you have?
☐ How many staff do you need to offer this service?
☐ What are their skills and interests?
☐ Do you have access to accredited pharmacist services?
☐ Do you have a private counselling area with a sink?
☐ Do you have time to spend with customers to perform testing?
☐ How much time and money can you afford to invest in your service?
☐ What is your relationship like with the local GPs?
☐ Do you have formal channels of communication with your local GPs?

Opportunities and Threats

☐ What is the mix of concessional and general patients in your community?
☐ How many people do you service who take warfarin?
☐ What are their age/located/residential/transport details?
☐ What are their likely needs in relation to their warfarin therapy?
☐ Which of these needs are currently unmet or poorly met?
☐ Which service would suit these people best?
☐ How much do you think these patients would be likely to pay for these services?
☐ What other warfarin-related services are available in your community?
☐ How receptive will local health professionals be to this service?

Consider the above questions, and any others relevant to your pharmacy, when deciding on the SWOTs for your pharmacy in relation to providing an anticoagulation service. A blank SWOT analysis table is provided on the following page to assist you in this process. The factors you identify will inform your decision on which service you feel is best suited to your community.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

SWOT Analysis Tool

Liaison Strategies

Helpful
to a successful service

Harmful
to a successful service

Internal origin
(attributes of the pharmacy)

Strengths

Weaknesses

External origin
(attributes of the community)

Opportunities

Threats

Implementation Toolkit for Point of Care INR Monitoring Services in Community Pharmacy
Liaison Strategies

Once you have identified the service(s) you feel would be the most appropriate for your pharmacy to offer, it is time to consult others in your community to gain support for the service and identify and address any concerns other healthcare professionals may have.

Step One: Identify the stakeholders.

The most important stakeholders in this process are the people you service who are taking warfarin. These are the people who you want to use your service and you may discover some useful information on the type of service they would be likely to utilise.

Other stakeholders may include the local GPs, practice nurses, pathologists, hospital staff, community nurses, and anyone else in your community who plays a role in the care of people taking warfarin. The range of professionals you need to consult in your decision making process will depend on the community that your pharmacy services and the variety of other professionals and services offered in your region.

Step Two: Contact the stakeholders.

Ideally, a decision on what service is to be offered should be made by all stakeholders. Contact all the identified stakeholders and provide them with some background information on what you are trying to achieve. This should cover the range of possible services you are able to offer, and perhaps even an indication of which one(s) you would prefer to offer.

Step Three: Engage the stakeholders.

Face to face discussion is always a valuable tool for decision making, especially if it’s possible to get a number of stakeholders in the room together at the same time. If you are able to have a group discussion on the service that would be ideal, but given the difficulties you may encounter in simply talking to the stakeholders one-by-one, this may not always be possible.

Engage the stakeholders in discussion and take on board their opinions and address any concerns and suggestions they may have before deciding on the service to implement. Ensure you adopt a collaborative approach to deciding what service will be offered.

Step Four: Provide feedback to the stakeholders.

Keep the stakeholders informed of the decision that is made and the details of the service you will implement. These people will be vital providers of support and may also be the source of referral for many of the people who will utilise your service.
Deciding on a Service Checklist

1. Identify the service which is best suited to your business and community
   - Perform a SWOT analysis, taking into account the attributes of your pharmacy, the likely users, and the features of your community which may impact on the success of your service

2. Identify stakeholders in the community involved in the care of people on warfarin
   - May include: GPs, practice nurses, pathologists, hospital staff, community nurses, and clients

3. Contact the stakeholders, in person or via a letter
   - Provide background information – the range of possible services you can offer, why you’d like to offer them and which you’d prefer to offer

4. Engage the stakeholders
   - Discuss the possible services and which are best for your area
   - Ideally face to face as a group, can be individually and over the phone if necessary
   - Address their concerns
   - Adopt a collaborative approach to the decision

5. Provide feedback to the stakeholders
   - Keep them informed of the service you will provide
   - Seek support in providing and promoting your service
   - Invite them to refer clients to your service
Business Models

Every business operates under different business models and factors in different aspects of service provision when assessing the likely benefits to be derived from any given service.

Direct costs are often balanced both against direct profits and also against indirect profits such as customer loyalty and increased script volumes. It is important to remember that while it is possible to look at the theoretical costs and profits on paper it is in reality impossible to isolate any one service completely from other aspects of the business.

We will describe possible scenarios for each of the services in isolation and will attempt to identify areas where a more complex interplay of factors is likely to occur and further consideration is likely to be necessary.
Business Models

Pharmacy-based Service

A pharmacy-based service is one where INR monitoring is conducted within the pharmacy by the pharmacist, or under direct supervision of the pharmacist. It involves testing a patient’s INR with a portable monitor and relaying the result to the patient’s doctor.

There are a number of costs which may be taken into account when considering a pharmacy-based INR monitoring service. These may include:

- Cost of any consumables – e.g. test strips, lancets, gloves
- Cost of communication of results – e.g. phone or fax costs
- Staff costs for time
- Equipment costs – one off cost of the monitor
- Quality assurance costs – annual cost of enrolment in an external QA program
- Training costs – both initial and ongoing updates
- The rental cost for the space and the duration of time that the space is used

Pharmacies will have to decide what fee they wish to charge when providing an INR monitoring service. It may be useful to look at how much consumers should pay for the service to be profitable and compare this to how much they would be willing to pay. Pharmacists may need to ask a selection of people to whom they dispense warfarin how much they would pay for such a service. Pharmacies will then have to decide on a model to calculate this fee, taking into account both what may be acceptable to patients and what will be sustainable for the business.
Costs involved in providing a service:

In calculating a fee for your service there are a number of costs you may wish to take into consideration. (Calculations are based on estimated average wholesale costs.)

Fixed costs per test:
- Strip: $1.45/pk of 24 - 1 strip = $6.04
- Gloves: $1.45/pk of 50 - 2 gloves = $0.16
- Lancet: $1.45/pk of 200 - 1 lancet = $0.43
- Ph/Fax: $0.25/call - up to 2 calls = $0.50

Fixed costs = $7.13/test

You may also wish to pass on portions of the cost of the monitor and the external QA enrolment. (This assumes the life of a monitor is two years, although it is likely to be far greater than this.)

Monitor: CoaguChek XS - $800 - cost per month (over 2 years) = $33.33/month
External QA: RCPA enrolment - $490/pa - cost per month = $40.83/month

Costs = $114.16/month

Including a portion of the monitor and QA costs in the calculation will result in the cost per test differing depending on the number of tests performed by the service per month. As with many things, the more tests performed the lower the cost per test.

<table>
<thead>
<tr>
<th>Number of tests/month</th>
<th>Cost per test ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>21.96</td>
</tr>
<tr>
<td>10</td>
<td>14.54</td>
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<td>15</td>
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<tr>
<td>45</td>
<td>8.77</td>
</tr>
<tr>
<td>50</td>
<td>8.61</td>
</tr>
</tbody>
</table>

Table: Cost per test based on an average number of tests per month over two years.

For example, if you were to conduct 25 tests per month and charge $10 per test you would break even here.

Figure: Cost of test vs. average number of tests per month over two years.
Business Models

Costs to patient:
Pharmacists may determine the patient charge in a manner which best suits their business and patient demographic. For simplicity, we present three examples of charges to the patient. Costs are calculated based on performing an average of 25 tests per month over a two year period, with an average test cost of $10 per test (as shown in Table 1 above). The profit at varying numbers of tests per month for each example is presented in figure 2 below.

Example One
Cost recovery only – in this example the cost to patient would be $10 per test (remember – this example is based on performing an average of 25 tests per month over two years, if your estimated average number of tests per month you will need to adjust the $10 figure accordingly).

Example Two
Addition of a professional fee of $5 – this example is based on the current model of payment for dispensing a PBS item. That is, the payment is the cost of the item plus a professional fee. In this example the cost to the patient would be $15 per test.

Example Three
Addition of a professional fee of $10 – in this example the cost to the patient would be $20 per test.

![Profit per month vs. number of tests per month](image)

Figure 2: Profit per month vs. number of tests per month
As you can see from the above examples, the calculation of what to charge the patient for this service may be influenced by a number of factors. Factors may include patient demographics, demand for the service, and the charging structure for other professional services offered by the pharmacy.

The major factor influencing the profitability of the service is the number of tests that the pharmacy expects to perform per month. In Example One, charging on a cost recovery basis, a pharmacy will need to perform 25 tests per month to break even. Pharmacies may wish to consider the addition of a professional fee, as in Examples Two and Three, to increase the profitability of the service, particularly at lower testing volumes.

It is also important to remember that these services will not operate in isolation. The bigger picture takes into account the potential for increased dispensing volumes, increased patient loyalty, and in the case of POC INR monitoring, increased patient interest in the POC device. Exposing patients to the concept of using the portable monitor is a powerful tool. It can be used as a means of encouraging patients who are suitable for and interested in self-monitoring to purchase a device and take on this task themselves. As outlined below, training a patient for self-monitoring and providing them with the device and consumables can be very profitable.
Business Models

Outreach Services

Outreach services are defined as those offered outside the pharmacy environment by a pharmacist, for example in a patient’s home or in a residential care facility. They are ideally offered in conjunction with a pharmacy-based service. This will ensure that the monitor is enrolled in an external QA program, and that the training requirements are governed by the individual pharmacy's policy on anticoagulation monitoring.

In such a situation the cost of performing a test outside the pharmacy, for example during a Home Medicines Review (HMR), would be the pharmacist’s time, travel costs, and the consumables. The cost of consumables, including around 10 minutes time, is around $13.80 per test.

There are a number of possible ways to cover this cost.

If the test is being performed as part of an HMR the suggested options would be:

- Absorb the cost of the time and consumables in the HMR payment
- Charge the patient for the cost of the consumables and a professional service fee
- If the service is offered in the pharmacy and this patient is a client of your service, the test performed during the HMR would ideally coincide with one of the scheduled tests and it would then be appropriate to charge the patient whatever the pharmacy fee usually is

If the test is being performed as a service to a residential aged care facility, or other residential facility, it would be appropriate to negotiate a cost with the facility that takes into account the increased convenience of having testing performed in their facility and results available for immediate dose adjustment. This fee may be impacted on by the current cost of that testing to the facility and perhaps any transport costs this new monitoring service would save them.

Above all, it’s important to ensure there is value in performing a test outside a pharmacy. That is, it is important to ensure the test will be performed at a time which will allow for rapid dosage adjustment, or the value of the POC testing method will be negated.
Self-Monitoring Training

Patient self-monitoring involves the patient monitoring their INR themselves and communicating the result to their doctor for dose adjustment. It is strongly recommended that the sale of POC INR devices is accompanied by comprehensive education on anticoagulation and training in the use of the device.

Training patients for self-monitoring and supplying all the necessary equipment and consumables can be the most profitable anticoagulation service a pharmacy can provide.

Pharmacies can firstly facilitate the purchase of a portable device. Depending on the wholesale price your pharmacy receives, and the retail price placed on the device, the profit derived from the sale of a device can be attractive. There is also the ongoing profit to be made on the sale of the strips and the lancet devices. On top of this the pharmacy has the potential to derive an income from training the patient to use the device.

Training is the most important step in this process and should be conducted by a pharmacist who has undergone additional training in anticoagulation theory and the use of the portable device (for more information on pharmacists in your area who have undertaken this training, or to undertake the training yourself, please contact UMORE). It is not something that should be rushed or brushed over. In saying this, there are a number of models available for remuneration for training a patient to perform self-monitoring.

- The ideal option is to obtain an HMR referral from the patient’s GP. All patients taking warfarin, particularly those commencing a new monitoring method such as self-monitoring, are eligible for an HMR as they are taking “a medication with a narrow therapeutic index or medications requiring therapeutic monitoring”. The suggested structure for the HMR is to cover basic HMR topics as well as spending a large portion of time on an intensive warfarin education session. This is then followed by training in the accurate use of the device.
- The second option is to absorb the cost of training in the profit derived from the sale of the monitor. This is not the ideal method but would be encouraged if there is no other avenue to pursue to cover the cost of training. Training should always be provided to people purchasing a device.
- The third is to obtain payment from either the patient or a third party (perhaps a health insurer). This method may be possible in a small number of cases.

Obtaining an HMR referral is the preferred option for a number of reasons:

- It involves the patient’s GP in the care process and the GP receives a report on the outcome of the training;
- The training is at no cost to the patient; and
- The payment for the training is in line with the amount of time required for comprehensive training to be delivered.

This is a profitable service to provide to interested and suitable patients and it may be used to complement a pharmacy-based service.
Standard Operating Procedures

Introduction
Aim of service
- To offer standardised and clinically effective monitoring of patients undergoing oral anticoagulation therapy in order to ensure good INR control and to reduce complications.

Objectives
- To ensure patients have equitable access to a convenient, community-based INR monitoring service tailored to local needs;
- To provide comprehensive and ongoing education and support of patients so that they understand their therapy better, in terms of their indication for warfarin, optimal range for INR, the effects of poor control, diet, lifestyle, and drug interactions;
- To cater for patients with special needs such as poor compliance and unstable INR controls;
- To ensure complete and accurate documentation of the service, including quality control procedures; and
- To facilitate education and training sessions for patients who wish to monitor their own INRs, in consultation with the patients and their doctor.
Standard Operating Procedures

Point of Care INR Monitoring

POC INR monitoring may occur in a pharmacy-based monitoring service or at the patient’s home, and may be conducted by a suitably trained person or by the patient themselves.

Contraindications to POC INR testing depend on the type of testing service in question. The major contraindication is a diagnosis of antiphospholipid antibodies, including lupus anticoagulant, as POC INR devices cannot currently guarantee accuracy for these patients.

Pharmacy-based service

Where POC monitoring (or self-monitoring) is available, and medically appropriate, patients should be informed of the options. A record should be made of the patient’s choice.

Routine monitoring should be managed by a regular appointment system, with prompts for contacting people who do not attend their appointment. There should be the flexibility to arrange prompt additional INR tests as appropriate (due to interacting medications or change in patient condition) whether initiated by the service or by the supervising medical officer.

The service should ensure that each patient has current documentation which includes a record of diagnosis and the therapeutic range to be obtained. Quality control should be obtained through participation in an external quality assurance (QA) program, and may be complemented by periodic comparisons between POC and pathology results.

The service must actively promote the education of patients (and/or carers where relevant) so they can understand the treatment and management of their condition better.

Outreach services

Pharmacies may wish to provide outreach INR monitoring services, for example performing an INR check whilst conducting an HMR. In these instances the POC device should adhere to the same quality control measures as those based in a pharmacy-based monitoring service.

Patients should provide consent to be tested and the result must be communicated to the responsible medical officer in an appropriate time frame.

Education of patients and/or carers must be provided in this setting also.

Patient self-monitoring

Patients wishing to self-monitor their INR should be encouraged to discuss this with their doctor.

It is strongly advised that supply of the POC device be accompanied by a comprehensive education and training session. All relevant aspects of warfarin therapy should be discussed and followed by hands on instruction on the accurate use of the monitor. An INR record book should be provided and the importance of recording the INR results and communicating them to their doctor in a timely manner should be emphasised. Quality control must be included and could be provided by periodically comparing POC tests with pathology results or participation in an external QA program.

Ongoing support should be offered to consumers performing PSM.
Infection Control

POC INR monitoring services are not without risk to the person conducting the test. These risks can be minimised through correct infection control procedures.

Testing should only be conducted in the designated professional area, not in the general retail area. The work area should be cleaned daily with surgical spirit or similar, and all blood spills should be cleaned up immediately using 70% ethanol or an appropriate disinfectant.

Standard infection control precautions

Standard precautions for infection control apply to INR monitoring. Standard precautions are the minimum requirements for skin puncture procedures and should be adhered to regardless of the infectious state of the patients. Standard precautions include:

- **Using single use gloves**
  - Gloves should be used whenever INR testing is performed
  - The pharmacist should wash their hands before and after using gloves
  - Gloves should be taken off carefully and discarded immediately following INR testing
  - Gloves should be changed in between patients to minimise the risk of cross infection
  - Where gloves become damaged, they should be changed immediately

- **Proper hand washing**
  - Hands must be washed:
    - Before and after performing INR testing and in between patients
    - After contact with body fluids irrespective of whether gloves are worn or not
    - After contact with equipment soiled with blood or body secretions (including dried blood)
    - After going to the toilet and before and after eating or smoking
  - Hands should be washed using either plain soap or alcohol based rub (see the Hand Washing Guide in the Toolkit Templates)

- **Appropriate and safe handling of sharps**
  - Handle sharps and needles with care at all times
  - Single use lancet devices should be used

- **Cleaning/disinfecting all instruments and equipment**
  - Single use equipment should be used to minimise the risk of cross contamination. INR meters should be disinfected using a damp cloth with 70% ethanol after each patient.

- **Waste disposal**
  - All sharps must be disposed of in an approved sharps container after use. It is the responsibility of the user of the sharp to ensure its safe disposal.
Standard Operating Procedures

In the event of a needlestick injury:

- Wash the injured area well with soap and water (antiseptic soap if available)
- Record the incident including:
  - Where and when the incident occurred
  - Nature of activity
  - The persons involved
  - Details of the injury
  - What type of instrument was involved in the injury (as much detail as possible)
  - Amount of exposure to bodily fluid and type of bodily fluid

An example incident Report Form is provided in the **Toolkit Templates**

- Call the National Needlestick Hotline (1800 804 823) for further advice
- Consult your doctor for necessary follow-up testing
Standard Operating Procedures

Instructions for Use – CoaguChek XS

For more detailed instructions refer to the CoaguChek XS Training Guide in the Toolkit Templates or the CoaguChek XS User’s Manual.

Setting up and obtaining a result:

- Check the expiry date of the test strips.
- Ensure the client’s hand is warm – wash under warm running water and dry first.
- Insert a test strip into the monitor, with the arrows facing towards the monitor.
- Confirm the displayed batch number is correct before pushing the ‘M’ button.
- Wait until the monitor has warmed up and begins to count down from 120 seconds.
- Using a single use lancet (e.g. AccuChek Safe-T Pro Plus) perform a puncture on a finger pad (usually to the side of the finger pad causes less pain).
- Lower the hand to facilitate good blood flow to the puncture site.
- Apply a drop of blood to the test strip within 15 seconds of lancing. The drop can be applied to the top or the side of the strip.
- Ensure the drop is large enough to fill the cut out. The machine will beep when the blood has been received.
- Apply a cotton ball to the finger and ask the patient to apply firm pressure.
- It will take around 45 seconds for the result to be displayed on the screen.
- Dispose of the test strip and lancet into a biohazard container.
- Avoid excessive squeezing of the finger to obtain a sample.

If the INR result falls outside the range established by the supervising medical officer, it is usually recommended to repeat the procedure and record the higher of the two readings.

When repeating a reading it is important to recognise that the clotting process will have been initiated in the first finger. A new finger needs to be used for each subsequent attempt.

Refer the patient to their doctor or to pathology to have any unusual results confirmed.
Standard Operating Procedures

Troubleshooting:

- Common causes of sample collection problems:
  - Hand too cold
    - Avoid by ensuring the hand is warm by running under warm water and drying before testing
  - Not enough blood
    - May be due to:
      - Shallow skin puncture leading to insufficient blood flow
      - Puncturing in an awkward spot
      - Collecting blood which has been smeared away from puncture site
      - Scooping blood along the skin as it dribbles from the puncture site
  - Avoid by setting the lancet device to the appropriate depth and puncturing a site on the finger pad. Only collect blood that has formed a ‘hanging drop’ at the puncture site. Never add more blood to the strip after the test has begun.
  - Other causes of result error
    - Squeezing the finger too hard to obtain a sample
    - Reusing a puncture site after an unsuccessful test
    - Avoid by elevating the elbow and lowering the hand. Always use a new finger for each new sample.

- Error codes – CoaguChek XS
  
  For more detailed error codes refer to the Error Codes sheet in the Toolkit Templates or the CoaguChek XS User’s Manual!

  - Error 000 – Time allowed to apply sample has been exceeded
  - Error 3 – Expired strips
  - Error 4 – Unusable strip
  - Error 5 – Insufficient blood applied to strip
  - Errors 6 & 7 – Measurement errors
  - Error 8 – Diagnostic testing error
  - Test strip symbol flashing – Either a strip is in the monitor when turned on (needs to be removed and re-entered) or the test strip is unusable
  - Temperature symbol flashing – Monitor too warm or too cold
  - Battery symbol flashing – Battery level too low
    (replace batteries)
  - QC symbol flashing – Test strip unusable (failed QC)
  - Code symbol flashing – Error with the code chip

  Another common error is that people may accidentally press the set button, changing the date format or the date itself, resulting in the machine reading the test strip as expired.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Standard Operating Procedures

Maintenance

There should be designated responsible person(s) for overseeing the INR monitoring equipment. This person should be responsible for the maintenance of stocks of consumables and reagents within their shelf-life, and ensuring the monitor is functioning properly. This includes checking expiry dates and ordering necessary equipment.

Servicing and warranty

It is important to keep a record of any maintenance, faults and corrective actions and repairs that are carried out on the monitor. These details should be recorded in the machine's logbook. If there is only one monitor in the pharmacy these details can be recorded in the service's logbook (a template is provided in the Toolkit Templates). If there is more than one monitor, a logbook should be kept for each.

Every machine is covered by a manufacturer's warranty. For more details, refer to the package insert.

Battery replacement

When the batteries are losing capacity the battery symbol will lose segments. Batteries should be replaced as soon as practical after this begins.

Temperature

The monitor is temperature sensitive and will only function between 18°C and 32°C. The monitor will display the thermometer symbol outside this range and will not give a result. Wherever possible, testing should be performed in an environment within this range.

Cleaning

Always clean the monitor before starting a new box of test strips or if it becomes visibly dirty.

Procedure for cleaning:

For more details on maintaining the monitor refer to the CoaguChek XS User's Manual

- Ensure the monitor is turned off.
- Use a clean moistened cloth or cotton bud to wipe the external surface of the monitor, with particular emphasis on the area around the test strip chamber. Use water (with or without washing up detergent) or 70% ethanol or isopropyl alcohol.
- Dry the monitor with a soft cloth.
- To clean the test strip chamber, lift the blue flap until it is fully open.
- Clean the easily accessible white areas with a lint free swab or cotton bud.
- Allow the area to dry for around 10 minutes before reattaching the housing.

Cleaning the test strip chamber
Standard Operating Procedures

Quality Assurance

Quality Assurance broadly describes any measures taken to ensure the reliability of testing and reporting. Thus, it encompasses the calibration of the monitor, taking the sample from the patient, analysis and accurate recording of the results.

Quality Assurance is comprised of two equally important entities. These are internal quality control (IQC) and external quality control (EQC). Both are essential in demonstrating that any monitoring system is providing precise and accurate INR results.

Internal Quality Control

IQC establishes the day-to-day consistency of results from one monitoring system. Therefore, IQC is a measure of precision only and variances may alert to problems with the storage of test strips or the workings of the monitor. Basically, IQC ensures that the results obtained from the system are consistent enough to make a decision regarding the next dose of warfarin.

All of the portable INR monitors available in Australia feature inbuilt IQC in the test strips. An INR result will not be provided if there is a problem with the IQC test.

External Quality Control

EQC is used to identify the accuracy of the results against a standard, and the degree of agreement of measurements from one centre to those of another. Thus, EQC assesses the accuracy of the results obtained from a given system compared to a standard measure.

There are a number of possible approaches to EQC for POC INR monitors. One is to periodically compare results between a POC device and a laboratory, known as parallel testing. For example, a client can have a pathology sample drawn and have a POC INR test performed within four hours of the pathology sample being taken. INR deviation of up to 15% is considered acceptable for clinical purposes (Murray, 2003).

There is also a formal external QA program, provided by the Royal College of Pathologists of Australasia. The POC-INR program distributes samples for 5 surveys at the beginning of the survey year to periodically analyse performance for the INR test. Contact details for enrolment in this program or assistance with the samples can be found in the Contacts section of this manual. More detailed instructions on how to perform EQA with these samples can be found in the Toolkit Templates.

Whatever approach is used, it is imperative that EQC is conducted at regular intervals and the results documented to ensure the accuracy of the monitor, as is a requirement for pathology and hospital laboratories.
Accreditation

There is currently no formal pharmacy-based accreditation process for pharmacies to offer anticoagulation services. However, there are a number of suggestions to assist pharmacists run an effective and efficient service.

Staff

All staff involved in providing care for patients must have the necessary training and skills to undertake their duties safely. This should be reviewed annually (ideally as part of the standard staff appraisal process) and attendance at update training sessions should be mandatory.

Training should be conducted by someone who has undergone comprehensive training themselves. It should cover both the theoretical and practical aspects of warfarin and INR monitoring. That is:

- An introduction to oral anticoagulant therapy, an understanding of the test to be performed, the INR and how it is derived.
- An understanding of the POC device used, setting up and using the device.
- The target INR, how it is related to the diagnosis and actions if results are outside limits.
- Recording of results and quality assurance materials.
- Occupational health and safety – disposal of sharps.

Trainees should be given access to written training materials, prior to the training session if possible. On completion of training, the theoretical and practical instruction should be formally tested by the trainer. If possible, candidates should have a period of testing under supervision to check competence before performing monitoring alone. After successful completion of training, trainees should be given a certificate of competence (an example is provided in the Toolkit Templates). If possible, encourage a representative from the manufacturer of the POC device to be involved in supporting hands on training.

Quality Care Pharmacy Program

It would be useful to incorporate the procedure for INR monitoring into the pharmacy’s QCPP procedure, in the same manner as there are procedures for blood glucose testing (see an example provided in the Toolkit Templates).

Quality Assurance

The service must be able to demonstrate acceptable external QA procedures, such as participation in the RCPA program described on the previous page. An operator or device that fails to perform to specification of this program must be withdrawn immediately from service until full remedial action has been completed.

Parallel testing with patient and pathology samples, as described above, may also be beneficial every three to six months to confirm the ongoing accuracy of the service being provided.
Standard Operating Procedures

Record Keeping

Successful warfarin management relies on well kept records, both for monitoring services and for individuals.

Registers

The pharmacy should hold an up to date register of all patients participating in the service including patient name, date of birth, indication for and duration of treatment, and the target INR (a template is included in the Toolkit Templates). All patients' results and details must be treated as confidential and kept in a secure place.

All patient and QC/QA results must be recorded in a service log book, a record held by the patient, and sent to the appropriate GP or medical officer (a template is included in the Toolkit Templates). The patient log must include unequivocal patient identity, time of test, the result, and the identity of the staff member who conducted the test. A record must be kept of all QC results, and a machine maintenance log, including the batch and expiry details of the test strips in use, must also be kept.

Results

A monitoring service should have a strict procedure in place for reporting the INR results to the patient's medical officer. Individual arrangements may be made with particular doctors.

In the absence of an individual arrangement it is recommended that:

- The INR result is recorded in the service logbook, the patient file and the record book/form held by the patient.
- A copy of the INR result is forwarded to the doctor for inclusion in the patient file by a method convenient to the local surgery (in the absence of a preference from the surgery, fax is the recommended method). This may be done immediately after each patient visit, or at the end of each day, depending on the number of clients seen by the service and the preference of the supervising medical officers.
- If the INR result is outside the target range, or there is another indication for contacting the doctor, the result should be transmitted by telephone while the patient is still in the pharmacy to allow for prompt action to be taken.
- If the INR is above 5, assist the patient to get an appointment with their doctor that day.
- If the INR is greater than 7, advise the supervising doctor. If the doctor is not immediately available, refer the patient to hospital.

Always record any action you take to report out of range results in the patient log.
Appointments

Running the service with appointments ensures the opportunity exists to identify patients who do not attend their scheduled tests. A specified staff member needs to be given the responsibility to track and follow up patients who miss their appointments. This task should be performed daily. It is the pharmacist’s responsibility to remind patients or their relevant medical officer if they fail to attend for planned testing. It may be most efficient to run the service as a clinic, with appointment times made in advance in an appointment book (a template is included in the Toolkit Templates).

Anticoagulation Monitoring Services

It is a good idea to make the service an agenda item at staff (or dispensary) meetings. This gives the staff member in charge of running the service a chance to update the rest of the team on any issues that may arise.

Patient Self-Monitoring

Patients should be encouraged to keep a record of their warfarin dose and INR results in a patient held INR record book.

<table>
<thead>
<tr>
<th>Week beginning (date)</th>
<th>Recommended Warfarin Dose</th>
<th>Date of test</th>
<th>INR result</th>
<th>Next appointment/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/02/09</td>
<td>X X X X X X X</td>
<td>12/02/09</td>
<td>2.3</td>
<td>26/02/09</td>
</tr>
<tr>
<td>18/02/09</td>
<td>X X X X X</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(“X” shows where you would write your warfarin dose.)

Example of an INR record book.

They should be encouraged to record pathology INR results on this form, when conducted, to confirm the accuracy of their testing method compared to pathology. Also, any comments, missed doses or illnesses should be noted in such a record to explain variances in INR results when reviewed.

An example of an INR record form can be found in the Toolkit Templates.
Standard Operating Procedures

Incident Reporting

Procedures must be in place for dealing with adverse incidents. These may include unexpected results, unpleasant encounters, and problems that occur during testing. All staff providing the service should have appropriate indemnity cover to meet in full any claims made against them as individuals.

Unexpected results

A clear procedure should be in place for dealing with INR results outside the patient’s target range. It is recommended that the test be repeated to confirm the result. If the result is still outside the target range a referral process needs to be in place. It is recommended that the doctor be contacted to oversee the decision making.

Generally, the patient should be referred for a pathology test to confirm the reading and action should be taken to correct the INR.

There should be an arrangement in place with the local surgeries to facilitate timely communication between the doctor and the pharmacist on the course of action to be followed. This communication should be recorded in the patient log.

Unpleasant encounters

Unpleasant encounters, including patients being unhappy with how a puncture was obtained, should be dealt with in line with pharmacy policy. If the pharmacy doesn’t have a procedure for recording such occurrences, it is recommended that the details of the event are recorded in the patient file for future reference. An example of an Incident Report Form is provided in the Toolkit Templates.

Problems occurring during testing

This may include staff contact with patient body fluids, needle stick injuries or the patient becoming unwell.

The pharmacy policies on dealing with biologicals, sharps and skin contact should be followed. Generally, this is a low risk testing procedure. Following the pharmacy procedure and using the recommended equipment will further minimise the risk of incidents occurring.

- **Always** use single use lancets. This will mean that staff can only be punctured by unused needles.
- **Always** wear gloves.
- **Always** provide the patient with a cotton ball or tissue and ask them to apply pressure to their own puncture site.
- **Always** clean up any spills immediately, wearing gloves, with disinfectant or soapy water.

In the event of suspected contamination, flush the area with cold water and soap or disinfectant, follow the pharmacy policy, and obtain medical advice.

If the patient becomes acutely unwell the relevant pharmacy policies for this should be followed.
Anticoagulation Service Procedure

It is important that all staff are trained and confident in the testing procedure. Only staff whose training and competence has been established and documented should use the device. Highly visual laminated posters with simple step-by-step instructions to consolidate detailed information into a practical, workable format are useful to display in the testing area to prompt staff on how to perform a POC test. (See the Wall Chart and CoaguChak training guide provided in the Toolkit Templates)

Practical considerations for providing an in-pharmacy INR testing service include:

- The availability of a dedicated ‘professional services’ area. An area where confidential consultations can take place with access to a sink and sharps disposal. Ideally, this area should be set up to facilitate provision of the services offered, and all the equipment for these services should be readily available in this area.
- The ability to contact a GP or the responsible medical officer at the time of the test, in the event that the result is outside the range. The availability of the patient’s doctor may determine the times that you are able to provide testing. If there is no doctor available in your area on Saturday mornings, there may be no value in providing testing at this time unless an appropriate protocol is in place to deal with the results and for dosage adjustments to be determined. Methods of communicating the result to the relevant medical officer are suggested in the Record Keeping section.
- The mechanism for the transfer of results from the device to the patient record, log book, and doctor must be clearly understood by every staff member providing the service.

An anticoagulation monitoring service should strive to provide more than simply an INR result. Counselling patients with respect to their anticoagulant treatment is fundamental and significantly improves patient’s knowledge and quality of anticoagulation. Patient knowledge is important for safe and effective anticoagulant treatment. It is important to discuss with patients:

- The reason for taking warfarin and how it works;
- The INR and the concept of the target range;
- The importance of compliance and of recording missed doses;
- The possible effects of poor INR control – including bleeding and thrombotic events;
- Appropriate action in the event of bleeds or illness;
- Interacting medications and appropriate actions before changing treatments;
- The role of vitamin K, diet, and alcohol; and
- Practical advice on minimising bleeding risk.

See also the Checklist for Counselling in the Toolkit Templates.

Patients should be provided with an INR record booklet and encouraged to keep it up to date, and to take it to all doctors’ appointments and INR test appointments.

A pre-test questionnaire can be a valuable tool for identifying possible causes for unexpected results including compliance issues and interactions (an example questionnaire is provided in the Toolkit Templates).
Outreach Service Procedure

Performing POC INR testing during an HMR, or as an outreach service to those in their homes, can be a valuable service to offer.

A few points for consideration in offering such a service include:

- Will this service be offered to every patient taking warfarin referred for an HMR?
- How will the test be paid for? Will it be absorbed as a portion of the HMR payment or will the patient pay?
- What procedure will be followed for out of range results obtained outside the hours the patient’s doctor is contactable?

Ideally the monitor used for outreach services will be one which is based in a pharmacy. This will ensure that it is governed by the same maintenance and QC procedures as a pharmacy-based monitor. Monitors owned privately by a pharmacist should still follow the same QC principles, and should be enrolled in an external QA program to ensure accuracy of results.

The pharmacist performing the testing should have undergone the same comprehensive training as pharmacists performing pharmacy-based services.

The testing procedure followed should be the same as that used in a pharmacy-based service, including the use of gloves, single use lancet devices and the availability of a biohazard container.

There should be a procedure in place for reporting the results. It is suggested that this be similar to the pharmacy-based service procedure. Results which are out of range should be reported to the patient’s doctor by telephone as soon as possible to allow for action to be taken. Results within the range may be reported to the doctor that day or may simply form part of the HMR report. This may be something that needs clarifying with the relevant medical officers in the area if offering this service.
Self-monitoring Training

Point of care INR monitors are now readily available from all major pharmaceutical wholesalers. There is an increasing awareness of the devices among consumers and as such an increasing importance to train consumers to accurately use the device.

Equally as important as training patients to use the device is giving them the knowledge to know what the result means and what they need to do with the result once obtained.

There are a number of models available for training patients to use the monitor. Most cover a number of common components involving warfarin theory and hands on training.

Where possible, it is recommended that the training is conducted in the patient’s home. An ideal model for this is the HMR model, which allows for both remuneration for the service provided and the involvement and feedback to the patient’s GP.

If incorporating into an HMR, the training should ideally include:

- An HMR that covers all important aspects of the patient’s therapy, with the main focus warfarin therapy and training.
- Warfarin education (covering all the usual counselling points – see the Checklist for Counselling in the Toolkit Templates).
- Hands on training on the use of the portable monitor, including practice using the monitor.
- Discuss the correct finger prick procedure, possible sources of error, and recording of results.
- Discussion of the run in phase to compare POC results with pathology, the method of transmitting results to the GP, and the people to contact if having trouble with the device.

(See also the Checklist for Training in the Toolkit Templates)

Ideally the pharmacist who conducts the training will have undergone a comprehensive training course to up-skill them in the delivery of warfarin education and the training of consumers for self-monitoring. A training manual and DVD modules are available for accredited pharmacists interested in training patients to self-monitor. Please contact UMORE to obtain these materials.

Additionally, a manual is available to assist in the training of patients to self-monitor. It covers comprehensive warfarin information and training advice. To obtain copies of this manual please contact UMORE (details in the Contacts section).
Standard Operating Procedures

Modifications to the Standard Operating Procedures

It is important to periodically review the SOPs to ensure they are up to date and reflect the procedures that are implemented in practice.

It is essential to update them when a new device is purchased or if the manufacturer’s instructions for use change.

It may be useful to update them when updating QCPP procedures every second year unless the need arises earlier.
Getting Started Checklist

1. Determine the service most suited to your business
   - SWOT Analysis
   - Engage your stakeholders
   - Provide feedback to your stakeholders (may be in combination with marketing)

2. Training
   - Train selected staff
   - Participate in continuing education programs where appropriate
   - Subscribe to external quality assurance program

3. Procedures
   - Read the procedures supplied
   - Modify and implement the procedures for your pharmacy

4. Marketing (use whichever is appropriate to your business and community)
   a. To patients
      - Use your dispensing database to identify patients on warfarin
      - Contact/inform these patients, whether in person or by letter, regarding the new services being offered
      - Hang posters in prominent locations
      - Display a sample of the CoaguChek XS packaging
      - Provide patient with the promotional brochure
      - Advertise in local media
      - Mention the benefits of home and in-pharmacy testing
   b. To health professionals
      - Mail a letter of introduction about your services to the General Practitioners of your anticoagulated patients
      - Mail a letter of introduction about your services to healthcare facilities
      - Post the promotional poster in medical clinics with their approval
      - Organise a continuing education session with other health professionals in your area
      - Contact/inform the local pathology provider if appropriate

5. Set up the testing area
   - Establish a patient file management system
   - Establish an appointment booking system
   - Establish a logbook system for results and maintenance
   - Display procedures
   - Purchase equipment:
     - Monitor
     - Test strips
     - Single use lancets
     - Alcohol swabs
     - Gloves
     - Biohazard disposal container
     - Tissues/cotton balls
     - Cleaning equipment (alcohol-based)
Letter to Doctor

Re: PHARMACY-BASED INR MONITORING SERVICE

Dear Doctor,

Following consultation with healthcare professionals in the area, we are pleased to inform you that our pharmacy will soon begin offering an anticoagulation monitoring service to patients on warfarin.

This service will include education, point of care INR testing, and liaison with the patients’ general practitioner to convey an appropriate dose adjustment.

We hope to offer this service to any interested patient, but will encourage them to discuss the service with their GP prior to participation. Patients will be given a short form to fill out in consultation with their doctor detailing their target INR, indication for warfarin, and desired frequency of testing. An example is attached.

You will receive test results and all other relevant information about your patients by phone or fax, as you prefer, through a patient follow-up form. An INR file for each patient will be available at the pharmacy.

Our service will utilise a CoaguChek XS device which offers laboratory-comparable INR results in just minutes. Our pharmacists have completed specialised training and the pharmacy is enrolled in an external Quality Assurance program to ensure patients receive accurate and precise results and quality care.

Benefits to your practice and patients may include:

- Less time needed to manage anticoagulated patient files
- Rapid follow-up on INR testing results
- Immediate dosage adjustment for better therapeutic management
- Increased support from another healthcare professional

If you have any questions about the service please do not hesitate to contact us on the above details.

We look forward to working with you to enhance the care of people taking warfarin in our community.

Yours Sincerely,
Local Newspaper Advertorial Suggestion

People taking the anti-clotting medication warfarin will be able to take advantage of a new service to monitor their therapy, offered by XXX Pharmacy, from this week.

Warfarin is a medication taken by an estimated 200,000 Australians. It is very effective in reducing the risk of stroke and other clotting complications. Unlike many other medications, there is no easy way of working out what dose a person needs to take. Doses are adjusted for each individual person using regular blood tests, and a person’s dose may change over time in response to many changes in their food and alcohol intake, other medications, general health and well-being and other factors. As such, it is important that people taking warfarin have blood tests at least once a month to ensure that their warfarin dose is appropriate and doesn't need adjusting.

XXX Pharmacy is now offering a service which allows people to have their warfarin therapy monitored by a fingerprick blood test performed in the pharmacy. Trained staff will use a new machine, which looks a bit like a blood sugar monitor, to perform these blood tests. The result is available immediately and will be reported to the person and their doctor so that dose adjustments can occur quickly and easily. As the test uses a fingerprick sample of blood, it's a great option for people who have trouble with usual blood tests.

If you are interested in finding out more about having your warfarin monitored using this new service, call in and see XXX or one of the other pharmacists at XXX Pharmacy or call XXX.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen
INR Monitoring Service – Consumer Advice and Consent Form

Statement to Consumer

Thank you for your request for an INR test. You have voluntarily asked to participate in a monitoring service which involves a blood test where a blood sample is obtained via a finger prick method.

You advise us that you have no communicable disease or other medical condition that would otherwise prohibit you from participation in this monitoring service.

We provide the monitoring service under strict health and safety guidelines. We also assure you that the privacy and security of all of your details is protected by law. Please ask to see our privacy policy for further details.

Consumer Full Name: __________________________
Address: ______________________________________
Date of Birth: ___/___/____ Phone (or mobile): ________________________________
Doctor: _______________________________________

Consumer Declaration

I have read and understood the above information. I have had time to ask staff questions prior to testing, am satisfied with the procedures, and voluntarily agree to participate. I understand that the test results will be forwarded to my doctor.

Consumer signed: ___________________________ Date: ___/___/____

Staff on duty witness: __________________________
### Appointment Book Template

<table>
<thead>
<tr>
<th>TIME</th>
<th>Mon</th>
<th>Tues</th>
<th>Wed</th>
<th>Thurs</th>
<th>Fri</th>
</tr>
</thead>
<tbody>
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<tr>
<td>12.00</td>
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</tr>
</tbody>
</table>

**INR Monitoring Service:** Appointment Book

**INR Monitoring Services in Community Pharmacy**

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**Implementation Toolkit for Point of Care INR Monitoring Services in Community Pharmacy**

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Ella Claire van Tienen
Pre-Test Questionnaire

Name: 
Date: ___/___/___

How did you take you warfarin over the last two weeks?
- Strength and/or colour of tablets: 
- Number of tablets per day: 
- Number of times per day: 
- Time taken: 

<table>
<thead>
<tr>
<th>Orphans</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Do you take any over-the-counter medication? (please write on the back if you need more space)
Please specify: 

Do you take any natural products? (please write on the back if you need more space)
Please specify: 

Do you take any food supplements? (please write on the back if you need more space)
Please specify: 

Are you suffering from any new health problems that can or cannot be treated by medication? (e.g. high blood pressure, thyroid problems, diabetes)
Please specify: 

Have you stopped taking any medication?

Has there been a change in dosage of any of your medication?

Have you forgotten any of your warfarin doses in the last 2 weeks?
How many?

Have you significantly increased your physical activity level?

Have you significantly increased your diet of green vegetables? (e.g. broccoli, asparagus, spinach, cabbage, lettuce)

Have you had any bleeding since the last INR test?
Recently, have you had diarrhoea?
... vomiting?
... fever and/or shivers?
Recently, have you been sick?

Did you stop drinking on a regular basis?
Did you stop smoking? If yes, when?

Have you significantly decreased your physical activity level?

Have you significantly decreased your diet of green vegetables? (e.g. broccoli, asparagus, spinach, cabbage, lettuce)

Implementation Toolkit for Point of Care INR Monitoring Services in Community Pharmacy
### INR Monitoring Service - Consumer File

<table>
<thead>
<tr>
<th>Last Name:</th>
<th>First Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>Phone (home):</td>
</tr>
<tr>
<td></td>
<td>Phone (w/mob):</td>
</tr>
</tbody>
</table>

**INDICATION FOR WARFARIN THERAPY:**

<table>
<thead>
<tr>
<th>Target INR:</th>
<th>Doctor:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment start date:</td>
<td>Surgery:</td>
</tr>
<tr>
<td>Expected duration:</td>
<td>Phone:</td>
</tr>
<tr>
<td>Warfarin brand:</td>
<td>Fax:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DATE</th>
<th>INR</th>
<th>COMPLICATIONS/FOLLOW-UP</th>
<th>OLD DOSE</th>
<th>NEW DOSE</th>
<th>NEXT TEST</th>
<th>Init.</th>
</tr>
</thead>
</table>

*Implementation Toolkit for Point of Care INR Monitoring Services in Community Pharmacy*
<table>
<thead>
<tr>
<th>DATE</th>
<th>INR</th>
<th>COMPLICATIONS/FOLLOW-UP</th>
<th>OLD DOSE</th>
<th>NEW DOSE</th>
<th>NEXT TEST</th>
<th>Init</th>
</tr>
</thead>
</table>

Implementation Toolkit for Point of Care INR Monitoring Services in Community Pharmacy
Result Reporting Form (to patient)

Your Pharmacy logo

REPORT FOR PATIENT

Anticoagulation Therapy

Your Name:

Doctor:

We have collected a specimen by capillary puncture in order to determine an INR result.

INR: ________________________
Initials: ________________

Date of test: ____/____/____

Time:

☐ Your doctor has received a report of this result

REMARKS:

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Optimising warfarin management: An exploration of pharmacist-delivered models of care

<table>
<thead>
<tr>
<th>Result Reporting Form (to doctor)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your Pharmacy logo</td>
</tr>
<tr>
<td>REPORT URGENT</td>
</tr>
<tr>
<td>Anticoagulation Therapy</td>
</tr>
<tr>
<td>DATE:</td>
</tr>
</tbody>
</table>

**ATTENTION: Dr**

MEDICAL CLINIC:

FAX:

**Patient Name:**

Date of Birth:

Telephone:

Pharmacist:

We have collected a specimen by capillary puncture in order to determine an INR result.

**INR:**

**INR result with CoaguChek XS**

Date of test: ___/___/____

Time:

Signature of CoaguChek XS User:

REMARKS:

Implementation Toolkit for Point of Care INR Monitoring Services in Community Pharmacy

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Ella Claire van Tienen
## Incident Report Form

### Details of patient affected by incident
- **Name**
- **Address**
- **Date of birth/Age**
- **Sex**

### Doctor/Prescriber details (if applicable)
- **Name**
- **Telephone number**
- **Address**

### Incident details
- **Date of incident (#)**
- **Time of incident**
- **What was the location of incident? (#)**
  - Pharmacy:
  - Other:
- **Type of incident? (#)**
- **Please describe what happened (#)**
  (State facts only and **not opinions**).

### Degree of actual harm (severity (#))
- Near miss
- No harm
- Low
- Moderate
- Severe
- Death

Describe any action which minimised the impact on the patient.

If harm occurred, describe the injury (#).

Describe any apparent contributing factors.

Describe any actions taken to prevent a recurrence.

In your view, what were the underlying causes or events which, if rectified, may prevent another incident?

What follow up is required?

### Details of staff involved
- **Name**
- **Role in incident (#)**
- **Name**
- **Role in incident (#)**

**Note:** Items marked with (#) are compulsory.
<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Batch No.</th>
<th>Patient Init.</th>
<th>QC passed?</th>
<th>INR result</th>
<th>Staff Init.</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-03-09</td>
<td>11.30</td>
<td>122</td>
<td>E.I.</td>
<td>✓</td>
<td>2.2</td>
<td>L.S.</td>
<td>example</td>
</tr>
</tbody>
</table>
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen
Anticoagulation monitoring now available at your pharmacy

We are pleased to offer you a new way to have your INR tested. We now have pharmacists trained to perform INR tests with a monitor in the pharmacy.

The test requires only a fingerprick sample of blood and the INR result is known in under one minute.

Come in today for more information

- **Simple and fast** - Three easy steps to get your INR result within one minute.
- **Safe and precise** - Multiple built-in safety features.
- **Accessible** - Available in your pharmacy now.

Your Pharmacy logo and details etc

Implementation Toolkit for Point of Care INR Monitoring Services in Community Pharmacy
How to wash and dry hands with soap and water

- Remove jewellery and cover abrasions
- Wet hands with warm water, then apply soap or liquid soap
- Lather for 15–20 seconds
- Rinse hands under running water
- Dry hands with clean towel

During the lather, pay particular attention to the backs of hands and fingers, fingernails, fingertips and the webbing between fingers.

Hand hygiene is crucial in reducing transmission of infections. It includes both hand washing with plain or antimicrobial soap and water, and use of alcohol-based products (gels, sprays, foams). Hand washing is considered to not require the use of water if hands are visibly soiled or contaminated with respiratory secretions, wash hands with soap, then rinse with water. In the absence of safe washing of hands, approved alcohol-based products for hand disinfection may be used. If you have skin sensitivity to hand-washing (i.e. hand eczema) and cold running water is not available, consider alcohol-based hand rubs.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

INR Testing Procedure Wall Chart

1. Gather necessary equipment
   - Monitor
   - Test strips
   - Gloves
   - Lancets
   - Sharps container
2. Ensure hand is warm
   - Wash under warm running water and dry
3. Follow testing instructions
   - Insert strip into machine
   - Confirm batch number of strips
   - Allow machine to warm up – wait for beep
   - Obtain a hanging drop of blood from patient
   - Apply blood to test strip
   - Confirm QC was successful
   - Read result
   - Discard items appropriately
4. Record result
   - On log sheet, in patient file, in patient INR record book
5. Relay results to GP
   - Via their preferred method (phone or fax)

Implementation Toolkit for Point of Care IN
### CoaguChek XS Error Codes

<table>
<thead>
<tr>
<th>Error Message</th>
<th>Brief Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error number 000</td>
<td>Allowed time for blood application exceeded</td>
</tr>
<tr>
<td>Error number 3</td>
<td>Test strip unuseable</td>
</tr>
<tr>
<td>Error number 4</td>
<td>Blood application error</td>
</tr>
<tr>
<td>Error number 5</td>
<td>Measurement error</td>
</tr>
<tr>
<td>Error number 6</td>
<td>Measurement error</td>
</tr>
<tr>
<td>Error number 7</td>
<td>Diagnostic testing error</td>
</tr>
<tr>
<td>Error number 8</td>
<td>Code strip error</td>
</tr>
</tbody>
</table>

- **Test strip symbol flashing**: Monitor too warm or too cold
- **Temperature symbol flashing**: Battery level too low
- **Battery symbol flashing**: Measured chamber cover open
- **IR symbol flashing**: Infrared download error
- **QC symbol flashing**: Quality control; test strip unuseable
- **Code symbol flashing**: Code strip error
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Checklist for counselling patients commenced on warfarin

- Discuss with the patient the reason for warfarin treatment, ensure they are clear of the reason they are taking it
- Briefly explain warfarin’s mechanism of action
- Explain the INR, the concept of a target range and emphasise the importance of regular testing
- Emphasise the importance of compliance (discuss the maintenance of an INR diary, and recording doses—especially missed doses)
- Explain the possible effects of poor anticoagulation control:
  - Bleeding or severe bruising
  - Recurrence of thromboembolism
- Discuss the appropriate action if excessive bleeding or bruising occurs
- Discuss the appropriate action if diarrhoea or vomiting occurs
- Discuss starting new treatments or changing the dose of current treatment
- Explain the existence of common OTC medication interactions, such as aspirin, NSAIDs, paracetamol, complementary therapies and laxatives. Emphasise the importance of discussing new treatments with you or another healthcare professional
- Explain the role of vitamin K, and the importance of consistency in regards to vitamin K rich foods in the diet, rather than avoidance
- Explain the importance of minimising their alcohol intake and why
- Discuss ways to minimise high risk activities associated with an increased risk of physical trauma
- Suggest wearing a MedAlert® bracelet/necklace and carrying a warfarin ID card
- Let them know about www.anticoagulation.com.au if they are interested in finding out more information

The information in this resource is provided for general information only. It is not intended as medical advice, and should not be relied upon as a substitute for consultations with qualified healthcare professionals who can determine your individual medical needs.

This information has been downloaded from www.anticoagulation.com.au

Ella Claire van Tienen
Checklist for training consumers to self-monitor

**Warfarin education component:**
- Discuss with the patient the reason for warfarin treatment, ensure they are clear of the reason they are taking it.
- Briefly explain warfarin's mechanism of action:
  - Discuss starting new treatments or changing the dose of current treatment.
  - Explain the existence of common OTC medication interactions, such as aspirin, ibuprofen, paracetamol, complementary therapies and insist that the importance of discussing new treatments with you or another healthcare professional.
  - Explain the role of vitamin K, and the importance of consistency in regards to vitamin K rich foods in the diet, rather than avodance.
  - Explain the importance of minimising their alcohol intake and why.
  - Explain the INR, the concept of a target range and emphasise the importance of regular testing.
  - Emphasise the importance of compliance (discuss the maintenance of an INR diary, and recording doses—especially missed doses).
  - Explain the possible effects of poor anticoagulation control:
    - Bleeding or severe bruising.
    - Recurrence of thromboembolism.
  - Discuss the appropriate action if excessive bleeding or bruising occurs.
  - Discuss the appropriate action if diarrhoea or vomiting occurs.
  - Discuss ways to minimise high risk activities associated with an increased risk of physical trauma.
  - Suggest wearing a MedAlert® bracelet/necklace and carrying a warfarin ID card.
  - Let them know about www.anticoagulation.com.au if they are interested in finding out more information.

**Practical training component:**
- Train on use of point of care INR monitor:
  - How to use the machine.
  - How to obtain an accurate sample.
  - How to obtain an accurate result.
  - Discuss how the INR results is to be transmitted to the GP and preferred times for the patient to contact the GP.
  - Explain the run in phase (of two INR tests comparing the monitor result to pathology) and discuss how and when these will take place.

The information in this resource is provided for general information only. It is not intended as medical advice, and should not be relied upon as a substitute for consultation with qualified health professionals who can determine your individual management needs.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Toolkit Templates

Pre Self-Monitoring Assessment

educating consumers... supporting health professionals...
anticoagulation.com.au

Pre self-monitoring assessment
for consumers who have undergone training

Patient: ..............................................................
Doctor: ..............................................................
Pharmacist conducting assessment: ..............................................................

THEORETICAL ASSESSMENT

Please answer the questions in the space provided:

How does warfarin work?

How often should you test your INR?

What is meant by target INR?

What is your target INR?

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Theoretical Assessment

What are the signs of too much warfarin?

What are the signs of too little warfarin?

What is QC and when do you need to do it?

Practical Assessment

To be completed by accredited pharmacist

Finger-pricking technique: □ Competent

Point of Care monitor competency:
* Placing of sample: □ Competent
* Two tests recorded with a discrepancy of not more than 15%: □ Competent

Maintenance of POCT monitor and test strips: □ Competent

Additional comments:

Implementation Toolkit for Point of Care INR Monitoring Services in Community Pharmacy
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen
6. When is it safe to take a medication that interacts with warfarin?
   - If you take the warfarin in the morning and the interacting medication at night
   - If your healthcare provider is aware of the interaction and checks your INR regularly
   - If you take your warfarin every other day
   - It is never safe to take a medication that interacts with warfarin

7. The INR test is:
   - A blood test used to monitor your warfarin therapy
   - A blood test that is rarely done while on warfarin
   - A blood test that checks the amount of vitamin K in your diet
   - A blood test that can determine if you need to be on warfarin

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

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

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

11. A person on warfarin should seek immediate medical attention:
    - If they skip more than two doses of warfarin in a row
    - If they notice blood in their stool when they go to the bathroom
    - If they experience a minor nosebleed
    - If they develop bruises on their arms or legs
12. Skipping even one dose of warfarin can:
   - Cause your INR to be above the 'target range'
   - Increase your risk of bleeding
   - Cause your INR to be below the 'target range'
   - Decrease your risk of having a clot

13. Drinking alcohol while taking warfarin:
   - Is safe as long as you separate your dose of warfarin and the alcohol consumption
   - May affect your INR
   - Does not affect your INR
   - Is safe as long as you are on a low dose

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

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

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

17. When it comes to diet, people taking warfarin should:
   - Never eat foods that contain large amounts of vitamin K
   - Keep a diary of all of the foods they eat
   - Be consistent and eat a diet that includes all types of food
   - Increase the amount of vegetables they eat
18. Each time you get your INR checked, you should:
   - Skip your dose of warfarin on the day of the test
   - Avoid eating high fat meals on the day of the test
   - Avoid foods high in vitamin K on the day of the test
   - Let your doctor know if you missed any doses of warfarin

19. Which of the following over-the-counter products is most likely to interact with warfarin?
   - Nicotine replacement therapies
   - Herbal/dietary supplements
   - Antigen medications
   - Calcium supplements

20. A patient with an INR value above the ‘target range’:
   - Is at an increased risk of having a clot
   - Is more likely to have drowsiness and fatigue from warfarin
   - Is at an increased risk of bleeding
   - Is less likely to experience side effects from warfarin
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen

Toolkit Templates

edaging consumers...
supporting health professionals...

Scoring the questionnaire

Correct answers are as follows:

- One: B
- Two: A
- Three: D
- Four: B
- Five: D
- Six: B
- Seven: A
- Eight: A
- Nine: B
- Ten: B
- Eleven: B
- Twelve: C
- Thirteen: B
- Fourteen: B
- Fifteen: B
- Sixteen: B
- Seventeen: C
- Eighteen: D
- Nineteen: B
- Twenty: C

This resource has been downloaded from www.anticoagulation.com.au

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CoaguChek XS Training Guide

1. Insert the test strip into the CoaguChek XS. The LED light will turn green.
2. Press the test button. The LED light will turn red and the result will be shown on the display.
3. Calibrate the CoaguChek XS if the calibration light is not on.
4. Place a small drop of blood on the test strip. The test strip will turn blue.
5. Wait for the result to be displayed on the CoaguChek XS.
6. Record the result in the CoaguChek XS log book.
7. Clean up the test strip and dispose of it in the correct way.
8. The CoaguChek XS can be used up to 10 times before needing to be replaced.

Implementation Toolkit for Point of Care INR Monitoring Services in Community Pharmacy
## Patient INR Record Form

<table>
<thead>
<tr>
<th>Name</th>
<th>Referring doctor</th>
<th>Warfarin brand</th>
<th>INR range required</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Week beginning (date)</th>
<th>Mon</th>
<th>Tue</th>
<th>Wed</th>
<th>Thur</th>
<th>Fri</th>
<th>Sat</th>
<th>Sun</th>
<th>Date of test</th>
<th>INR result</th>
<th>Next appointment/Comments</th>
</tr>
</thead>
</table>

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Ella Claire van Tienen
RCPA EQAP Instructions

At the beginning of the enrolment year the RCPA QAF group will send you all the samples for that year. You will receive 10 samples, along with distilled water and Calcium Chloride (CaCl₂) for reconstitution. The samples should be stored in the refrigerator in their box once received.

RCPA has five testing periods throughout the year where you will need to test your CoaguChek XS device with the samples. The testing periods are generally open for two weeks, during which time you may run the sample at a time that is convenient to you.

The testing periods fall in February, April, June, August, and October. It may be useful to make a note of these dates in the clinic appointment book or in another calendar that is likely to assist you to remember to do the tests.

In each testing period you will need to run two samples. The samples are numbered according to the month (e.g. 02 for the February samples, 04 for the April samples, etc) and each number will have both a sample 'a' and 'b'. For example, in October 2009 you will need to run the samples labelled POC9-10a and POC9-10b. There are two samples because generally one will fall within the therapeutic range and the other will either be above or below. This is to test the accuracy of the machine in various situations.

Once you have obtained results for each of the samples you should record your results on your result sheet and in the clinic log. The results should be returned to the RCPA either on the sheet or via their web site to allow the performance of your CoaguChek XS to be compared to other devices around Australia.

To run a sample:

1. Select the two samples for the test period (a and b) and take 2 lots of distilled water, 2 lots of CaCl₂, and 2 plastic pipettes. Check the labels carefully.
2. Take the first sample, remove the cap and the rubber stopper. Take the distilled water and cut the tip off as close to the end as possible. Transfer all the water to the sample vial, add the stopper and gently swirl for around 10 seconds. Leave the sample to sit for around 10 minutes.
3. Have the CaCl₂ and the pipette ready to use. Prepare your CoaguChek XS device and insert the strip into the machine. While the strip is warming up remove the stopper from the sample. Cut the tip off the CaCl₂, as close to the end as possible and transfer it all to vial. Replace the stopper and swirl gently for 10-15 seconds.
4. Within 30 seconds of adding the CaCl₂ use a plastic pipette to draw the sample up and down a few times to mix well. Then apply a drop of the sample to the strip during the countdown period.
5. Record your result.
6. Repeat this process for the second sample.
References

Optimising warfarin management: An exploration of pharmacist-delivered models of care

Optimising warfarin management: An exploration of pharmacist-delivered models of care

Bibliography

4 Steps to setting up a CoaguChek Service in your community pharmacy. Roche Diagnostics Canada; 2007.


Position statement: point of care testing. The Royal College of Pathologists of Australasia; 2006.


Shepherd M. How to set up and manage a POCT service. The Clinical Biochemist Newsletter 2004;June:36-41.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Contacts

Unit for Medication Outcomes Research and Education
UMORE is at the forefront of point of care INR monitoring research and training in Australia.
Contact the Tasmanian School of Pharmacy:
Ph: 03 6226 2190
Fax: 02 6226 7627

UMORE
Private Bag 26
Hobart TAS 7001

www.pharmacy.utas.edu.au/UMORE.htm

Roche Diagnostics
Customer service:
Ph: 1800 802 409
Fax: 1800 066 598

Roche Diagnostics Australia Pty Ltd
31 Victoria Avenue
Castle Hill, NSW 2154

www.rochediagnostics.com.au
For CoaguChek technical support: 1800 645 619

RCPA
RCPA is accredited by the National Association of Testing Authorities, Australia.
Contact RCPA Haematology QAP Office:
Ph: 02 9845 7038
Fax: 02 9891 3376

RCPA Haematology QAP
PO Box 50
Westmead NSW 2145


National Needlestick Hotline
Ph: 1800 804 813

Implementation Toolkit for Point of Care INR Monitoring Services in Community Pharmacy

Ella Claire van Tienen
Appendix 18: Implementation Toolkit Pilot Study

Recruitment Promotion

Warfarin services pilot study

The University of Tasmania's School of Pharmacy is looking for expressions of interest to participate in a pilot study aimed to improve the anticoagulation services offered by rural and remote pharmacies.

This project will provide three pharmacies with the access to training and resources to provide improved anticoagulation services to their community. Pharmacies will be given the opportunity to implement any of a number of service options, ranging from providing self-monitoring training services to consumers who purchase portable INR devices, pharmacy-based INR monitoring services, or improved anticoagulation education to consumers. Pharmacies will be provided with implementation toolkits and support for the duration of the trial.

The trial aims to assist pharmacies to improve the anticoagulation management that is offered in rural and remote Australia. For more information, or to register your interest in participating, please contact Dr Luke Bonomi or Ella Jeffrey on 03 6225 2195/03 6220 1068, or email info@anticoagulation.com

The program is funded by the Australian Government Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement through the Rural Pharmacy Workforce Program Small Projects Funding Scheme managed by the Pharmacy Guild of Australia.
Appendix 19: Implementation Toolkit Pilot Study
Evaluation Questionnaire

Evaluation Survey - Development and implementation of a flexible anticoagulation monitoring service for rural community pharmacies.

To help us evaluate the anticoagulation resources, we would appreciate you taking the time to complete this survey.

Please circle your answer, and add any brief comments you may have under each question. Only answer the questions relating to the services you provided.

1. General
   a. How useful did you find the implementation toolkit?

   - Very useful
   - Not at all useful

   Are there any aspects of this toolkit you particularly liked?

   • Pharmacy 1: The Toolkit
   • Pharmacy 2: -
   • Pharmacy 3: Toolkit - templates

   Are there any aspects of this toolkit that could be improved?

   • Pharmacy 1: -
   • Pharmacy 2: -
   • Pharmacy 3: -

   b. What service(s) did you implement in your community? (Please provide brief details)

   • Pharmacy 1: Trained 2 customers to self-monitor INR levels; helped a customer visiting from Victoria to monitor INR levels whilst on holiday
   • Pharmacy 2: Unfortunately non – I was intending to do monitoring in the pharmacy
   • Pharmacy 3: Implemented an INR testing service

   c. How did you decide which service to implement?

   • Pharmacy 1: Was provided with a Roche CoaguChek monitor
   • Pharmacy 2: Based on talking with the local GPs and asking patients receiving warfarin
   • Pharmacy 3: Decided that this was something that complements other services that we provide. There may also be a need in the community.
d. How many patients (approximately) had contact with your service(s)?

- Pharmacy 1: 4
- Pharmacy 2: -
- Pharmacy 3: ~6 expressed interest; 1 INR test performed

e. I feel the service(s) had a positive impact on my relationship with my patient(s)

   - Strongly agree
   - Strongly disagree

f. How many GPs (approximately) had contact with your service?

- Pharmacy 1: 3
- Pharmacy 2: 6 at the local practice
- Pharmacy 3: one

g. I feel the service(s) had a positive impact on my relationship with my local GP(s)?

   - Strongly agree
   - Strongly disagree

h. If you have any interesting quotes/anecdotes relating to any aspect of your service please describe them below:

- Pharmacy 1: Customer came into pharmacy and started rolling up his sleeves all ready to give an IV blood sample. Was amazed to hear the test was done with a finger prick!
- Pharmacy 2: Good relationship with GPs already existed and I think the idea that we were trying to do this was received well.
- Pharmacy 3: The one doctor I spoke to did not wish to be involved because he would not be paid to interpret results/made dosage changes.
2. Online Resources

Train-the-trainer package

a. I found the online training modules easy to use.
   - Strongly agree
   - Strongly disagree

b. I found the training modules informative.
   - Strongly agree
   - Strongly disagree

c. The content of the training modules was appropriate to the service I wanted to provide.
   - Strongly agree
   - Strongly disagree

d. Do you have any suggestions for changes to the training modules?
   - Pharmacy 1: No
   - Pharmacy 2: -
   - Pharmacy 3: -

www.anticoagulation.com.au

e. I found the web site easy to use.
   - Strongly agree
   - Strongly disagree

f. I found the web site a useful resource.
   - Strongly agree
   - Strongly disagree

What aspects of the web site did you like best?
   - Pharmacy 1: I appreciate being able to print out information for patients to take home.
   - Pharmacy 2: Patient friendly, warfarin resources.
   - Pharmacy 3: Fact sheets.
What aspects of the website did you like least?

- Pharmacy 1:
- Pharmacy 2:
- Pharmacy 3:

  g. What other features would you like to see included on the website?

- Pharmacy 1:
- Pharmacy 2:
- Pharmacy 3:
3. Pharmacy business cases

a. Pharmacy-based INR monitoring services

i. What were the major reasons for implementing this service?

- Pharmacy 1: Better patient services
- Pharmacy 2: -
- Pharmacy 3: Already offering other tests e.g. BP, BGL, cholesterol; Need in the community.

ii. Did you promote this service within your community? If so, how?

- Pharmacy 1: Yes-verbally
- Pharmacy 2: -
- Pharmacy 3: Posters in store, ad in local paper.

iii. How successful do you feel this service is?

- Pharmacy 1: Moderately successful – with GP involvement the service will improve more.
- Pharmacy 2: -
- Pharmacy 3: At present – not very successful. I hope to grow the service though.

iv. What would you do differently if you were to implement this service again?

- Pharmacy 1: Advertising in the local community newspaper.
- Pharmacy 2: -
- Pharmacy 3: Dedicate MORE time to promotion/implementation.

v. What aspects of the business case for this service did you find useful?

- Pharmacy 1: Cost involved in providing service.
- Pharmacy 2: -
- Pharmacy 3: Models.

vi. What changes would you suggest to the resources provided about this service?

- Pharmacy 1: None – resources were very comprehensive.
- Pharmacy 2: -
- Pharmacy 3: - All good.

---

_Evaluation Survey - Development and Implementation of a flexible anticoagulation monitoring service for rural community pharmacies._

_Ella Claire van Tienen_
Optimising warfarin management: An exploration of pharmacist-delivered models of care

b. PSM training services
   i. What were the major reasons for implementing this service?

   _______________________________________________________
   _______________________________________________________

   ii. Did you promote this service within your community? If so, how?

   _______________________________________________________
   _______________________________________________________

   iii. How successful do you feel this service is?

   _______________________________________________________
   _______________________________________________________

   iv. What would you do differently if you were to implement this service again?

   _______________________________________________________
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   v. What aspects of the business case for this service did you find useful?

   _______________________________________________________
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   vi. What changes would you suggest to the resources provided about this service?

   _______________________________________________________
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c. Consumer training package

i. I found the consumer training package easy to use.

[Scale from Strongly agree to Strongly disagree]

ii. I found the package a useful resource.

[Scale from Strongly agree to Strongly disagree]

What aspects about the package did you like best?

____________________________________________________________________________________

What aspects did you like least?

____________________________________________________________________________________

iii. Do you have any suggestions to improve this resource?

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Optimising warfarin management: An exploration of pharmacist-delivered models of care

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<tr>
<td>d.</td>
<td>INR monitoring during HMR interviews</td>
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<tr>
<td>i.</td>
<td>What were the major reasons for implementing this service?</td>
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<td>ii.</td>
<td>Did you promote this service within your community? If so, how?</td>
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<td>What aspects of the business case for this service did you find useful?</td>
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<td>What changes would you suggest to the resources provided about this service?</td>
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*Source: Evaluation Survey - Development and Implementation of a flexible anticoagulation monitoring service for rural community pharmacies.*
e. Liaison strategies
i. Did you consult other healthcare professionals about the anticoagulation service(s) you implemented? If so, did you use the liaison strategies in the toolkit to assist in these discussions? Please provide details of your discussions:

________________________________________________________________________

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f. Sustainability
i. I see the service(s) I implemented as being sustainable.

Strongly agree

Strongly disagree

ii. Do you have any suggestions to improve the sustainability of these services?

Pharmacy 1:

Pharmacy 2: Good service to have – unfortunately I did not receive adequate support from my hoe and therefore failed to get the project up and running. I do believe that it can be sustainable.

Pharmacy 3:
4. Any additional comments on any aspect of this project, the resources, or your experiences are welcome:

- Pharmacy 1: I believe there is a lot of potential for this service in rural communities where there are no path labs. The resources are excellent and make self training easy – no travel necessary for pharmacists keen to take the training (Roche Rep was very helpful with initial demonstration). Thank you!

- Pharmacy 2: My experience of community pharmacy in Australia is one that does not promote the concept of professional services. A lot needs to happen on a higher level to ensure the sustainability and viability of these types of services. I don’t think most pharmacies are set up to just run these after a ‘training session’. Perhaps having a dedicated person to physically come to the pharmacy to assist would be good – not sure how practical though.

- Pharmacy 3: -
Appendix 20: Pharmaceutical Defence Limited Letter

15th June 2009

Professor Gregory Peterson
Head of School
University of Tasmania
Tasmanian School of Pharmacy
Private Bag 26
Hobart Tas 7001

Dear Greg,

Thank you for your correspondence dated 20th April in which you supplied information on the Unit for Medication Outcomes Research and Education (UMORE) studying the use of Point of Care (FOC) INR monitoring.

Following the meeting of the Risk Management Committee of Guild Insurance Ltd on the 9th June at which the INR testing matter was discussed. It was agreed to approve this procedure under the existing PI (Professional Indemnity) policy, Subject to the pharmacist notifying PDL that they have completed an accredited course.

Yours sincerely,

[Signature]

John R Coppock
Chairman
Appendix 21: Implementation Toolkit Follow-Up Study
Evaluation Questionnaire

Evaluation Survey
Development and implementation of a flexible anticoagulation monitoring service for community pharmacies.

To help us evaluate the anticoagulation resources provided, we would appreciate you taking the time to complete this survey.

Please circle your answer, and add any comments you may have under each question. Please attach additional sheets if required.

1. General
   a. How useful did you find the implementation toolkit?

Vary useful

Not at all useful

Are there any aspects of this toolkit you particularly liked?

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

Are there any aspects of this toolkit that could be improved?

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

Please return this questionnaire at your earliest convenience

By email: ella@utas.edu.au

By fax: 03 6226 7627

By post: Private Bag 26, Hobart, 7001

Evaluation Survey - Development and implementation of a flexible anticoagulation monitoring service for community pharmacies.
b. What service(s) did you implement, or attempt to implement, in your community? (Please provide brief details)

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

c. How did you decide which service to implement?

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

d. How many patients (approximately) had contact with your service(s)?

________________________________________________________________________

e. “I feel the service(s) had a positive impact on my relationship with my patient(s)”

[Strongly agree] [Strongly disagree]

________________________________________________________________________

f. How many GPs (approximately) had contact with your service?

________________________________________________________________________

g. “I feel the service(s) had a positive impact on my relationship with my local GP(s)”

[Strongly agree] [Strongly disagree]

________________________________________________________________________

h. If you have any interesting quotes/anecdotes relating to any aspect of your service please describe them below:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Evaluation Survey - Development and Implementation of a flexible anticoagulation monitoring service for community pharmacists.
2. Online Resources

"Train-the-trainer package" (Manual and powerpoint presentations provided on CD)

a. I found the DVD training modules easy to use.
   - Strongly agree
   - Strongly disagree

b. I found the training modules informative.
   - Strongly agree
   - Strongly disagree

c. The content of the training modules was appropriate to the service I wanted to provide.
   - Strongly agree
   - Strongly disagree

d. Do you have any suggestions for changes to the training modules?

---

www.anticoagulation.com.au

f. I found the web site easy to use.
   - Strongly agree
   - Strongly disagree

g. I found the web site a useful resource.
   - Strongly agree
   - Strongly disagree

What aspects of the web site did you like best?

---
What aspects of the web site did you like least?

h. What other features would like to see included on the web site?
3. Pharmacy business cases

Question 3 relates to the different services you implemented, or attempted to implement. Of parts a, b, c, and d, please only answer the parts applicable to the services you attempted. Please also answer parts e and f on page 9.

a. Pharmacy-based INR monitoring services
   i. What were the major reasons for implementing this service?

   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

   ii. Did you promote this service within your community? If so, how?

   __________________________________________________________
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   iii. How successful do you feel this service was?

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   iv. What would you do differently if you were to implement this service again?

   __________________________________________________________
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   v. What aspects of the business case for this service did you find useful (from the Toolkit)?

   __________________________________________________________
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   vi. What changes would you suggest to the resources provided about this service?

   __________________________________________________________
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b. **PSM training services (for training people to self-monitor)**

i. What were the major reasons for implementing this service?

ii. Did you promote this service within your community? If so, how?

iii. How successful do you feel this service is?

iv. What would you do differently if you were to implement this service again?

v. What aspects of the business case for this service did you find useful?

vi. What changes would you suggest to the resources provided about this service?
c. Consumer training package (to assist educating people on warfarin)
   i. I found the consumer training package easy to use.
      - [ ] Strongly agree
      - [ ] Strongly disagree
   ii. I found the package a useful resource.
       - [ ] Strongly agree
       - [ ] Strongly disagree

   What aspects about the package did you like best?

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   __
d. INR monitoring during HMR interviews
   (not applicable)
   i. What were the major reasons for implementing this service?
      ____________________________________________________________
      ____________________________________________________________
      ____________________________________________________________

   ii. Did you promote this service within your community? If so, how?
      ____________________________________________________________
      ____________________________________________________________
      ____________________________________________________________

   iii. How successful do you feel this service is?
      ____________________________________________________________
      ____________________________________________________________
      ____________________________________________________________

   iv. What would you do differently if you were to implement this service again?
      ____________________________________________________________
      ____________________________________________________________
      ____________________________________________________________

   v. What aspects of the business case for this service did you find useful?
      ____________________________________________________________
      ____________________________________________________________
      ____________________________________________________________

   vi. What changes would you suggest to the resources provided about this service?
      ____________________________________________________________
      ____________________________________________________________
      ____________________________________________________________
e. **Liaison strategies**
   i. Did you consult other healthcare professionals about the anticoagulation service(s) you implemented? If so, did you use the liaison strategies in the toolkit to assist in these discussions? Please provide details of your discussions:

   ____________________________________________________________
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f. **Sustainability**
   i. I see the service(s) I implemented as being sustainable.

   ![Strongly Agree/Disagree Scale]

   strongly
   agree

   strongly
disagree

   ii. Do you have any suggestions to improve the sustainability of these services?

   ____________________________________________________________
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Evaluation Survey - Development and Implementation of a flexible anticoagulation monitoring service for community pharmacies.
4. Any additional comments on any aspect of this project, the resources, or your experiences are welcome. We are particularly interested in things which helped or hindered you in your attempt to implement a service.

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Appendix 22: Implementation Toolkit Advertorial Addition

People taking the anti-clotting medication warfarin will be able to take advantage of a new service to monitor their therapy, offered by ... Pharmacy, from this week.

Warfarin is a medication taken by an estimated 200,000 Australians. It is very effective in reducing the risk of stroke and other clotting complications. Unlike many other medications, there is no easy way of working out what dose a person needs to take. Doses are adjusted for each individual person using regular blood tests, and a person's dose may change over time in response to many changes in their food and alcohol intake, other medications, general health and well-being and other factors. As such, it is important that people taking warfarin have blood tests at least once a month to ensure that their warfarin dose is appropriate and doesn't need adjusting.

... Pharmacy is now offering a service which allows people to have their warfarin therapy monitored by a finger prick blood test performed in the pharmacy. Trained staff will use a new machine, which looks a bit like a blood sugar monitor, to perform these blood tests. The result is available immediately and will be reported to the person and their doctor so that dose adjustments can occur quickly and easily. As the test uses a finger prick sample of blood, it's a great option for people who have trouble with usual blood tests.

If you are interested in finding out more about having your warfarin monitored using this new service, call in and see ... or one of the other pharmacists at ... Pharmacy or call ....
### Appendix 23: Implementation Toolkit Follow-Up Study

**Pharmacy Demographics**

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<td>36</td>
<td>NSW</td>
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Appendix 24: Implementation Toolkit Modified Resources

<table>
<thead>
<tr>
<th><strong>REPORT</strong></th>
<th><strong>URGENT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anticoagulation Therapy</strong></td>
<td></td>
</tr>
<tr>
<td><strong>DATE:</strong></td>
<td></td>
</tr>
</tbody>
</table>

**ATTENTION:** Dr

| **MEDICAL CLINIC:** |
| **FAX:** |

| **Patient Name:** |
| **Date of Birth:** |
| **Telephone:** |
| **Pharmacist:** |

We have collected a specimen by capillary puncture in order to determine an INR result.

<table>
<thead>
<tr>
<th><strong>Date of test:</strong> <strong>/</strong>/____</th>
<th><strong>REMARKS:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INR:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Current dose:</strong></td>
<td></td>
</tr>
</tbody>
</table>

Dr to complete

| **Suggested next dose:** |
| **Date of next test:** |
| **Dr signature:**       |
We are now offering INR testing to patients who are taking Warfarin. This INR testing service:

- Can be done in store, while you wait for your scripts
- Uses a finger prick test (similar to that of blood sugar monitoring)
- Provides a quick and accurate INR reading.

This service will include a fee of $10 to cover the cost of the equipment required to perform the test.

Patients with an INR reading outside the appropriate range will be referred to QML pathologies or their GP for further investigation.

Please do not hesitate to ask our staff if you have any further queries.
Optimising warfarin management: An exploration of pharmacist-delivered models of care

Ella Claire van Tienen

Warfarin usage has increased by some 14% per year and the adverse events from warfarin use alone in Australia is estimated to cost over $130 million per annum in direct hospital costs.

We are seeking accreditation to provide INR monitoring to patients via the new CoaguChek XS (Roche) involving a simple finger prick and result in one minute. We could immediately contact you with the result, thus aiming to improve the time spent in the therapeutic range.

As this meter costs around S$100, we are asking if you would kindly let us know if this service would be of benefit to your patients on warfarin, by ticking the appropriate box below and returning your reply in the self-addressed envelope.

In addition, we have a sleep scientist working on a part-time basis who can investigate for Obstructive Sleep Apnoea or other Sleep Breathing Disorders via Home Sleep Study. This home study is convenient, comfortable and private with a prompt report within 48 hours emailed or sent to your surgery. Many people have expressed frustration at the long waiting time (often months) for a sleep lab appointment. We can also provide all the CPAP machines and equipment (eg Resmed, Respironics, DeVilbis) at much better than the retail prices quoted elsewhere.

Please indicate if you would be interested in this service or would like more information by ticking below.

We are accredited for Diabetes Education and one of our FREE services include downloading readings of most Blood Glucose Monitors generating colour graphs or charts which can help illustrate patterns in patients readings.

Yours sincerely,

B. Pharm

Yes, the INR service would be beneficial for my patients at $8.00 per test.

Unsure, I need more information about the INR test.

No, not interested in INR testing.

I am interested in the Home Sleep Study.

Please send me more info about Home Sleep Study

Dr
Dear colleague,

We are participating in a trial being run by the University of Tasmania to study the viability of conducting INR testing in the community pharmacy setting.

Over the next 3 to 6 months we will be offering INR testing to patients in our pharmacy using the Roche CantoCheck XS monitor which has been specifically designed for quick and accurate INR testing.

The process involves a simple finger prick test very similar to blood glucose monitoring. The fee for this service will be $10 which will cover the equipment required for the test.

Patients with an INR reading outside the appropriate range will be referred to a pathology clinic or their GP for further investigation.

If you have any further questions about this service or any other services offered by our staff, please do not hesitate to contact [Contact Information] at the pharmacy.

Kind Regards

[Pharmacist]
Appendix 25: Patient Self-Monitoring Recruitment Flyer

[Image of flyer]

Who is suitable?

Adults
Long term indication for warfarin*

Interest in learning more about warfarin and monitoring their INR

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

anticoagulation.com.au

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

* An indication for warfarin of 6 months or greater is necessary to participate in self-monitoring. Conditions which may require this duration of anticoagulation include prosthetic heart valves, atrial fibrillation, deep vein thrombosis or pulmonary embolism. Unfortunately patients with antiphospholipid syndrome are unable to self monitor their therapy as the point of care device is unable to produce accurate results in this condition.
Appendix 26: EQ-5D Health Questionnaire

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

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

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

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

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

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

© EuroQol Group 1990
To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.
Appendix 27: Oral Anticoagulation Knowledge Test

Warfarin Knowledge Questionnaire

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

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

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

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

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

5. Which of the following vitamins interacts with warfarin?
   - [ ] Vitamin B12
   - [ ] Vitamin A
   - [ ] Vitamin B6
   - [ ] Vitamin K
6. When is it safe to take a medication that interacts with warfarin?
   □ If you take the warfarin in the morning and the interacting medication at night
   □ If your healthcare provider is aware of the interaction and checks your INR regularly
   □ If you take your warfarin every other day
   □ It is never safe to take a medication that interacts with warfarin

7. The INR test is:
   □ A blood test used to monitor your warfarin therapy
   □ A blood test that is rarely done while on warfarin
   □ A blood test that checks the amount of vitamin K in your diet
   □ A blood test that can determine if you need to be on warfarin

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

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

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

11. A person on warfarin should seek immediate medical attention:
    □ If they skip more than two doses of warfarin in a row
    □ If they notice blood in their stool when they go to the bathroom
    □ If they experience a minor nosebleed
    □ If they develop bruises on their arms or legs
12. Skipping even one dose of warfarin can:
   - Cause your INR to be above the ‘target range’
   - Increase your risk of bleeding
   - Cause your INR to be below the ‘target range’
   - Decrease your risk of having a clot

13. Drinking alcohol while taking warfarin:
   - Is safe as long as you separate your dose of warfarin and the alcohol consumption
   - May affect your INR
   - Does not affect your INR
   - Is safe as long as you are on a low dose

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

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

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

17. When it comes to diet, people taking warfarin should:
   - Never eat foods that contain large amounts of vitamin K
   - Keep a diary of all of the foods they eat
   - Be consistent and eat a diet that includes all types of food
   - Increase the amount of vegetables they eat
18. Each time you get your INR checked, you should:
   - Skip your dose of warfarin on the day of the test
   - Avoid eating high fat meals on the day of the test
   - Avoid foods high in vitamin K on the day of the test
   - Let your doctor know if you missed any doses of warfarin

19. Which of the following over-the-counter products is most likely to interact with warfarin?
   - Nicotine replacement therapies
   - Herbal/dietary supplements
   - Allergy medications
   - Calcium supplements

20. A patient with an INR value above the ‘target range’:
   - Is at an increased risk of having a clot
   - Is more likely to have drowsiness and fatigue from warfarin
   - Is at an increased risk of bleeding
   - Is less likely to experience side effects from warfarin
Appendix 28: Patient Self-Monitoring Evaluation Questionnaire Responses
6. I feel confident in knowing what lifestyle factors (such as diet or other medications) may affect my INR. (n=39)

7. I understand the importance of taking my medication as per my doctor’s instructions. (n=39)

8. I was satisfied with the way I communicated my INR results to my doctor and they communicated the appropriate dosage directions to me. (n=39)

9. I feel that my overall quality of life has improved as a result of being able to monitor my own warfarin therapy at home. (n=39)

10. I would prefer to monitor my warfarin therapy at home rather than through pathology testing. (n=39)
Warfarin Home Monitoring Study – General Practitioner Evaluation

1. I found self-monitoring to be a valuable way of managing my patient(s) therapy. (n=16)
   - Strongly agree
   - Strongly disagree

2. I would feel more confident in managing patients on warfarin if this was a regular service. (n=16)
   - Strongly agree
   - Strongly disagree

3. I received adequate feedback and assistance from the support staff. (n=16)
   - Strongly agree
   - Strongly disagree

4. I believe that more patients would benefit from this type of service. (n=16)
   - Strongly agree
   - Strongly disagree

If so, what proportion of all patients on warfarin do you feel would benefit? (n=13)
   - Median: 50% (range: 5-100%)

5. I believe that my patient(s) found this to be a worthwhile service. (n=17)
   - Strongly agree
   - Strongly disagree
6. My patient(s) coped well with the Warfarin Home Monitoring model. (n=17)

7. I am confident with the accuracy of the CoaguChek XS portable INR monitor that my patient(s) used. (n=17)

8. My study patient(s) had a lower rate of warfarin related adverse events than patients receiving usual care. (n=17)

9. My study patient(s) spent more time in their target INR range than patients receiving usual care. (n=17)

10. My study patient(s) had improved levels of warfarin knowledge than patients receiving usual care. (n=17)
11. I feel that this project has had a positive impact on my relationship with my patient(s). (n=17)

Strongly agree  Strongly disagree

12. I see this model of care as a feasible way for me to manage suitable patients on warfarin. (n=15)

Strongly agree  Strongly disagree
6. My patient coped well with the Warfarin Self-Monitoring model. (n=7)

7. I received adequate feedback from the support staff. (n=6)

8. My study patients had improved levels of warfarin knowledge than patients receiving usual care. (n=6)

9. I feel that this project has had a positive impact on my relationship with my patient(s). (n=7)

10. I feel that this project has had a positive impact on my relationship with the local general practitioner(s). (n=6)