Guidance on the Safe Use of Warfarin in Primary Care

Health and Social Care Board

Directorate of Integrated Care

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Acronyms

AF	Atrial fibrillation
BCSH	British Committee for Standards in Haematology
BMJ	British Medical Journal
BNF	British National Formulary
CDSS	Clinical decision support system
DVT	Deep vein thrombosis
EQC	External quality control
GP	General Practitioner
HCP	Health care professional
HSCB	Health and Social Care Board
INR	International normalised ratio
IQC	Internal quality control
IPNSM	Interface Pharmacist Network for Specialist Medicines
LMWH	Low molecular weight heparin
MAR	Medicine administration record
MHRA	Medicines and Healthcare Products Regulatory Authority
Mg	Milligrams
NEQAS	National External Quality Assurance Scheme
NES	National Enhanced Service
NPSA	National Patient Safety Agency
NPT	Near Patient testing
PE	Pulmonary embolus
PMR	Patient medication record
SPC	Summary product characteristics
QA	Quality assurance

Introduction

Anticoagulants are one of the classes of medicines most frequently identified as causing preventable harm and admission to hospital. Managing the risk associated with anticoagulants can reduce the chance of patients being harmed in the future.

In 2007 the National Patient Safety Agency (NPSA) issued recommendations for healthcare practice in their document 'Actions that can make anticoagulant therapy safer'[1] One of the recommendations was that healthcare providers update and review their protocols for the safe use of oral and injectable anticoagulant therapy.

This guideline has been developed as a reference source for primary care to use in the development of practice protocols for warfarin therapy. It brings together national (British Committee for Standards in Haematology, BNF & National Patient Safety Agency) and regional (NI Regional Anticoagulant Sub Group) recommendations, with the aim of making practice safer.

Where standardised approaches have not yet been agreed, service providers will be referred to their local Trust policy as appropriate.

The target audience for this guidance is all healthcare staff involved in the management of patients receiving warfarin in primary care.

This guidance is available on the primary care intranet:
http://primarycare.hscni.net/PharmMM_Resources_Clinical%20Resources_Anticoagulants.htm

Section 1 NI LES Anticoagulation Monitoring Service

1.1 Regional N.I. Local Enhanced Service (NI LES) Anticoagulation Monitoring

Summary of the service outlined in the Regional NI Local Enhanced Service 2013[2]:

1. Development and maintenance of a register
2. Call and recall
3. Professional links
4. Referral policies
5. Education and newly diagnosed patient
6. Individual management plan
7. Clinical procedures
8. Record-keeping
9. Audit
10. Training
11. Annual review & audit

1.1.1 Service levels 2013/14

There are 4 service levels under the terms of the NI LES and a separate fee for domiciliary visits. Practices can decide on the level(s) of service they wish to provide. **Note** the addition of service level 2a which applies when a near patient testing INR sample is taken by Trust staff working in primary care e.g. CoaguChek® sample taken and analysed by a Trust employed treatment room nurse.

Level	Sample taken by	Sample taken in	INR test done by	Dosing by	Fee per patient p.a. 2013/4
2	Trust or other externally funded staff	Practice	Lab	Practice	£95.16
2a	Trust or other externally funded staff	Practice	Practice	Practice	£103.32
3	Practice funded staff	Practice	Lab	Practice	£103.32
4	Practice funded staff	Practice	Practice	Practice	£110.92
Domiciliary visit £4.35					

1.1.2 Untoward event reporting

It is a requirement of the NI LES that adverse events are notified to the responsible clinician and Directorate of Integrated Care at HSCB using the AIF1 (GMS) form:

- Near misses and incidents within 72 hours or
- Serious untoward events e.g. hospitalisation or death within 24 hours.

These incidents and any near-misses should also be discussed within the practice as part of clinical governance. The AIF1 (GMS) form is available on the HSCB primary care intranet and can be emailed or posted to the local office (details on form). http://primarycare.hscni.net/risk_management.htm

1.1.3 Annual NI LES review and audit

The NI LES specification includes an annual review and audit which may include details of:

- Numbers of patients being monitored, the indications and the duration of treatment
- Computer-assisted decision-making equipment used and arrangements for internal and external quality assurance
- Near patient testing equipment used and arrangements for internal and external quality assurance
- Training and education undertaken
- Standards used for the control of anticoagulation e.g. % time in range (the range taken as 0.5 INR units of the target)
- Control of INRs within different patient groups e.g. in-house, district, social care.

The HSCB warfarin audit tool (see appendix 1) and the audits available as part of Computerised Decision Software Systems (CDSS) e.g. RAT will also provide valuable information for practices to enable them to review their service and address gaps, along with providing baseline information for service delivery.

Section 2 Warfarin Monitoring Services

2.1 Clinical governance issues

- A clinical member of the practice staff should be nominated to be responsible and oversee the provision of the warfarin monitoring services, with deputising arrangements as necessary
- Service providers should ensure that contingency plans are in place to cover periods of absence or sickness leave both for the running of clinics and for advice to patients who have queries or problems
- The General Medical Council advises doctors that "When delegating care you must be satisfied that the person to whom you delegate has the knowledge, skills and experience to provide the relevant care or treatment; or that the person will be adequately supervised" and "When you delegate care you are still responsible for the overall management of the patient" [3]
- In relation to dosing:
  - ❖ Only suitably qualified prescribers can change the dose of warfarin
  - ❖ The prescriber can provide a patient specific direction on warfarin dose adjustment for nurses who are not suitably qualified prescribers.
- The Medical Protection Society have stated that it is unlikely that GP practice vicarious liability would cover claims made against nursing staff undertaking advanced tasks[4]
- The Medical Protection Society has published advice regarding healthcare assistants and warfarin dosing[5]
- The Royal College of Nursing also provides advice on the extended role of healthcare assistants[6]

- A GP should be available at all times when warfarin monitoring services are offered to patients by the practice
- Practice protocols should ensure that clinical responsibilities are clear
- Trust staff working within primary care should refer to their Trust for guidance.

2.2 Costs

The warfarin monitoring service will incur set-up and on-going costs including:

- Near patient testing device
- QC costs
- CDSS – purchase & support
- Postage
- Accommodation
- Training
- Nursing/doctor/pharmacist time
- Administration staff time

2.3 Practice protocols

Practices must have comprehensive protocols for all aspects of the service level(s) that they provide. These should be available to all staff, including locums, be signed & dated by staff and reviewed on a regular basis. Warfarin clinic practitioners should also follow the relevant health & safety protocols regarding infection control, venous sampling, near patient testing, disposal of clinical waste, spillages and the safe use of reagents.

2.4 Staff training & competencies

Each GP practice must ensure that all staff involved in providing **any** aspect of care under the NI LES have the necessary training and skills, both at the point of induction for new staff and on an on-going basis for update training. All external and in-house training should be recorded in the practice training log. Refer to appendix 2 for suggested training resources and a sample practice training log.
The NPSA has six work competences (an expectation of work performance) for anticoagulant therapy: [1]

- Initiating anticoagulant therapy
- Maintaining anticoagulant therapy
- Managing anticoagulants in patients undergoing dental surgery
- Dispensing oral anticoagulants
- Preparing and administering heparin therapy
- Reviewing the safety and effectiveness of an anticoagulant service

In addition, practices using near patient testing devices must be able to operate the meter and determine/interpret INR and quality control results.

2.5 Clinical Decision Support Systems (CDSS)

There are a number of CDSS in use in primary care e.g. RAT and INR Star. Practices should ensure that they are using the latest version of their CDSS and sign up to receive notification of system updates. A 'back-up' of the information in the CDSS should be made on a regular basis and checked to ensure that it works.

The dose and review date recommended by the CDSS is a *recommendation* only and the HCP needs to make a decision to either accept it or modify it using their own clinical judgement in each case.

Incidents have been reported where over-reliance on the CDSS to guide warfarin dosing was a contributory factor. In particular, clinical judgement must be exercised when patients are:

- Recently discharged from hospital
- Recently initiated or reloaded on warfarin
- In the high risk period, 4-6 weeks following acute thromboembolism
- A new resident in a care home where administration of warfarin is supervised (INR may increase due to improved compliance).

2.6 Near patient test strips, lancets & control solutions

Test strips (CoaguChek®, Hemosense-INRatio® & ProTime®) and sterile, single use lancets for near patient testing can be ordered as follows:

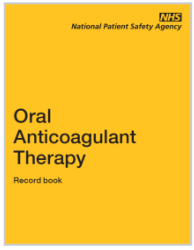
- **Stock** requisition order for clinic/practice use
- **HS21** prescription for patients who self-test at home

Quality control solutions are **not available** on the NHS and must be purchased by the user. Whilst most NPT device test strips can read an INR with a minimum blood volume of 10 micro litres or less, lancets with a higher blood releasing capacity are used to ensure that blood quickly reaches the test strip e.g. size 1.8mm depth or similar.

2.7 Oral anticoagulant booklets

Oral anticoagulant patient information is available as a pack which contains:

- Anticoagulant alert card
- Oral anticoagulant therapy patient information pack.
- Oral anticoagulant therapy record book (for INR results).



Items can be ordered from the Business Support Organisation tel: 02890 535652 as:

- Oral anticoagulant therapy pack (all 3 parts)
- Oral anticoagulant record booklet (also available individually)

Specify the practice/pharmacy name & address and quantity of each required (max 20 per order due to parcel size). Trust facilities can also obtain these items directly from BSO/PALS distribution.

All patients must be given the full anticoagulant therapy pack at the start of treatment i.e. at the first appointment to initiate warfarin.

- These books are intended to be patient held and should not be retained by the warfarin clinic
- All INR results and the current recommended dose should be entered into the record book
- The NPSA recommend that the record book should be presented by the patient to the practice and pharmacy when ordering and collecting prescriptions for warfarin.[1]
- Read code 'Patient held anticoagulant therapy record issued'

Other patient information booklets are available on the NPSA website:

- Information for patients undergoing dental treatment
- Oral anticoagulant therapy patient information booklet in different languages

2.8 Warfarin clinic checklist

At each warfarin clinic attendance or whenever a sample is taken for INR testing, asking the following type of questions which may give an early indication of loss of anticoagulant control, thrombosis, bleeding or reasons why the INR may have changed:

- Are they feeling generally well? i.e. do they have any illness that may affect the INR e.g. diarrhoea
- Have they been in hospital lately?
- Any unusual bleeding e.g. from nose, gums, bowels or bruising?
- Any pain in their face, arms or legs?
- Any loss of vision, speech or movement in arms or legs?
- Any numbness in some parts of the body?
- Has the patient been taking their warfarin as directed by the warfarin clinic/GP or have they missed any doses?
- Any changes to medicines, herbal remedies, over the counter products?
- Any major changes in diet?
- Any changes in alcohol consumption?

Refer to the GP if necessary. Check patient contact details on a regular basis. Relevant information should be recorded in the patient record and CDSS.

2.9 Strength of tablets

In Northern Ireland, Trusts and primary care have adopted a regional policy of only using the 1mg (brown) and 3mg (blue) tablets. This is to reduce the potential for confusion around the use of the 500microgram and the 5mg tablet.
Where clinically possible, warfarin should be prescribed as a whole number, e.g. either 1mg or 2mg, not 1.5mg. If there is deviation from the regional policy due to clinical need e.g. extreme warfarin sensitivity, a clinical note should be made in the patient record indicating reasons and that the risks have been fully explained and understood by the patient.
Drug defaults/messages can be used on clinical systems to discourage the use of warfarin 500microgram & 5mg strengths and prevent inadvertent prescribing.
In the exceptional circumstances where pharmacies are required to stock the strengths outside regional policy, they should ensure that additional measures are in place to prevent mix-ups e.g. shelf warnings, double checks.

2.10 How to write the prescribed dose

The NPSA has found that patients taking warfarin prefer their dose to be prescribed in the following ways:[1]

- Use the least number of tablets each day
- Use constant daily dosing and not alternate day dosing
- Not requiring half tablets.

Check that the patient has a supply of the warfarin tablets needed to make up the required dose and that they understand how the dose is to be taken.
For each INR, the dose instructions in the record should include:

- Daily dose in milligrams
- Number of tablets (consider adding this if risk of confusion)

Anticoagulant Treatment Record (example)

Date	INR	Daily dosage (mg)	Comments	Signature
5/08/2013	2.3	5mg (1 x 3mg blue + 2 x 1mg brown)	Review 2 weeks	G Dixon

2.11 How to communicate the prescribed dose & review date

Practices are strongly advised to develop a protocol for communicating warfarin doses and review dates to all patient groups and how this process is recorded.

CDSS print outs may define the total weekly dose; take care when referring to this as incidents have occurred when this information was misinterpreted as a daily dose.

2.11.1 Patient/carer

- A record of the latest INR, warfarin dose and the date for next INR must be held by the patient in the oral anticoagulant record book or as a print-out from the CDSS
- The information can be added to the record book by a healthcare professional or by the patient[1]
- If this information is given verbally to the patient/carer to enter into their book, practices should ensure that a named person in the practice is responsible for this and that the patient/carer has been instructed on how to document the dose clearly.

2.11.2 Patients using medication compliance aids or in care homes

See Sections 3.4 and 3.5

2.12 Record keeping

Service providers should keep a comprehensive record for each patient, this should include:

1. Patient name & address
2. Date of birth
3. Indication for treatment
4. Intended duration of treatment
5. Target INR
6. Record of patient counselling
7. Frequency of missed appointments
8. Medical conditions likely to affect anticoagulation
9. Bleeding episodes and adverse effects
10. Significant adverse events reported to HSCB
11. Date of discontinuation
12. Name of initiating specialist or prescriber
13. Contact details
14. Records of telephone calls or other communications
15. Name & contact number for community pharmacist (if relevant).

In relation to INR monitoring, other records may include:

1. Strength of warfarin tablets held by the patient
2. INR results
3. Dosage regimen
4. Date of next appointment
5. Information from the patient about unusual bleeding or bruising, missed doses, changes in medication, dental treatment or planned surgery
6. Changes in OTC medication including herbal remedies.

CDSS can be used to record necessary information for the running of the warfarin clinic. However, all relevant clinical information should also held in the patient record on the practice clinical system. Practices should consider the use of ‘alerts’ on the clinical system to facilitate this.

2.13 Near Patient Testing Quality Assurance

The GP practice is responsible for the QA of their near patient testing device. It is essential that proper checks are carried out regularly and that records of these checks are maintained in the log provided and kept with the device. Internal and external quality control steps are necessary in order to validate test results.

2.13.1 Internal Quality Control (IQC) Checks

*The **example** used here is for the* CoaguChek XS Plus® device. Details will vary for other products.

There are 3 IQC checks:

1. Internal device check when the device is first switched on; any errors detected at this stage will be displayed on the control panel.
2. Internal check with each blood sample to verify the integrity of each test strip; if the strip were to fail this check the result will not be given. Before each use, ensure the batch code number displayed matches the test strips in use.
3. A quality control sample which is carried out by the operator:
    - When a new batch of strips is opened
    - If the NPT device has not been used for a while
    - If you suspect incorrect storage and handling of the test strips
    - If an abnormal result is obtained
    - If the NPT device is dropped

The batch number of the control sample and test strip should be noted and the INR result must be logged in the "Quality Control Log" kept with the machine. Quality Control Log books for recording the results of quality assurance tests are available from the device manufacturer/ company representative.

INR test strips are expensive (£2.65 each) and strips should not be discarded because numbers remaining in a pack/batch are insufficient to cover a clinic. The quality control for each new batch opened takes approximately 3 minutes of clinic time.

2.13.2 External Independent Control (EQC) Checks

GP practices using near patient testing devices are required to participate in an external quality assessment scheme (EQA). See appendix 1 for further details.
All EQA records should be retained for at least 2 years or for the lifetime of the NPT device.

In addition to EQA, the practice may also consider sending venous samples to the local laboratory for routine testing as part of the practice external QA programme (This is not a formal EQA service with the lab). The number and frequency of venous samples sent depends on INR activity and recent performance but is usually every 2 months. The practice should use INR samples from stable patients who are within range. The INR results should be within 0.5.

Section 3 Patient management

Repeat prescriptions for warfarin should only be issued if the prescriber has checked that the patient is regularly attending the anticoagulant clinic, that the INR test result is within safe limits, and that the patient understands what dose to take.[1]

3.1 Individual risk assessment & review

Before initiating or whilst assessing a patient on warfarin, there are a number of factors which must be considered; the risk/benefit of continued anticoagulation, any changes to health, social circumstances or well-being that may affect anticoagulation and potential complications. The initial risk assessment and the individual's annual review of warfarin therapy must ensure that therapy is and remains effective and safe. The prescriber should ensure regular review of INR results and anticoagulant control. The benefit of having a therapeutic INR must be weighed against the risks of having an uncontrolled INR. See appendix 5 for a suggested risk assessment tool. This checklist is used widely in the UK as a guide for prescribers in balancing risks. In addition, The European Society for Cardiology recommends that for patients with atrial fibrillation, the CHA_2DS_2-VASc tool is used for stroke risk assessment and the HAS-BLED tool for bleeding risk assessment.[7]

Read code for 'initial warfarin assessment', 'follow up warfarin assessment' or 'annual warfarin assessment' (appendix 3).

3.2 Patient counselling

It is essential for the safe use of warfarin that patients and carers receive adequate verbal and written information about their treatment. This should be provided:

- Before the first dose of warfarin is taken
- Reinforced at hospital discharge
- At the first warfarin clinic visit
- When necessary throughout the course of their treatment.[1]

A record of information given must be made in the patient record. Include a record if the patient was counselled in hospital when warfarin has been initiated in secondary care (check the Trust warfarin discharge form). Patient counselling is facilitated by the information in the Oral Anticoagulant Information packs and a suggested template for a counselling checklist that can either be photocopied or scanned into the patient record is provided in appendix 4.

Read code 'medication counselling' (appendix 3)

See also:

- Sources of warfarin patient information (appendix 1)
- Advice on travel (section 4.5)

3.3 Managing patients who fail to attend

The practice should have a policy for managing those patients who do not attend for INR monitoring. Consider the following:

- Check if the patient is in hospital
- Contact the patient directly to check the reason for not attending and arrange an alternative appointment. If they cannot be contacted within a reasonable time e.g. 24 hours, inform the GP.
- Appointments should be rebooked for within one week of the missed INR
- Recurrent non-attendees should be notified to the GP who may decide that risks outweigh benefits for continued therapy in the absence of monitoring.
- Note action taken in the patient record.

3.4 Patients using medication compliance aids or monitored dosage systems (MDS)

The NPSA recommends that medication compliance aids are not used routinely for warfarin due to the inflexibility of managing the box contents when doses are changed[1]. This advice also applies to the use of monitored dosage systems in care homes (see section 3.5). This does not preclude their use and if, following a risk or needs assessment by the GP or pharmacist, they are considered essential for an individual whose INR is stable:

- The GP and pharmacist should record relevant details in the PMR e.g. HCPs involved in the decision, date
- The GP and pharmacist must have agreed procedures in place for ensuring how dose changes will be actioned on the day they are needed e.g.
    - How a record of the dose change & INR will be communicated to the pharmacist filling the compliance aid
    - How a record of the dose change & INR will be communicated to the patient/carer
    - How the contents of the compliance aid will be changed before the next dose.
    - How the existing compliance aid will be returned to pharmacy.

Ideally, the information should be provided in writing to the patient/care home and pharmacist. Verbal dose changes may be required in the first instance but must always be confirmed in writing as soon as possible.[1]

3.5 Patients living in care homes

The NPSA has issued guidance to social care providers:[1]

- Attach the written confirmation of the warfarin dose (anticoagulant record book or CDSS print out), supplied by the clinic, to the Personal Medication Record (PMR)
- Verbal dose changes may be required in the first instance but must always be confirmed in writing as soon as possible
- See section 3.4 regarding the use of medication compliance aids.

3.6 Management of patients requiring surgery [8,9,10]

The specialist will assess the thrombotic risk of patients requiring surgery and the bleeding risk of the procedure. Patients assessed as high risk will be given a low molecular weight heparin (LMWH) during the pre and post-surgery period when their warfarin is discontinued (bridging therapy). The Trust may have a shared care pathway for management of these patients or they may liaise directly with GPs to make arrangements. There is currently no regional policy in Northern Ireland for managing this 'bridging' period.

Minor procedures with a low risk of bleeding include upper GI endoscopy, cataract surgery, diagnostic endoscopic ultrasound, skin biopsy and joint or soft tissue aspiration. The bleeding risk is minimal and the potential bleeding site is accessible. Warfarin is usually continued for these procedures providing the INR is within the therapeutic range. See local Trust guidelines for details.

The British Dental Association, the National Patient Safety Agency and the British Society for Haematology issued joint guidelines for the management of patients requiring dental procedures whilst taking warfarin.[1, 11]

- If patients on warfarin who required dental surgery have an INR below 4, they can usually receive their treatment in primary care without needing to stop or adjust their warfarin.
- For patients who are stable on warfarin, an INR check is recommended 72 hours prior to dental surgery.
- The risk of thromboembolism after temporary withdrawal of warfarin outweighs the risk of oral bleeding following dental surgery.
- Patients taking warfarin tend to bleed more than normal, but this can usually be controlled with local measures.
- Patients taking warfarin should not be prescribed NSAIDs or COX-2 inhibitors as analgesia following dental surgery.

A leaflet providing advice for patients on warfarin who require dental treatment is also available from the NPSA.[1]

3.7 Patient self-monitoring

The availability of portable NPT devices makes it possible for some patients on long-term warfarin therapy to test their INR at home.[12] At present, patients need to buy their own device (CoaguChek® XS – price Dec 2013 £299 excl. VAT) but the test strips, lancets and sharps container are available on prescription.
Patients being considered for self-monitoring need to be well informed about, and trained in self-monitoring and should be managed within a programme agreed with the service provider e.g. Trust or GP practice.

The British Society for Haematology has issued guidelines for patient self-testing and management of oral anticoagulation.[13,14,15]

3.8 Interface with secondary care

Warfarin is an amber subgroup drug in the NI Regional Group on Specialist Medicines list.[16] This means that GPs have the option to accept or decline responsibility for warfarin monitoring, e.g. if they do not provide warfarin monitoring services or have reached their capacity to accept new referrals, management can be arranged via the Trust warfarin clinic (either short term or long term). GPs should discuss or notify the hospital specialist as soon as possible if this is the case.

Hospital trusts in NI have adopted the use of a discharge/referral form to facilitate the transfer of information following initiation of warfarin and/or at discharge for all patients taking warfarin. Discharge arrangements for warfarin monitoring must be clearly established and documented. Responsibility for the discharge arrangements lies with the clinician referring the patient. Patients should remain the responsibility of the hospital team until arrangements and agreement have been made with the GP to take over. Arrangements should not be made so that INR samples are required to be taken in primary care over the weekend or on bank holidays. Similarly, results of INRs cannot be acted on over these periods, when GP practices are closed.

3.9 Referrals back to secondary care

Warfarin is an amber listed drug and patients can be referred back to the initiating consultant/department or Trust warfarin clinic where the service provider in primary care feels that the management of the patient is outside their area of competence or if the GP practice does not participate in the NI LES for anticoagulation monitoring.

Section 4 Factors affecting the INR

It is important to remember; that in addition to changes to drug therapy, a number of factors can co-exist which increase the likelihood of a raised INR, particularly during periods of acute illness e.g. reduced renal/hepatic function, poor oral intake, pyrexia and infection. Prescribers must consider all such factors and the clinical condition of the patient when deciding about re-checking the INR and not focus solely on the potential for a specific drug interaction or the duration of drug treatment.

4.1 Drug interactions

- Refer to latest BNF for a list of drugs known to interact with warfarin (look under *coumarins*). For further information see references and resources in appendix 1.
- If no information is provided for a specific drug, the possibility of an interaction should still be considered. Where there is doubt about the extent of the interaction, consider increased monitoring.
- An effect on the INR is typically observed within 3 to 5 days for interacting drugs with short half-lives, the effect on the INR of drugs with longer half-lives will be further delayed [17]
- Remember to check the INR after stopping an interacting drug where the warfarin dose has been adjusted to compensate for the interaction.[17]

As a guide, The British Society for Haematology recommends:
All patients on warfarin who are prescribed a drug that may interact with it should have an INR performed after 3-5 days.[8]

4.2 Herbal and vitamin products

Patients should be advised to discuss the use of any herbal products or supplements they wish to try or are taking. When there is no information on a product, an increase in monitoring or bleeding tendency is advised.

Examples of herbs and supplements which may affect warfarin[18]	
Monitor closely or avoid	**Advise the patient or consider monitoring or both**
Glucosamine with or without chondroitin St John's Wort (see below) Vitamin K Co-enzyme Q-10 Danshen (Salvia miltorrhiza) Dong quai (Angelica sinensis)	Fish oils Ginger Gingko biloba Ginseng Wintergreen (topical methylsalicylate)

Herbal preparations containing St John's Wort (*Hypericum perforatum*) must not be used whilst taking warfarin due to a proven risk of decreased plasma concentrations and reduced clinical effects of warfarin.[19] Note that some multivitamin supplements may contain ingredients that affect warfarin levels e.g. Seven Seas Multibionta 50+® (containing ginseng).

4.3 Alcohol

Acute ingestion of a large amount of alcohol may inhibit the metabolism of warfarin and increase INR. Conversely, chronic heavy alcohol intake may induce the metabolism of warfarin. Moderate alcohol intake can be permitted.

4.4 Food, drinks and food supplements

There is a possible interaction with cranberry juice leading to an increased INR.[20] Patients should be advised to avoid cranberry products. Increased supervision and INR monitoring should be considered for any patient taking warfarin and regular cranberry juice.[19] Limited evidence suggests that grapefruit juice may cause a modest rise in INR in some patients taking warfarin.[19]

Certain foods e.g. broccoli, liver, Brussels sprouts and leafy green vegetables contain large amounts of vitamin k and sudden changes in the intake of these foods or in their usual diet e.g. Atkins Diet can potentially affect control of anticoagulation. An information sheet for patients listing foods that are high in vitamin k is available from Anticoagulation Europe (see appendix 1). Patients should be advised to consult with their GP before making major changes to their diet.

Good practice:

- **Practices must have access to up to date information on warfarin interactions**
- **Patients should be educated on the effects of interactions**
- **Patients should be advised that they must inform their GP or anticoagulant practitioner if there are changes to taking medicines, supplements, complementary therapy or diet**
- **Prescribers should liaise with the warfarin clinic if altering drug therapy and an interaction is known or suspected in order to co-ordinate increased monitoring**
- **Ensure a record is kept of the arrangements made to monitor any warfarin interactions e.g. anticoagulant record book, CDSS, clinical system.**

4.5 Travel

Patients should be reminded of the potential effect of changes in alcohol intake and diet when they are on holiday. ‘Anticoagulation Europe’ produces a patient information leaflet on how to get an INR test done whilst on holiday (see appendix 1). See also BCSH guidelines on travel related venous thrombosis.[21]

4.6 Clinical conditions affecting the INR[19]

In addition to the effect of other drugs, the following conditions cause warfarin sensitivity i.e. need for reduced dose:

- Liver dysfunction
- Heart failure
- Hyperthyroidism
- Acute pyrexial episode
- Weight loss
- Cessation of smoking

Some conditions cause warfarin requirements to be increased i.e. need for higher dose:

- Hypothyroidism
- Vitamin K e.g. herbal or enteral feeds
- Diarrhoea, vomiting - due to malabsorption of warfarin
- Weight gain

4.7 Factors affecting venous sample INR results

Cause	Result	Notes
Under filled samples	High INR	For accurate INR results, the recommended Vacutainer® system should be used. Allow the tube to fill to the full extent of the vacuum and blood flow ceases. Check the expiry date as vacuum can be lost if the tube is expired. Using a 'butterfly' cannula can cause under fill of the Vacutainer®, as part of the vacuum will be used to draw air along the cannula line. If a 'butterfly' is essential, air should be removed from the blood collection set by priming the line and using the shortest length possible.
Mixing the contents of under filled sample tubes	High INR	Vacutainer® tubes for INR samples contain a small volume of liquid citrate. The ratio of citrate to blood volume is 1:9. If this ratio changes, the INR result is adversely affected. Under-filling and mixing samples are common causes for inaccurate results due to this effect.
Samples kept in fridge		Samples should be stored at room temperature

Section 5 Warfarin Clinical Guidelines

5.1 Target INR and duration of treatment

See British Committee for Standards in Haematology Guideline (2011) for full detail.[8]

Condition	Target INR (Range)	Recommended Duration
Calf vein thrombosis	2.5 (2.0 – 3.0)	At least 6 weeks
Cancer associated VTE	Therapeutic LMWH	At least 6 months
Pulmonary embolus and/or proximal vein thrombosis (including popliteal)	2.5 (2.0 – 3.0)	At least 3 months
Unprovoked proximal vein thrombosis and/or pulmonary embolism	2.5 (2.0 – 3.0)	Consider long term
Recurrent unprovoked DVT/PE	2.5 (2.0 – 3.0)	Long term
Recurrent DVT/PE whilst on warfarin at therapeutic INR	3.5 (3.0 – 4.0)	Long term
Atrial Fibrillation	2.5 (2.0 – 3.0)	Long term
Atrial fibrillation for non-urgent D/C conversion	2.5 (2.0 – 3.0) Higher range may be used. Refer to Trust policy	Target INR recommended for min 3 weeks before and 4 weeks after DCC
Mitral or aortic valve disease	2.5 (2.0 – 3.0)	Long term
Cardiomyopathy	2.5 (2.0 – 3.0)	Long term
Tissue heart replacement valve	2.5 (2.0 – 3.0)	At least 3 months
Mechanical prosthetic valve	Range may vary depending on valve type	Long term
Mural thrombus	2.5 (2.0 – 3.0)	3 months

5.1.1 Recording the target INR and duration on CDSS

CDSS programmes may be set to a default entry for target range and duration based on BCSH Guidelines.[8] On occasion specialists may recommend values outside these limits based on individual risk. Warfarin clinic practitioners must discuss any such variations with the patient's GP and ensure that the appropriate recommendations are followed and document the reason for the variation in patient's notes & CDSS.

5.2 Initiation

Prior to initiating warfarin therapy in primary care, it is important that the following are considered:

- Access to INR results on the same day as sample taken (near patient testing or prior arrangement with laboratory for urgent return of INR results)
- Protocol for initiation
- Training on initiation of anticoagulants
- NPSA workforce competence 'Initiating oral anticoagulant therapy'.

At the first appointment to initiate warfarin, it is essential that the patient is given the relevant information and education. The relevant sections of the yellow patient held booklet must also be completed and issued to the patient.
See appendix 6 for a checklist that can be used by GP practices when initiating warfarin.

5.2.1 Pre- Treatment Tests

A pregnancy test is recommended for women of childbearing age as warfarin is a teratogen

Baseline tests:
Note: Initial dose should not be delayed whilst awaiting the results below.

- Coagulation screen (includes baseline INR/ Prothrombin time)
  Plus recent:
- U&E (to exclude renal impairment)
- Full blood count (to exclude thrombocytopenia)
- Liver function test (to exclude hepatic impairment)

5.2.2 Slow Initiation

- Two protocols are used in Northern Ireland for the slow initiation of warfarin
- Used for non-acute thrombotic conditions e.g. AF
- The majority of patients are within target range by 3-4 weeks
- Once the INR is stable, the time between monitoring can be increased to 2, then 4, and eventually longer periods up to 12 weeks as recommended by the BNF[22]
- Generally if a patient is already taking aspirin for primary prevention of CHD or AF, this can be stopped when warfarin is started.

Option 1 - Slow initiation using 2mg daily (Oates) [23]

If baseline tests and INR are normal:

Prescribe warfarin 2mg taken daily at 6pm for 2 weeks

Check INR at day 8 and day 15 and adjust INR at end of second week according to table below.

Caution: If the patient is very sensitive to warfarin & the INR is already > 1.8 on day 8, do not continue with the loading schedule, reduce the dose and continue careful monitoring until stable.

Slow Initiation Schedule (Oates) *Agreed by Regional Anticoagulant Sub-Group June 2010*			
If baseline tests and INR are normal, Prescribe warfarin 2mg taken daily for 2 weeks.			
Male		***Female***	
INR at end of week 2	Maintenance dose (mg/day)	INR at end of week 2	Maintenance dose (mg/day)
1.0	6	1.0 – 1.1	5
1.1 – 1.2	5	1.2 – 1.3	4
1.3 – 1.5	4	1.4 – 1.9	3
1.6 – 2.1	3	2.0 – 3.0	2
2.2 – 3.0	2	>3.0	1
>3.0	1		

- The INR on day 14 predicts the maintenance dose. Any subsequent changes based on routine checks on days 21, 28, 35 and 42 (or other dates as arranged) are based on the INR

Option 2 - Slow initiation using 3mg daily (Janes 2004 - modified)[24]

If baseline tests are normal and INR is <1.4 before treatment (If INR >1.4, consider reasons for raised INR and consider if warfarin definitely indicated):

Prescribe: Warfarin 3mg PO daily at 6pm, for 3 days
Unless patient is frail, is on amiodarone or has impaired liver function (ALT 2 x ULN), then use 2mg PO daily at 6pm.

Check INR on Day 4

<table>
<tr><td colspan="2">Slow Initiation Schedule (Janes) Agreed by Regional Anticoagulant Sub-Group Sept 2013</td></tr>
<tr><td colspan="2">If baseline tests are normal & INR <1.4,

Prescribe warfarin 3mg taken daily for 3 days.</td></tr>
<tr><td>On Day 4: INR below target range - Continue with 3mg once daily and check INR on Day 8</td><td>On Day 4: INR at or above target range - Refer to maintenance dose advice section 5.3 and check INR on Day 8</td></tr>
<tr><td>On Day 8:
INR below target range – continue with 3mg once daily and check INR on Day 12
INR at or above target range – refer to maintenance dose advice and check INR on Day 12</td><td>Refer to maintenance dose advice and check INR on Day 12</td></tr>
<tr><td>On Day 12:
INR below target range – continue with 3mg once daily and check INR on Day 15
INR at or above target range – refer to maintenance dose advice and check INR on Day 15</td><td>Refer to maintenance dose advice and check INR on Day 15</td></tr>
<tr><td colspan="2">Day 15 onwards use maintenance dose advice see section 5.3</td></tr>
</table>

5.2.3 Fast Initiation Schedule

Fast initiation for acute thrombosis requires initial treatment with a low molecular weight heparin. The BCSH guidelines state that patients should receive heparin for at least 5 days and until the INR ≥2 for at least 24 hours.[8]

Fast Initiation Schedule[25] *Agreed by Regional Anticoagulant Sub-Group June 2010*			
Day	INR	Dose (mg)	Follow up
1	< 1.4	10	Next INR day 2
2	<1.8 1.8 – 2.0 >2.0	5 1 Omit	Next INR day 3
3	<2.0 2.0- 2.2 2.3- 2.5 2.6- 2.9 3.0- 3.2 3.3- 3.5 >3.5	5 4 4 3 2 1 Omit	Next INR day 4
Predicted maintenance dose based on day 4 INR			
4	<1.4 1.4- 1.5 1.6- 1.7 1.8- 1.9 2.0- 2.3 2.4- 3.0 3.1- 3.2 3.3- 3.5 3.6- 4.0 >4.0	>7 7 6 5 4 3 2 1 Omit Omit	Continue close INR monitoring until stable

5.3 Maintenance doses

Ideally, warfarin should be taken at or around **6pm.** This allows time for warfarin clinics to contact the patient and alter the next dose before it is taken, should the INR fall outside the recommended range. If morning dosing is preferred to aid compliance or to suit carers, then omit the evening dose and recommence at the same dose the following morning. Make a record in patient notes that warfarin dose is taken in the morning.

The guidance below has been developed locally for use in Trusts and has not been formally validated.

Manual adjustment of maintenance doses
(Avoid half mg doses)

Agreed by Regional Anticoagulant Sub-Group June 2010

Deviation of INR from target range	Dose adjustment	Next INR test
Greater than 0.5 below	Increase total **weekly** dose by 20%	3 days
0.1 – 0.5 below and obvious cause identified and resolved	Do not alter dose	3 days
0.1 – 0.5 below and **NO** obvious cause identified	Increase total **weekly** dose by 10%	3 days
Within desired range	Do not alter dose	3 – 7 days
0.1 – 0.5 above and obvious cause identified and resolved	Do not alter dose	3 days
0.1 – 0.5 above and **NO** obvious cause identified	Decrease total **weekly** dose by 10%	3 days
Greater than 0.5 above AND **INR** less than 5.0	Omit 2 doses & Decrease total **weekly** dose by 10%	2 days
INR greater than 5.0	**Stop** and refer to over-anticoagulation guidelines (see section 5.6)	

5.4 Frequency of INR Monitoring

Frequency of INR monitoring will initially depend on the initiation schedule followed.

Consider the use of the 'weekly review' option on CDSS when the INR is variable e.g. during illness, recent admission to care home etc.

The maximum interval recommended until control is stable is weekly INR, thereafter; the frequency of recall can be extended up to 12 weeks.[10,22] The maximum duration should be shorter for patients whose target INR is higher than 2.5 e.g. mechanical heart valves as the risk of running high INRs is more likely. Frequency will also depend on the incidence of high and low INRs.

5.5 Sub therapeutic INR

If an INR falls below 1.7 on 2 or more consecutive INR tests, a clinical decision will need to be made on whether to initiate LMWH. There is no definitive guidance on under-anticoagulation, but practitioners may find the following information helpful:

a) BCSH 4th edition guidelines recommend anticoagulant bridging for the following risk groups: [8]
   - Patients with a VTE within the previous 3 months
   - Patients with AF and previous stroke or TIA or multiple other risk factors
   - Patients with a mitral mechanical heart valve.

b) Belfast Trust GP website provides advice from Dr Gary Benson on under anticoagulation: "FAQ: does a sub therapeutic INR need LMWH bridging treatment?" http://rvhwp.hscni.net/gpbhsct/?page_id=621

c) For prescribing advice on low molecular weight heparins, see the BNF[22] SPC[26] and the N.I. Shared Care Guidelines[16]

   - Follow the dose indicated for *treatment* of DVT
   - Note dose reduction in renal impairment
   - Continue LMWH treatment until the INR is back within therapeutic range on 2 consecutive days.

For further advice on individual cases, contact the referring Trust specialist.

5.6 Management of high INRs and bleeding

Major Bleeding
Arrange urgent transfer to hospital emergency department in the event of: A. Emergency Surgery B. Major Haemorrhage

1. Minor Bleeding		
INR	**Action**	**Additional Information**
>8.0	1. Stop warfarin 2. Send to hospital for IV vitamin K 3. Restart when INR <5	Phytomenadione (vitamin K_1) 1mg to 3mg by slow iv injection. Patient will need INR check 24 hours later or sooner if clinical deterioration. Dose of phytomenadione may have to be repeated if INR still too high after 24 hours.
5.0 – 8.0	1. Stop warfarin 2. Send to hospital for IV vitamin K 3. Restart when INR <5	Phytomenadione (vitamin K_1) 1mg to 3mg by slow iv injection. Check INR in 24 hours or sooner if clinical deterioration.
Therapeutic or sub-therapeutic INR	Investigate possible cause	
2. No Bleeding		
INR	**Action**	**Additional Information**
>8.0	1. Stop warfarin 2. Send to hospital or treat in primary care 3. Restart when INR <5	Phytomenadione (vitamin K_1) 1mg to 5mg <u>orally</u> using Konakion MM Paed Injection® Patient will need INR check 24 hours later or sooner if clinical deterioration. Dose of phytomenadione may have to be repeated if INR still too high after 24 hours.
5.0 - 8.0	Stop warfarin Restart when INR < 5	Stop warfarin for 1-2 doses and reduce subsequent maintenance dose. Investigate cause.

Ref: BNF[22] & BCSH[8]

5.6.1 High INR results & error messages using Near Patient Testing

- All high INRs should be confirmed by doing a second near patient test.
- If the result is confirmed, follow advice on over-anticoagulation in section 5.6
- Always send a venous sample to the laboratory indicating that NPT test was high and state the INR result.
- If the second test result deviates by more than 0.5 from the first consider a fault with the NPT device. Run internal QC checks. Send a venous sample to laboratory.
- Note that near patient testing devices will not record a specific measurement for an INR that is >8.
- The NPT device may also display an error message if INR >8. It is very important that operators are aware of this message and its significance and act accordingly. If a second test results in an error message, a venous sample should be sent to the laboratory.
    - CoaguChek XS plus® devices display 'error 7' or 'error 406' when INR is >8 and over the measuring range of the meter.
    - In May 2013, Roche issued a Safety Field Notice to warn that CoaguChek meters may also display 'ERROR 6' when INR is >8.

'TREAT THE PATIENT – NOT THE INR'
Check the INR immediately if the patient has concerns or any signs of bruising or bleeding
Do not delay the administration of oral/IV vitamin K or referral to hospital whilst awaiting confirmation of high INRs
IF IN DOUBT, REFER URGENTLY TO HOSPITAL FOR ASSESSMENT

5.6.2 Assessment of potential warfarin overdose

Once appropriate treatment for bleeding or over anticoagulation is underway, either in primary care or in hospital, the next immediate step is to establish if an accidental overdose has been taken and if so, the extent of the overdose. Staff should question the patient/carer and examine the patient's warfarin packs.[27]

5.6.3 Use of Oral Phytomenadione (Vitamin K)

- Practices should consider holding stock of Konakion MM® paediatric injection 2mg/0.2ml (unlicensed use) – stock requisition order
- Oral doses should be given using the dropper provided
- The dropper is graduated to 1mg & 2mg doses
- Patients should be given a drink of water/ juice to aid swallowing and absorption of the small volume given and to mask the taste
- Refer to product information for further details[26]

5.7 Stopping warfarin

The intended duration of warfarin will be documented in the initial referral form, the patient's record and the oral anticoagulant treatment book/written record.
There is no need to reduce treatment gradually; warfarin can be stopped abruptly without adverse effect. Patients who have completed the recommended treatment period should be reviewed before their treatment is stopped to ensure that their symptoms have resolved and any existing risk factors have been resolved e.g. the patient is fully mobile again following a fracture which led to a DVT. In addition, a new indication for continued anticoagulation may have developed e.g. new AF during treatment for a DVT. Letters should be reviewed to validate the original indication. Consideration may need to be given to the early discontinuation of therapy in situations where the risks outweigh the benefits of continued treatment e.g. in patients not attending for regular monitoring, those unable to follow the dosage regimen etc.

Authorisation:

- The anticoagulant practitioner should notify the patient's GP when treatment is nearing the intended duration
- The GP should review the notes, ensuring that there is no other condition requiring anticoagulation
- The GP should authorise final discontinuation of the warfarin.

Communication:

- Inform the patient of the intended date to stop warfarin and discuss the need for any other treatment e.g. restarting aspirin, advise of possible symptoms or signs of recurrence of clotting
- Inform community nursing/ care home/ pharmacist if appropriate e.g. if patient using MDS.

Records management:

- Ensure that the yellow record book/written record is endorsed with stop dates
- Remove warfarin from the current prescription list & enter reason
- Read code discontinuation of warfarin (see appendix 3)
- Archive the patient record on the CDSS or remove from the manual register.

Section 6: Appendices

References:

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http://primarycare.hscni.net/enhanced_services.htm

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18. Stockley I & Lee R. Can I take herbal products or dietary supplements with my warfarin? The Pharmaceutical Journal 2009; 282:424

19. Stockleys Drug Interactions. Ninth Edition. 2012.

20. Warfarin: changes to product safety information. MHRA Dec 2009. http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON065505

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27. Regional learning from a Serious Adverse Incident (SAI) – death following accidental overdose of warfarin on a clinical trial. HSCB letter June 2012. http://primarycare.hscni.net/

Appendix 1 Resources

Audit

- HSCB Oral Anticoagulant Audit 2009:
  http://primarycare.hscni.net/PharmMM_Resources_Clinical%20Resources_Anticoagulants.htm

Patient information Leaflets

- National Patient Safety Agency
  http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814
- DXS patient information leaflets are available on GP clinical systems
- Anticoagulation Europe produce a number of information booklets that can be downloaded from the website e.g. INR Testing Abroad, Living with warfarin, Foods containing vitamin K
  http://www.anticoagulationeurope.org/publications
  http://www.anticoagulationeurope.org/files/files/booklets/Foods%20final_Layout%201.pdf
- Product manufacturer's patient information leaflets
  http://www.medicines.org.uk/emc/

Interactions

- BNF
- Electronic medicines compendium http://www.medicines.org.uk/emc/
- Trust Medicines Information Service
- National Electronic Library for Medicines http://www.nelm.nhs.uk/en/
- Drug Interactions involving warfarin: practice tool and practical management tips. Canadian Pharmacists Journal Vol 114 issue 1 January 2011
  http://cph.sagepub.com/content/144/1/21.full.pdf+html

Quality Assurance

- Trust Haematology Department
- UK National External Quality Assurance Scheme
  Four EQA checks per year
  Cost is £142+VAT per device per year (2013)
  http://www.uknegasbc.org
  Email:neqas@coageqa.org.uk
  Tel: +44 (0) 114 267 3300

- WEQAS Wales External Quality Assurance Scheme
  Six EQA checks per year
  Cost is £105 + VAT per device per year (2013)
  http://www.weqas.com/poct
  Email:weqas.poct@wales.nhs.uk
  Tel: + 44 (0) 292 074 8186

Appendix 2 Training

a) Training Resources

British Medical Journal Online Learning:
BMJ Learning has 2 modules relating to anticoagulant therapy (Free access following registration) www.learning.bmj.com/learning/register.html

- Starting patients on anticoagulants: How to do it
- Maintaining patients on anticoagulants: How to do it

Northern Ireland Centre for Pharmacy Learning & Development:
www.nicpld.org

National Centre for Anticoagulant Training NCAT (Birmingham)
Accredited courses ranging from MSc to 1 day courses
Cost £1500 for 3 day oral anticoagulant management course
www.anticoagulation.org.uk/

CoaguChek® Training
Contact Roche Diagnostics Point of Care Sales Specialist
Mobile: +44 (0) 7738574150
Email: shaz.elstner@roche.com
For other NPT devices, contact the company sales team for information

b) Sample Training Log

Warfarin Clinic Staff:
Name & designation of person responsible for warfarin clinic:

……
Name of others involved in warfarin clinic:

GPs:	Practice Nurses	Others:

Training:
List name and dates of training received by warfarin clinic staff

	GPs	Practice nurses:	Others:
Clinical			
BMJ learning modules:			
Other:			
Non - Clinical			
CDSS training			
NPT training			
Other			

Appendix 3 Anticoagulant read codes

Torex Emis Vision	The following list illustrates some read codes that may be used (List not exhaustive – August 2010)	Healthy Crosscare
66Q1.	Initial warfarin assessment	66Q1.
66Q2.	Follow up warfarin assessment	66Q2.
66Q3.	Warfarin side effects	66Q3.
66Q4.	Warfarin dose changed	66Q4.
66Q5.	Warfarin therapy stopped	66Q5.
66Q6.	Warfarin therapy started	66Q6.
66Q7.	Target INR	XaIOO
66Q8.	INR deviation from target	XaJel
66Q9.	Warfarin dose unchanged	XaK1z
66QA.	Warfarin treatment plan	XaKHR
66QB.	Annual warfarin assessment	XaL33
66QC.	Anticoagulant monitoring secondary care	XaL3h
66QD.	Anticoagulant monitoring primary care	XaMh8
66QE.	Self-monitoring INR	XaNbr
66QF.	Slow induction warfarin therapy	XaQVW
9NiH.	Did not attend hospital anticoagulant clinic	XaPCZ
9NiJ.	Did not attend general practitioner anticoagulant clinic	XaPCf
9364.	Patient held anticoagulant therapy record issued	XaMFk
9k23.	Patient held anticoagulant therapy book updated	XaPC1
6774.	Medication counselling	6774.
8HHW.	Referral for warfarin monitoring	XaK6c
8CAu.	Patient advised of anticoagulant dose	XaPx8
QoF Oral anticoagulant contraindications: persistent		
14LP.	H/O: warfarin allergy	XaJ60
TJ42.	Adverse reaction to anticoagulants	TJ42.
TJ421	Adverse reaction to warfarin sodium	TJ421
TJ422	Adverse reaction to nicoumalone	TJ422
TJ423	Adverse reaction to phenindione	TJ423
TJ42z	Adverse reaction to anticoagulants NOS	TJ42z
U6042	[X]Anticoagulants causing adverse effects in therapeutic use	U6042
QoF Oral anticoagulant contraindications: expiring (15 months)		
8I25.	Warfarin contraindicated	XaFsz
8I3E.	Warfarin declined	XaIIn
8I65.	Warfarin not indicated	XaIIh
8I71.	Warfarin not tolerated	XaJ5b
8I2R.	Anticoagulation contraindicated	XaKAB
8I3d.	Anticoagulation declined	XaKAD
8I6N.	Anticoagulation not indicated	XaKA7
8I7A.	Anticoagulation not tolerated	XaKA0

Appendix 4 Warfarin Patient Counselling Checklist

Patient Name: Patient ID:

Please initial & date to confirm counselling has taken place. Ensure that patient has been given the Oral Anticoagulant Therapy Information booklet, alert card & record book.

		Date	Initials			Date	Initials
1. What is an oral anticoagulant & mode of action	Refer to Anticoagulant Therapy information booklet			9. Surgery & dental treatment	Refer to Anticoagulant Therapy information booklet		
2. How to take oral anticoagulant & strengths of tablets	Refer to Anticoagulant Therapy information booklet. N.I. Regional policy to use 1mg & 3mg only.			10. Other medicines	Refer to Anticoagulant Therapy information booklet		
3. Monitoring the INR	Refer to Anticoagulant Therapy information booklet			11. Diet	Refer to Anticoagulant Therapy information booklet		
4. Clinic arrangements	Give details of the clinic arrangements & contact details. Refer to front page of Anticoagulant Therapy information booklet			12. Alcohol	Refer to Anticoagulant Therapy information booklet		
5. Ordering repeat prescriptions	Give details of practice policy and that patient may be asked to provide details about current INR & dose or present record book.			13.Pregnancy/ periods	Refer to Anticoagulant Therapy information booklet		
6. Side effects & action to take	Refer to Anticoagulant Therapy information booklet			14. Other illnesses	Advise of the effects of vomiting, diarrhoea, infections etc on absorption of warfarin or effect on INR		
7. Signs of poor anticoagulant control & action to take	Give details of signs of over anticoagulation e.g. bruising, bleeding and of under anticoagulation e.g. thromboembolism			15. Injections	Avoid intramuscular injections if possible		
8. Information to others e.g. pharmacist, dentist, podiatrist	Advice to inform all healthcare staff that they are taking warfarin			16. Sports & leisure	Avoid activities or sports which may result in a serious fall or head injury		

Appendix 5 Warfarin Risk Assessment Tool

The following points are intended as guidance only. Ticking 'yes' to the problem factors is not necessarily an absolute contraindication to warfarin but it should help the prescriber balance the risks.

Question	Yes	No	Action/Date	Initials
Is the CHA_2DS_2-VASC score >1?				
Has the patient a history of uncontrolled hypertension (systolic >180 & diastolic >100mm Hg)?				
Is there evidence of alcohol excess?			Advise accordingly	
Is there evidence of liver disease? e.g. abnormal LFTs			Investigate	
Is there any evidence of active bleeding lesions? (i.e. GI blood loss, peptic ulcer disease or cerebral haemorrhage)			Contra-indicated	
Has the patient any bleeding tendencies? (including coagulation defects and thrombocytopenia)			Discuss with Consultant Haematologist or consider referral	
Is there a concomitant use of medicines that affect the INR or haemostasis e.g. antiplatelets?			Note bleeding risk or need for increased monitoring. Discontinue if appropriate.	
Is there evidence of chronic kidney disease?			Reduced clearance of warfarin – monitor closely	
Is the patient being investigated for or receiving treatment for cancer?			Use LMWH	
Is the patient capable of safe compliance and understanding of the anticoagulant therapy?				
Does the patient have disabilities which could affect the way in which dosage adjustments are communicated e.g. visually impaired, hearing impaired or illiterate?				
If the patient has been previously on anticoagulant therapy, is there any evidence of non-compliance or instability of INR control?				
Is the oral anticoagulant still clinically indicated?				
Does the patient use a medication compliance aid?			Avoid if possible/Risk assess	
Prothrombin Time = **secs** **APTT result =** **secs** **Platelets =** **$x10^9$/l** **INR =**				

Remember to apply relevant factors to carers if they manage/administer warfarin.

This risk assessment tool has been adapted from Gwent Healthcare NHS Trust 'Discharge of Patients on Anticoagulant Therapy' 2008 which was endorsed by the N.I. Regional Anticoagulant Group 2010.
http://www.wales.nhs.uk/sitesplus/documents/866/Pathology%20Newsletter%20Issue%208%20Spring%202008.pdf

Appendix 6 Warfarin Initiation Checklist

Warfarin initiation checklist	Initials & date
Record initial warfarin risk assessment	
Record key info on clinical system	
Pre-treatment baseline tests arranged U&E/LFT/FBC/Coagulation screen/pregnancy	
Set up new patient on CDSS	
Patient counselled	
Oral anticoagulant books & alert card issued	
Prescribe warfarin 1mg & 3mg tablets	
Arrangements for INR testing: Appointment made, explained to patient & recorded in book	
Read code: Initial warfarin assessment Slow induction warfarin therapy Patient held anticoagulant book issued Medication counselling Anticoagulant monitoring primary care	
Initiation checklist complete & scanned to patient record	