Surrey Collaborative
Anticoagulant Working Group

Primary Care Oral Anticoagulation Monitoring Service Guidelines (Warfarin and VIT K Antagonists)

This guideline is intended to be used to support the anticoagulation management service commissioned by CCGs in Surrey. Not all practices will provide this service. Only accredited practitioners who meet the service specification and sign up to the service level agreement should provide this service.

- The NPSA recommends that NHS organisations review their local practice to simplify dosing schedules for patients and carers, incorporating the following characteristics
    - use the least number of tablets each day;
    - use constant daily dosing and not alternate day dosing;
    - not require the use of half tablets

  Local providers will have their own policies for safe prescribing and dosing
- All strengths of warfarin tablets should be used to best meet the needs of individual patients. Not all patients will need all strengths of tablets.
- Oral anticoagulant doses should be expressed in mg and not as the number of tablets.
- The patient should receive verbal and written information on anticoagulant therapy from the start of treatment and an induction process followed to ensure they understand the information.
- Each patient should be issued with an oral anticoagulation therapy (OAT) pack containing an anticoagulant record booklet (yellow booklet) which should be kept up to date.
- Practitioners managing oral anticoagulation should meet the required NPSA competencies.
- Warfarin is classified as a "critical medicine" as defined by the National Patient Safety Agency Rapid Response Report 18: preventing fatalities from medication loading doses. The use of loading doses of medicines can be complex and error prone. Incorrect use of loading doses or subsequent maintenance regimens may lead to severe harm or death.

Particular attention should be placed on assessing concordance and checking changes in medication, food and lifestyle and the impact of these on the International Normalised Ratio (INR).

New Oral Anticoagulants (NOACs) are now available and indicated for certain conditions. Please see Surrey wide Prescribing Clinical Network recommended treatment pathway for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation.

Approved by Medicines Management Committee **19th March 2008**
Updated by Surrey Downs CCG Anticoagulant Working Group **June 2014**
Approved by Prescribing Clinical Network **November 2014**

Acknowledgement:

We would like to acknowledge the work done by NHS Derbyshire, NHS Cumbria and NHS Wirral in developing guidelines on oral anticoagulation and allowing us to use their work in producing this document.

1.0 Contact Details

Please add practice staff details for your clinic:

General Practice Anticoagulant Clinic Staff and Contact Numbers:

General Practice Anticoagulant Clinic Times:

AMEND ACCORDING TO LOCAL PROVIDERS

Testing and Dosing Equipment		Tel
Roche diagnostic for repair of CoaguChek XS Plus		01444 256000
INR-star (available 9.00am to 5.30pm)		01209 710999
UK NEQAS 3rd Floor, Pegasus House, 463 A Glossop Road, Sheffield, S10 2QD		0114 267 3300 Fax: 0114 267 3309
Ashford and St Peters Haematology	Dr Tanya Bernard Lead consultant for anticoagulation	01932 723027
Ashford and St Peters Haematology	Sylvia Gillings Clinical Nurse Specialist for anticoagulation	01932 722945
Surrey Pathology Services	Ian Jackson-Sedgwick Blood Sciences General Manager	01276 526181
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Surrey Pathology Services	Glenda Penfold	01276 526566
Kingston Hospital Haematology	Dr Sangeeta Atwal Consultant Haematologist	020 8934 2032
Kingston Hospital Haematology	David Mcintire, Head of Blood Sciences	020 8934 2051
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Surrey and Sussex Haematology	Edward Onipede Lead BMS Haematology	01737 768511 Ext. 2192 /6470
Surrey and Sussex Haematology	Dr Barry Jackson Consultant Haematologist	01737 768511 Ext. 1693/6473

CCG contacts		
Contract lead		
Lead Commissioning Pharmacist		
Clinical Governance Lead		
CCG Anticoagulant untoward Incident Reporting (all significant events)		
Area Team Incident reporting (SUI)	NHS England South East (Kent, Surrey, Sussex)	ENGLAND.southeastsis@nhs.net

Anticoagulant Information, record books and alert cards can be ordered via the online portal at www.pcse.england.nhs.uk (see appendix 1 for full details).

Ten alternative language translated anticoagulant booklets are available to download form go to: http://www.nrls.npsa.nhs.uk/resources/?EntryId45=61777

2.0 Introduction

Anticoagulant drugs are used to treat and prevent thrombosis (abnormal blood clots) within the veins or arteries. The most commonly used drugs in the UK are the heparins and Warfarin. All anticoagulants are associated with an increased risk of bleeding and must therefore be used with care.

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

Warfarin has a narrow therapeutic index and regular titration of the dose against the anticoagulant effect in the blood, as assessed by the INR, is essential.

The patient should be maintained within their therapeutic range, as documented in section 13. Deviation from the therapeutic range is associated with an increased risk of haemorrhage (if too high), or thrombosis and increased risk of stroke (if too low).
Two other oral anticoagulants require INR monitoring, namely nicoumalone (acenocoumarol) and phenindione. These are used only when patients are allergic to warfarin or are particularly sensitive/resistant to warfarin.
New oral anticoagulants (NOACs) are now available which do not require INR monitoring. Currently, licensed NOACs in the UK are Dabigatran, Apixaban, Edoxaban and Rivaroxaban.

Practitioners managing anticoagulation should meet the required NPSA competencies:
http://www.nrls.npsa.nhs.uk/resources/?EntryId45=61790

National Guidance and Additional Resources

Guidance in this document is produced taking into account:

- BNF 72 September 2016.
- Atrial fibrillation. NICE clinical guideline 180 (2014).
- Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor) NICE diagnostics guidance 14 Issued: September 2014
- Guidelines on Oral Anticoagulation (warfarin): fourth edition – 2011. *Br J Haematology* **154** 311-32.
- Guidelines for point of care testing: haematology. British Committee for Standards in Haematology (BCSH) General Haematology Taskforce, updated 30/7/2008.
- British Committee for Standards in Haematology. Guidelines on Oral Anticoagulation (warfarin): third edition – 2005 update. *Br J Haematology*: **132**: 277-285.
- National Patient Safety Agency – Patient Safety Alert on actions that can make anticoagulant therapy safer, February 2007.
- National Patient Safety Agency. Risk assessment of anticoagulant treatment (2006).
- Fitzmaurice DA, Murray ET, Murray JA. Decentralised Anticoagulant care: Hospital or Community? CME Bulletin Haematology, 1998, Vol 1(3).
- Point of Care Testing – Requirements for Quality & Competence. British Standard BS EN ISO 22870:2006. Issued February 2006.
- Management & Use of IVD Point of Care Test Devices. Device Bulletin 9 February 2010 MDA DB 2010(02) NPSA: Actions that can make anticoagulant therapy safer – Patient safety alert 28 (March 2007).
- Murray et al. INRs and point of care testing. BMJ 2003; 326: 5-6.
- Walton R et al. Computer support for determining drug dosage: systematic review and meta-analysis. BMJ; 318: 984-990.

3.0 Aims and Objectives

Aims:

- To provide standardised and clinically effective warfarin management to patients in XXX CCG who are receiving warfarin therapy, by means of near patient testing (INR testing) within the local community and Computerised Decision Support Software (CDSS).

Objectives:

- To provide accessible, safe, standardised and clinically effective anticoagulation management to patients receiving warfarin therapy whilst minimising the risks associated with anticoagulation.
- To identify patients receiving warfarin and offer transfer of care from hospital to primary care clinics for appropriate patients.
- Ensure the same high quality of service to patients whether accessed in primary or secondary care. Wherever possible, near patient testing is the preferred method, allowing face to face communication between the patient and the health care professional responsible for deciding doses on their test result and any action required as a result.
- To initiate warfarin for suitable patients in primary care.
- To produce optimum management of INR control decreasing the risk of a thrombo-embolic event or extension of an existing event by maintaining clients' INRs at the optimal level of anti-coagulation therapy without producing an unacceptable risk of haemorrhage.
- To educate patients in understanding their treatment, in terms of their condition requiring warfarin, target range for INR, the effects of over and under anticoagulation, diet, lifestyle and drug interactions.
- To appropriately manage patients who are over anti-coagulated.
- To maintain a register of all patients receiving warfarin and have a treatment plan for each patient that is reviewed on a regular basis.
- To review the need for continuation of therapy at each visit.
- To identify and manage appropriately patients with specific needs i.e. poor compliance, unstable INR control or frequent non-attendees.
- To optimise care to patients receiving anticoagulant therapy in terms of accessibility, continuity and waiting times.
- To ensure complete and accurate documentation of the clinic process.
- Enhance the confidence and develop the skills of GPs and practice staff who have an interest in anti-coagulation monitoring.

4.0 Roles and Responsibilities

4.1 Responsibilities of Clinical Commissioning Group (XXX-CCG)

The role of the CCG is to ensure that services provided in primary care are in accordance with the service level agreement for the provision of anticoagulation services including the following;

- Ensuring the NPSA safety alert 18 (Actions that can make anticoagulant therapy safer) March 2007 is implemented in GP Practices.
- Develop, update and review the Primary Care Standard for Anticoagulation in Primary Care as necessary.
- Developing Anticoagulation Therapy Guideline, training pack and template Standard Operating Procedures to support GP practices to provide anticoagulation services.
- Ensuring anticoagulant guidelines are available for the management of under and over anticoagulation.
- Ensuring regular clinical audit is undertaken.
- Monitoring participation of sites in national laboratory quality assurance scheme and monitoring performance.

4.2 Responsibilities of GP practices offering an anticoagulant monitoring service

- Notify CCG of the level of service agreement they are to provide.
- Ensure Anticoagulant Monitoring Guidelines are distributed and available.
- To develop Practice Standard Operating Procedures or detailed policies, which are read and signed by all relevant staff and responsibilities of staff are clear and understood.
- Ensuring appropriate training is undertaken by all staff involved in anticoagulation and evidence of this training is documented. All competencies must be satisfactory before undertaking the service.
- Training on Computerised Decision Support Software (CDSS) is completed prior to implementation.
- The appropriate equipment for testing INR and vitamin K is available at the anticoagulation clinic/ GP surgery.
- Training on Near Patient Test meters (NPT) must be undertaken before testing can commence.
- Ensuring internal and external audit for the equipment used in anticoagulation is undertaken and results submitted to the CCG.
- Perform and record clinical audit annually.
- Ensure an anticoagulant nominated GP is available at all times when anticoagulation services are offered to patients by the practice.
- Ensure reception staff are aware of the importance of patients attending within a specified period so that appointments are not unwittingly delayed without guidance from appropriate clinical staff.

4.3 Responsibilities of patients' GP

Overall responsibility for the care of the patients continues to reside with the registered GP who will be providing prescriptions for anticoagulation therapy, and includes:

- Ensuring that dose recommendations and recall are guided by approved written protocols or Computerised Decision Support Software (CDSS).
- Ensuring patients receive education regarding anticoagulant therapy (Appendix 3).
- Giving advice on duration and intensity of anticoagulation as guided by initiating clinician.
- Being aware of the potential effects of additional therapy given to a patient on anticoagulants, and arranging earlier INR testing as required.
- Acting promptly to patients with bleeding problems and/or INR > 8 or who are otherwise considered to be at risk of bleeding.
- Dosing decisions should be made by health-care professionals (e.g. GP's, registered Nurses or registered Pharmacists) who have undergone an approved course for practitioners undertaking anticoagulant monitoring in primary care and who are deemed competent under the NPSA competency framework.
- Arranging admission to hospital if required.
- Issuing warfarin prescriptions.
- Ensuring that all patients receive appropriate monitoring, either with primary care anticoagulation service or in secondary care.
- To stop anticoagulant when specified duration is complete.
- On initiation of therapy the suitability of the patient is assessed to their ability to take warfarin safely (see risk assessment of patients for oral anticoagulation Appendix 2).
- Ensuring that patients who do not speak, read or write English or who have communication difficulties (including without limitation hearing, oral or learning impairments) are provided with appropriate assistance. A responsible person or carer should be identified who can assist patient with any dose alterations.

4.4 Responsibilities of Secondary Care

- Identify suitable patients for transfer into primary care.
- Able to provide urgent medical advice relating to anticoagulation.
- To accept patients who may not be suitable for anticoagulation monitoring in primary care ensuring that transfer of care from secondary to primary care is seamless in terms of patient's anticoagulant therapy.
- To provide INR testing from venous samples.

5.0 Training

Training is essential to ensure all provider staff or those contracted by the practice to provide the service have the necessary skills and knowledge to conduct anti-coagulation monitoring and use the equipment successfully. Training will involve point of care testing and clinical knowledge of anticoagulant monitoring.

The National Patient Safety Agency (NPSA) has issued guidance on the training and competency requirements for those involved with anticoagulation.

The clinical leads are responsible for ensuring that all members of the provider staff have attended training provided by the CCG or an approved anticoagulant training course. This includes **all** practice staff involved in near patient testing and/or dosing for anticoagulation clinics.

All staff involved in monitoring patients under the anticoagulation service must attend an annual update run by the CCG and commit to continual professional development related to INR monitoring each year.

The clinical leads for each practice will engage in local networking to develop close contact with local consultants, pharmacists and others providing this care to the patients.

The training should cover theoretical aspects of anticoagulation monitoring and should ensure that all staff involved have:

- The ability to safely manage a primary care based anticoagulation clinic using point of care testing for INR measurement where relevant, interpreting INR results and assessing the dose of oral anticoagulation in order to maintain results within their appropriate therapeutic ranges.
- A comprehensive understanding of the conditions requiring oral anticoagulation therapy and target ranges for warfarin therapy.
- An understanding of the pharmacology of warfarin and determine the relevance of; dosing, side effects, antidotes, interacting medication and lifestyle factors.
- The ability to critically analyse all aspects of anticoagulation management and therefore evaluation aspects for safe practice.
- The practical aspects of the training should involve providing evidence for set competencies.

Sources for additional training:
BMJ Learning -
This is advisable to all who are going to dose and prescribe anticoagulants.
www.bmjlearning.com
Two modules to undertake and complete:
1. "Starting patients on anticoagulants: how to do it"
2. "Maintaining patients on anticoagulants: how to do it" for GPs, practice nurses and other healthcare professionals.
It is possible to register to do this module as a guest user as long as you have an NHS email address.

MHRA learning module
www.mhra.gov.uk/Oralanticoagulants
Designed for use by all clinical practitioners, the module covers:

- description of important adverse effects
- factors that increase the risk of adverse effects
- how the clinician and the patient can reduce the risk
- specific treatment of the adverse effect

The learning module includes a quiz on important risks and their management and you download evidence of their learning.

Warwick Medical School -
Run a three-day course covering the theory underpinning anticoagulation management as well as the pharmacology of vitamin K antagonists and the relevant medication, side effects, antidotes, interactions and dosing. The course will also cover the management of anticoagulation and prevention of complications on the basis of current guidelines and research evidence. £1,500
And one day courses: at £175 each

- Introduction to Anticoagulation
- Anticoagulation Update Day
- Anticoagulation Management for HCAs and Assistant Practitioners
- Advanced workshop for nurses: Clinical Scenarios for managing warfarin and direct oral anticoagulants

https://warwick.ac.uk/fac/med/study/cpd/cpd/anticoag

Surrey Pathology Services run a CPD accredited course with multi-disciplinary input from local acute hospitals.
Nurse/HCA training sessions: these include an overview of the history of warfarin, the clotting cascade, patient groups (e.g. DVT, PE, AF), patient education, warfarin dosing, side effects, patient scenarios, heparin, the clinic, quality assurance, dealing with high/low INRs, responsibilities/accountabilities, INRStar, NOACs, general POCT issues and a hands on training session in the use of the CoaguChek device. A competency testing program is set up with the trainees. **Cost:** £350 per day for 1-12 people.
Annual refresher training for these staff can be provided. Cost: £200 per half day for 1-12 people.

https://www.cppe.ac.uk/programmes/l/anticoag-d-03 "Anticoagulation: managing patients, prescribing and problems" for Pharmacists.

6.0 Indication, INR targets and duration of therapy

Therapeutic indications:

- Treatment and prophylaxis of deep-vein thrombosis or pulmonary embolism.
- Antiphospholipid syndrome.
- Prophylaxis of stroke in atrial fibrillation.
- Mitral stenosis or regurgitation in patients with either atrial fibrillation, a history of systemic embolism, a left atrial thrombus, or an enlarged left atrium.
- Arterial embolism requiring embolectomy.
- Myocardial infarction.
- Prophylaxis of thrombo-embolism after insertion of prosthetic heart valve.

Contraindications:

- Pregnancy.
- Hypersensitivity to warfarin.
- Within 2 days of surgery.
- Bacterial endocarditis.
- Severe renal or hepatic disease.
- Documented evidence of CNS haemorrhage in the previous 6 months.
- Gastric-intestinal bleeding in the past 6 months.

The present indications for warfarin treatment including target INR and an estimation of the length of therapy can be found in table 1 and table 2 below:

Table 1: Warfarin Indication and target INR's and anticipated length of treatment

Indication	Target INR	Anticipated length of treatment
Pulmonary embolus	2.5 (2.0-3.0)	At least 3 months
Proximal deep vein thrombosis	2.5 (2.0-3.0)	At least 3 months
Calf vein thrombosis	2.5 (2.0-3.0)	6 weeks
Cancer associated venous thrombo-embolism (VTE) should initially be treated for 6 months with LMWH rather than warfarin.		
Recurrence of VTE when no longer on warfarin therapy	2.5 (2.0-3.0)	Long Term
Recurrence of VTE whilst on warfarin therapy and in therapeutic range	3.5 (3.0-4.0)	Long term
Symptomatic inherited thrombophilia	2.5 (2.0-3.0)	Long term
Antiphospholipid syndrome	2.5 (2.0-3.0)	Long term
Atrial fibrillation	2.5 (2.0-3.0)	Long term
Cardioversion Patients undergoing elective cardioversion should be anticoagulated for at least 3 weeks prior to and 4 weeks post cardioversion with a target INR of 2.5	2.5 or 3.0 *	*To minimise cardioversion cancellations due to low INR on the day of procedure a target INR of 3.0 can be used prior to the procedure
Patients with mitral stenosis or regurgitation who have AF or a history of systemic embolism or left atrial thrombosis or an enlarged left atrium	2.5 (2.0-3.0)	Long term
Mechanical heart valve	See table 2	
Where an embolic event occurs during anticoagulation within target, elevation of the INR target or addition of anti-platelet drug should be considered		
Bioprosthetic valve in mitral position	2.5 (2.0-3.0)	3 months
Bioprosthetic valve with history of systemic embolism	2.5 (2.0-3.0)	At least 3 months
Bioprosthetic valve and left atrial thrombosis at surgery	2.5 (2.0-3.0)	Until clot has resolved
Bioprosthetic valve and other prothrobotic risk factors	2.5 (2.0-3.0)	Long term
Arterial embolism and embolectomy	2.5 (2.0-3.0)	Long term
Warfarin used post MI (less common now)	2.5 (2.0-3.0)	
Cardiomyopathy	2.5 (2.0-3.0)	
Ischaemic stroke without Atrial fibrillation	Not indicated	
Peripheral vascular disease	Not indicated	Anti-platelet agents and medications to control other risk factors

*See Guidelines on Oral Anticoagulation (warfarin): fourth edition – 2011 *Br J Haematology*

Table 2 Recommendations for mechanical heart valves

Prosthesis Thrombogenicity	INR target (no patient risk factors)	INR target (patient risk factors)
Low - Carbomedics (aortic position), Medtronic Hall, St Jude Medical	2.5 (2.0-3.0)	3.0 (2.5-3.5)
Medium – Bjork-Shirley, other bileaflet valves	3.0 (2.5-3.5)	3.5 (3.0-4.0)
High – Starr-Edwards, Omniscience, Lillehei-Kaster	3.5 (3.0-4.0)	3.5 (3.0-4.0)

Patient risk factors – Mitral, tricuspid or pulmonary position; previous arterial thromboembolism; atrial fibrillation; left atrial diameter >50mm; mitral stenosis; left ventricular ejection fraction < 35%; left atrial dense spontaneous echo contrast.

7.0 Patient Selection

Patients who are currently on warfarin therapy in the primary care setting.
Patients currently in secondary care anticoagulant clinics who are 'stable'
Patients who need slow loading with anticoagulant.

NB. Anticoagulation may be initiated in selected patients (e.g. atrial fibrillation) if deemed appropriate by the lead clinician. This should only occur in established primary care clinics where the staff have experience in INR monitoring and have demonstrated competencies (NPT2).

The decision of which patients should remain under the care of the hospital haematology department is made according to the judgment of the lead clinicians for primary care clinic and the secondary care service.

Inclusion criteria:

- Atrial Fibrillation.
- Prophylaxis and treatment of venous thrombosis and pulmonary embolism.
- Artificial Heart Valves.
- Long-term anticoagulation for recurrent venous thrombosis (except antiphospholipid syndrome).
- Mural thrombus.
- Cardiomyopathy.

Exclusion criteria:
The decision of which patients should remain under the care of the hospital haematology department is made according to the judgment of the lead clinicians for primary care clinic and the secondary care service.

Practices new to anticoagulant monitoring services (NPT1) may choose to exclude the following patients:

- Patients taking Phenindione or Acenocoumaral.
- Patients with poor control or consistently unstable or high INR results. Factors which may cause this are:
    - Alcohol problems.
    - IV Drug use.
    - Severe heart failure.
    - Chemotherapy for malignant tumors; Note: LMWH may be required in long term malignancies.
- Patients who have had a DVT/PE in the past month.
- Children under 16 years (refer to Paediatrician).
- Patients undergoing Cardioversion.
- Patients with prosthetic heart valves.
- Other conditions the Consultant Haematologist considers should exclude the patient from management in primary care.

8.0 Referral Process

8.1 To Primary Care Anticoagulant Monitoring Services

Transfer of care should be arranged by written request between the general practitioner and the lead clinician for the hospital based anticoagulant service. This allows formal review of the patient's A/C records before transfer. Written referrals should include:

- Indication for anticoagulation.
- Therapeutic range.
- Duration of treatment.
- Past medical history (bleeding problems, liver disease, peptic ulceration).

- Drug history.
- INR results and doses advised to date.

A formal referral to primary care must be made from secondary care using the locally agreed transfer process.

The local guidelines for the referral and transfer of patients from secondary care to primary care should be added to Appendix 5, documentation needs to be completed for:

- Existing warfarin patients who are currently monitored by secondary care
- New warfarin patients initiated by secondary care
- Existing warfarin patients who are currently monitored in primary care who are admitted to and then discharged from secondary care
- Following written agreement from the primary care provider to take responsibility for anticoagulation of an individual patient, a clinic appointment in primary care must be made.
- Patients unable to be seen in primary care before their next hospital-booked clinic appointment will remain with their current arrangement until an appointment can be booked with the GP surgery.
- At the first patient consultation, appropriate anticoagulation documentation (see section 10) should be completed.

8.2 Referral from Primary Care to Secondary Care Management

Patients who are not eligible for treatment under an approved primary care anticoagulation service will remain under their present anticoagulation care management system.
If patients fail to attend their secondary care monitoring appointments then secondary care will contact the patient's registered GP to discuss further. Consideration may need to be made as to the patient's suitability to continue with anticoagulant therapy.
Patients should be referred to the Haematology department where the anticoagulation provider feels that the management of a patient is++ outside his/her sphere of competence or falls under exclusion.
Patients should be referred to secondary care if there are complications which do not require emergency treatment via A&E.
This should be done by written referral from the lead clinician for anticoagulant service.

9.0 Primary Care Anticoagulant Monitoring – clinic organisation

All patients will be seen in person either in a clinic, at a GP's surgery or at home by a Health Professional who has undergone training approved by the CCG as detailed in section 5.
Each GP practice will nominate a lead clinician who has responsibility for overall management of the service provided by that practice which includes the responsibility of ensuring that all practice staff involved in near patient testing and/or dosing for anticoagulation clinics have attended CCG training.

Each practice will have a practice specific SOP giving details of staff involved (typically a mix of GP, practice nurse and HCA), their roles and responsibilities within the clinic, how adequate cover will be provided for absence/AL by suitably trained personnel, clinic times, how patients may book/change appointments.
Each individual GP practice will organise their clinics. If there are only a few patients at one practice monitoring and dosing may be organised at another GP practice by local agreement. It is recommended to test patients' INR in the mornings to allow adequate time to obtain a venous sample and to organise treatment if required for patients with a high INR.

9.1 Clinic Attendance, Call and Recall Procedures

It is essential all warfarin patients keep their clinic appointments.

Non-attendees should be identified immediately. The patient should be given and informed of their new appointment within one week.

A systematic call and recall system should be in place, and the provider should implement appropriate strategies to ensure non-attendees are identified and monitored.
If a patient fails to attend a clinic, or is not at home (for a domiciliary visit), the provider will contact the person by telephone to ascertain the reason for the DNA, schedule a new appointment as soon as possible but within one week – the timing of the next appointment will be by agreement, taking into account clinical criteria and contact the non-provider GP.

If the patient again fails to attend, the patient should again be offered a further appointment unless there is information to suggest this is not necessary. The provider must notify the patient's GP.
The non-provider GP should then contact the patient to ascertain the reason for DNAs, check they have not attended elsewhere, inform the patient of continued monitoring and therapy, follow practice DNA procedure and complete a significant event report and email this to the CCG.
The registered GP may decide that continuation of therapy in the absence of monitoring is considered too risky. The patient's registered GP will then be responsible for ensuring that no further prescriptions are raised.

9.2 Individual Management Plans

The patient's registered GP in conjunction with the patient should prepare an individual management plan. The plan should outline, as a minimum, the diagnosis, planned duration of treatment and therapeutic range to be achieved.

9.3 Clinical Procedures

All clinical information is recorded in the patient's own GP held lifelong record, including completion of the "significant problem" record indicating that the patient is on warfarin and the indication for anticoagulation. At initial diagnosis, and on an annual basis, a comprehensive review of the patient's health needs to be undertaken to include the identification of potential complications. Additionally, regular review of the patient's own monitoring records should be undertaken.

9.4 Education of Newly Diagnosed Patients

All new patients prescribed warfarin must have a counselling checklist (Appendix 3) completed to ensure the patient has received all the appropriate information required. At the first appointment following transfer from secondary care, education should be reinforced (according to a Counselling Checklist - Appendix 3). The counselling should be comprehensive to ensure that patients are fully aware of their treatment and should include:

- The name of the drug and current dose.
- The reason they are taking the drug.
- Therapeutic goal and target INR.
- The anticipated length of treatment.
- What to do in the event of a missed dose.
- Symptoms of under/over anticoagulation and action to take if these occur.
- Drug/drug and drug/food interactions including lifestyle factors.
- Clinic arrangements and how to obtain further medicine supplies.
- What to do if dental treatment/surgery is required (warfarin does not usually need to be stopped for dental treatment. It may be stopped or reduced for surgery).
- What to do if a surgical procedure is required/indicated.
- To tell healthcare professionals they are taking warfarin and show their yellow book whenever they receive treatment or advice.
- Need to take yellow book when requesting warfarin prescriptions from GP and to collect from pharmacy.
- Who and how to contact regarding any worries or concerns relating to their anticoagulation management.

Check the patient has received a yellow Anticoagulant pack, known as OAT Information Pack (oral anti-coagulant therapy). This contains a yellow record booklet which they need to show to their GP/health practitioner whenever they seek medical or dental treatment or purchase medicines from a Pharmacy. Patients should be encouraged to carry their yellow credit-card-style information card with them at all times. It should be ensured that all newly diagnosed patients (and/or their carers and support staff) receive appropriate management of, and information regarding the prevention of secondary complications of their condition, including the provision of a handheld anticoagulation booklet.

Supplies of the yellow warfarin booklet can be ordered from
Primary Care Support England via the online portal at www.pcse.england.nhs.uk(see appendix 1 for full details)

The patient needs to present their yellow booklet to the Pharmacist when collecting their prescription of anticoagulant. The patient may be given a print out of their results and new doses from the Computer Decision Support Software (CDSS). The patient needs to take their yellow booklet or the CDSS printout with them before the prescription can be dispensed by the Pharmacy. Their prescription cannot be dispensed without proof their INR is being monitored and in range (NPSA safety alert).

9.5 Documentation in the clinic setting - Patient Register and Patient Records

Practices will be required to keep a record for each patient under their care. This information must be updated at each visit and will include:

- Patient name and address.
- Patient date of birth.
- NHS number.
- Indication for treatment.
- Length of treatment.
- Target INR.
- Named medical practitioner initiating treatment.
- Discontinuation date.
- INR results, dosage instructions and review dates.
- Missed days (i.e. a record of days when the patient has not taken their anticoagulant therapy in accordance with dosing instructions).
- Concurrent medication.
- Medical conditions, hospital admissions likely to affect anticoagulation such as an increased risk of haemorrhage (BSH Guidelines 2011).
- Bleeding episodes and adverse events.
- Any actions taken, as well as dosing and retest dates e.g. education, advice, whether the INR result is from near patient testing or central lab testing.
- Occasions when the patient failed to attend an agreed clinic appointment.
- Contact details for patient or for carers responsible for the administration of warfarin.

The patient's yellow warfarin booklet must be updated at each visit. If this booklet is not available, a temporary record booklet must be completed and given to the patient. A printout from CDSS is also acceptable, which must be kept with previous printouts to form the patient's hand-held records.

The front of the yellow warfarin booklet must be completed i.e. indication, INR target range and duration of treatment, person with clinical responsibility, and emergency contact number. The patient's registered GP will contact the initiating hospital if any of these details are omitted.

For new patients who need to be initiated on warfarin, a risk assessment needs to be completed (**see Appendix 2)** and a counselling checklist needs to be completed (**see Appendix 3**).

10.0 Warfarin Supply: Prescribing and Dispensing

10.1 Prescribing

Different people require different doses of warfarin. Some pre-existing conditions may make patients more or less sensitive to warfarin. Drugs, herbal remedies and diet also have the potential to interact dangerously with anticoagulants. Please consult the latest BNF and SPCs for details of potential interactions and/or contact a prescribing advisor in the CCG Medicines Management Team – if required.

Patients will be encouraged to take their warfarin daily and at a regular time, usually 6pm.

Warfarin will be supplied from the patient's registered GP via a prescription. Wherever possible the patient should not be provided with more than two strengths of warfarin. Tablets should be routinely supplied in 1mg and 3mg strengths to ensure a consistent approach across primary and secondary care and minimize the risk of confusion. In exceptional circumstances e.g. high warfarin sensitivity or high dosage requirements, warfarin may be prescribed in 0.5mg or 5mg strengths. In these instances the prescription must indicate the strength prescribed in both numbers and words ("half mg" or "five mg") to ensure that the correct tablet is given. The patient should be supplied with the least number of different strengths of tablets possible.

The table below shows the strength and colour of the different warfarin tablets available:

Strength	Colour
0.5mg	White
1 mg	Brown
3 mg	Blue
5 mg	Pink

Repeat prescriptions should only be issued if the prescriber has checked that the patient is regularly attending the anticoagulant clinic, that the INR is within safe limits and the patient understands what dose to administer.

Prescribers should arrange additional INR monitoring within 4-7 days and alert the monitoring service if an interacting medicine is started or stopped.

Specific dosing instructions will not normally appear on the dispensing label. All dosing instructions will be given verbally as well as written in the patient's yellow warfarin booklet or on a computerised dosing sheet.

10.2 Dispensing

The practitioner who dispenses the warfarin prescription must ensure it is safe to dispense – there may have been a delay between it being written and dispensing.

The practitioner should review the patient's yellow book (where available) checking the date of last blood test, latest INR, current dose and confirming this information with the patient or carer.

When dispensing or providing an interacting drug from the pharmacy the dispensing practitioner should check that the next test is planned within a week.

11.0 Initiating Therapy with Warfarin

A GP may choose, or be asked, to initiate warfarin for suitable patients who require non-urgent anticoagulation e.g. in atrial fibrillation. Warfarin should be initiated according to the anticoagulant (oral) therapy prescribing guidelines (section 12.0).

At the first appointment to initiate warfarin, it is essential that the provider must ensure that the patient is given all the relevant information and education verbally and in writing (see education of newly diagnosed patients above). The provider should also complete the relevant sections of the yellow hand-held warfarin book and issue this to the patient.

11.1 Treatment of Acute Thrombosis (DVT or PE)

Warfarin should not be given without heparin in presence of current thrombosis.

Warfarin Dose

A loading dose of 5mg daily has been found to be as effective as 10mg.
In elderly patients it may be more appropriate to use lower initiation doses. Re-check after 2-4 days and adjust dose according to clinical judgment. Transfer to using INR star for dosing when dose settled.

11.2 Prevention of thrombosis in Atrial Fibrillation (AF)

For outpatients who do not require rapid anticoagulation a slow-loading regimen is safe and achieves therapeutic anticoagulation in the majority of patients within 3–4 weeks.
Heparin is not required when initiating warfarin in AF.

Warfarin Dose

Patients may be started on 3mg of warfarin daily with an INR test after 5 to 7 days.
In the very elderly or patients taking potentially interacting medicines a dose of 2mg daily may be used.
In a young and otherwise fit individual with AF a dose of 5mg daily for 5 days is sometimes used.
Test on day 5 to 7 and adjust dose according to clinical judgement. Transfer to using INR star for dosing when dose settled.

12.0 INR Testing

Each time that a patient attends to have their INR tested, the practitioner should obtain the following information:

- Confirm the name and DOB of the patient and reason for attending the clinic.
- Inform the patient of the clinic process and gain full informed consent before procedure (verbally is acceptable).
- Perform an INR test using their own testing equipment to obtain an INR result.
- Ascertain if the patient experienced any signs of bleeding or bruising.
- Check whether the patient planning any dental or other surgery.
- Check whether the patient followed their advised dosage instructions.
- Ask if there has there been a change in the patient's other medications or dietary habits (change in salad, vegetable or cranberry juice intake) since their last test.
- Ask for changes in the pattern of alcohol consumption.
- If poor compliance is suspected, this needs to be documented and the clinic doctor and general practitioner should be informed.

If the practitioner undertaking the blood test is not giving the dosing instructions, then any relevant information obtained from the patient should be passed on to the relevant clinician to inform their dosing decision.

It is recommended to test patient's INR in the morning so if subsequent samples are needed, there is sufficient time to obtain results before the end of the day.

12.1 Special Precautions

General

Changes in the patient's clinical condition especially associated with inter-current illness or liver disease will require more frequent INR monitoring.

The following may exaggerate the effect of warfarin and may necessitate a dose adjustment and

more frequent INR monitoring:

- Loss of weight
- Elderly
- Acute illness
- Deficient renal function
- Decreased dietary intake of vitamin K
- Administration of some drugs (see interactions)

The following may reduce the effect of warfarin and may require a dose adjustment and more frequent INR monitoring:

- Weight gain
- Diarrhoea (can sometimes increase warfarin effect)
- Vomiting
- Increased dietary intake of vitamin K, fats and oils
- Administration of some drugs

More frequent monitoring of INR levels are necessary if any new medication (including non-prescription) is added or withdrawn from the regimen of a patient stabilised on warfarin, or if the dose of a concurrent medication is changed.

Pregnancy

Oral anticoagulants should not be used in pregnancy because of possible teratogenicity and foetal haemorrhage near term.
Women of childbearing age who are taking warfarin should be cautioned about the teratogenicity of warfarin. Stopping warfarin before the sixth week of gestation may largely avoid the risk of foetal abnormality. **Referral to secondary care is required if any patients are pregnant or have plans to become pregnant.**

Lactation

Warfarin is excreted into breast milk in extremely small quantities and is therefore considered compatible with breast-feeding.

Elderly

The elderly may be more susceptible to the effects of warfarin which may result in an increased risk of haemorrhage. Lower maintenance doses, weight for weight than those usually recommended for adults may be required for this group of patients.

12.2 Dose Adjustments of Oral Anticoagulants

The long half-life of Warfarin and some of the clotting factors means that any changes in dose can take about 3 days (72 hours) to be effective.
When Warfarin is stopped the INR may take several days to return to 1.0.
The anticoagulant effect of Warfarin may be overcome by the administration of vitamin K.

The anticoagulant dose should be adjusted by the practitioner, with reference to the patient's INR and any other changes that may be identified during the appointment (see INR testing above).
Dosage of oral anticoagulants should be **guided** by using Computerised Decision Support Software (CDSS)
Dosing should not be increased by more than 5-20% weekly dose.
There is no maximum dose of warfarin but most patients require 2mg to 10mg per day. A small proportion of patients (5%) are warfarin resistant and so will need higher than expected doses. It is important to determine if this could be due to noncompliance or diet rather than the genetic cause.

12.3 Computerised Decision Support Software (CDSS)

The INR result should be input into the CDSS that uses a validated equation for calculation of the recommended dose and date for review.
The recommended dose and review date should be accepted or overridden depending on whether they are acceptable taking into account all patient factors.
The clinician can alter dosage and / or reset review dates if clinically appropriate.

Calculate the person's TTR at each visit (New from NICE CG 180 – June 2014)

- Calculate TTR over a maintenance period of at least 6 months.
- Reassess anticoagulation for a person with poor anticoagulation control shown by any of the following:
- 2 INR values higher than 5 or 1 INR value higher than 8 within the past 6 months
- 2 INR values less than 1.5 within the past 6 months
- TTR less than 65%.

When reassessing anticoagulation, take into account and if possible address the following factors that may contribute to poor anticoagulation control:

- Cognitive function
- Adherence to prescribed therapy
- Illness
- Interacting drug therapy
- Lifestyle factors including diet and alcohol consumption.
- If poor anticoagulation control cannot be improved, evaluate the risks and benefits of alternative stroke prevention strategies and discuss these with the person.

13.0 INR Out of Range

- First check that the patient is taking the dose you think they are. Ask in terms of tablet colours as well as dose.
- Check for missed doses either deliberately (i.e. for surgery) or accidentally. Check for changes in medication (i.e. stopping/ starting interacting drugs).
- Check if using over the counter or herbal medications.
- Significant changes to diet- either increase or decrease in salad, vegetables or cranberry juice
- Changes in pattern of alcohol consumption
- Check that patient is following instructions correctly
- If poor compliance is suspected, this needs to be documented and the clinic doctor and general practitioner should be informed

13.1 Dealing with Low INRs

If INR is low, boosting (“one off”) doses should be approximately 50% greater than the patient’s regular maintenance dose e.g. if daily dose is 6mg, boosting dose should be 9mg. **Again, consideration should be given to patient’s previous pattern of response.**

For low INRs the CDSS may be overcautious and bring the patients back in one week rather than change the dose. Unless there is an obvious reason for the low INR, a dosage increase with two or three weeks to the next test may be preferred. **Clinical judgment should be used in these cases.**

Use of low molecular weight heparin for low INRs

An INR persistently or greater than 1.0 unit below the therapeutic range increases the thrombotic risk. This risk is greatest in patients with:

- DVT or PE within last 4 weeks
- Recurrent VTE

- Mechanical heart valve replacements
- Target INR 3.5

Discuss use of therapeutic LMWH with anticoagulant specialist GP or consultant haematologist if INR < 2.0 in patient from above groups.
LMWH does not need monitoring apart from the need for FBC if patient is on it > 5 days.
LMWH is difficult to reverse and, because it is given subcutaneously and has a long half-life, may be released into the circulation for up to 24 hrs. after administration.
LMWH will not affect the INR.

13.2 Dealing with High INRs

If the INR result is greater than 4.5, then repeat the patient's INR using a new finger stick test using near patient testing device (NPT e.g. CoaguChek® XS Plus).

If the second result is within 0.5 of the original result then accept the result and proceed. If the second test is more than 0.5 different from the first then disregard the results. Send a venous sample to the central laboratory and perform Internal Quality Control on NPT device (see section 15 and appendix 8).

The device will NOT record a specific measurement when an INR > 8.0. For any INR results above 8 repeat the test. If the second result confirms the first then send a venous sample to the central laboratory for testing. This is to obtain a specific INR measurement.

Record the actual INR reading in the CDSS patient record when available from the laboratory.

If a "test error" message is obtained, the NPT device will not provide a reading. Repeat the test and if a second "test error" message is obtained, a venous sample should be sent to the central laboratory for testing.

If a laboratory sample is required because of a high INR and there is no blood collection from the provider's base within 4 hours, arrangements for a venous sample need to be made depending on locality. Full patient contact details, including alternative telephone numbers, must be on the form in case of urgent need for out of hours providers to contact the patient.

If an unexpected result occurs (higher or lower than expected from the patient's past history e.g. difference of > 50% of previous result where there is no good reason found), repeat the INR test.

If the patient has significant anaemia or polycythaemia, this may lead to unreliable results and the device should not be used.

IF INR > 5.0 ACTION MUST BEEN TAKEN IMMEDIATELY!

Follow Guidelines of Treatment of Over-Anticoagulation (section 11.7.3).

The main adverse effect of oral anticoagulants is haemorrhage. Abnormal bleeding is the main sign of warfarin overdose and may be manifested by blood in the stools, haematuria, malaena, petechiae, excessive menstrual bleeding, excessive bruising or persistent oozing from superficial injuries.
Checking the INR and omitting doses where appropriate is essential. If the oral anticoagulant is stopped but not reversed, the INR should be measured 2-3 days later to ensure that it is falling.

An INR >5.0 is associated with an increased risk of bleeding, although patients may of course bleed at therapeutic INR especially if there is an underlying lesion such as a bladder carcinoma or peptic ulcer.

- Check that patient is following instructions correctly.
- Check for changes in medications (i.e., starting on interacting drugs or stopping a drug that reduced the effects of Warfarin).
- Check alcohol consumption.
- Check for signs of bleeding &/or bruising.

The following may act as a guide to practical dosing in cases of high INR, clinical judgment **must** also be used:

INR	Dosage Change	Next Visit
>5.0 (without bleeding)	Withhold 1 or 2 doses of warfarin and reduce subsequent maintenance dose	2-3 days to ensure INR is falling
>8.0 (without bleeding)	Give Vitamin K (phytomenadione) 1mg - 5mg by mouth using the intravenous preparation orally. Local advice from consultant haematologists is to give the contents of one ampoule - 2mg unless either: • clinical judgment that a higher dose is required **or** • patients with higher ranges 3-4 e.g.**valves**, in which case give 1mg and check the next day. Stop Warfarin & restart warfarin at lower dose when INR <4.5	2-3 days to ensure INR is falling

ALL PATIENTS WITH ACTIVE BLEEDING TO BE REFERRED DIRECTLY TO THE ACCIDENT AND EMERGENCY DEPARTMENT ASAP.

A&E may need to give vitamin K 5-10mg by slow IV injection and give pro-thrombin complex concentrate or fresh frozen plasma.

13.3 Frequency of INR Monitoring

The length of time between INR test dates varies; the maximum recommended length of time allowed between INR tests is 12 weeks (BCSH Guidelines 1998). For those with mechanical heart valves, the maximum recommended length of time is 8 weeks. The length of time between INR tests will depend on the patient's INR measurement stability and untoward occurrences likely to cause instability. https://cks.nice.org.uk/anticoagulation-oral#!scenario:3

There are different periods recommended between INR tests elsewhere in the world. In USA it is 4 weeks and in New Zealand it is 8 weeks.
For patients in whom no new factor has arisen, the frequency of monitoring can be guided by the criteria shown in Table 3 or by the use of CDSS**.**

Table 3: Warfarin therapy: maximum recommended recall periods during maintenance therapy (not initiation)

One INR high	Recall in 7 to 14 days (stop treatment for 1 to 3 days) (maximum 1 week in prosthetic valve patients)
One INR low	Recall in 7 to 14 days
One INR therapeutic	Recall in 1 to 2 weeks
Two INRs therapeutic	Recall in 1 to 2 weeks
Three INRs therapeutic	Recall in 3 to 4 weeks
Four INRs therapeutic	Recall in 4 to 5 weeks
Five INRs therapeutic	Recall in 6 to 8 weeks (maximum of 8 weeks for prosthetic valve patients)
More than 5 INRs therapeutic	Recall period can be increased in a step-wise fashion to a maximum of 12 weeks between appointments if stable.

NB. Patients seen after discharge from hospital with prosthetic valves may need more frequent INRs in the first few weeks (based on data from Ryan et al [1989] British Medical Journal 299, 1207-1209)

13.4 Communicating Dose Changes

The provider will need to update the yellow warfarin booklet giving dosage instructions to include: details of dose, frequency, colour and number of tablets, e.g. 7mg once a day (2 x 3mg – *blue tablets* and 1 x 1mg – *brown tablets*).

- A printout of new doses from CDSS will be acceptable to give to the patient, but these need to be kept to form the patient's hand held records, in accordance with the NPSA alert.
- Date of the next INR test and contact numbers for advice should be recorded.
- If dosing decisions are not given to a patient in an appointment, then appropriate arrangements should be made to ensure that results, dosage instructions and the next review date are given to the patient.
- If results are given over the phone, then practices should ensure that a named person is responsible for this.
- Verbal instructions should be followed up by a posted written instruction. Where practices identify patients for whom it is not appropriate to give results over the phone, then alternative arrangements should be made to ensure that information is received in a timely manner by the patient. Practices are strongly recommended to develop a protocol for this.
- Particular care should be taken when communicating dose changes to patients in social care settings (e.g. nursing or residential care homes). The nurse in charge should be informed of the warfarin dose and next review date over the phone. This information should be confirmed in writing by fax or by post as appropriate.
- Practices are strongly recommended to develop a protocol for this.
- It is recommended that a risk assessment is done on patients on Monitored Dosage Systems (MDSS) and warfarin. It may not be the most appropriate method of helping with medicine compliance and except in exceptional circumstances should be avoided.
- If a monitored dose system is deemed to be absolutely essential particular care should be taken when communicating dose changes to patients using Monitored Dosage Systems (e.g. NOMADs). Both the patient and the Pharmacist filling the monitored dosage system should be informed of the warfarin dose and next review date. The information will be confirmed in writing to the patient and the Pharmacist

13.5 Individual Annual Review

Patients should undergo an annual health check as part of the management of their condition. The responsibility of this lies with the patient's own GP.

13.6 Self- Monitoring and Self-Managing Warfarin Therapy

NICE recommends the CoaguChek XS system is recommended for self-monitoring coagulation status in adults and children on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease if:

- the person prefers this form of testing and
- the person or their carer is both physically and cognitively able to self-monitor effectively.

Near patient or point-of-care testing devices have made it possible for patients on oral anticoagulants to monitor their INR in the home setting.

However, self-monitoring or self-management is complex and has financial implications to the patient. GP practices signed up to the highest level of the Anticoagulant Monitoring Local Enhanced Service (NPT2) are responsible for educating eligible patients so as to allow them to self- monitor at home and clinicians involved in their care should regularly review their ability to self-monitor.

Each practice providing this service must have their own protocols in place to manage the risks associated with this process and the following criteria must also be met:

- The patient needs to have a long term indication for anticoagulant therapy.
- A locally approved point-of-care device needs to be used.
- The patient must give informed consent.
- A contract between the health care professional and the patient must be agreed (Appendix 10).
- Clinics signed up to the INR LES are not permitted to prescribe test strips and other consumables e.g. lancets on FP10.
- The patient must be competent to perform and interpret the result.
- The patient needs to attend the anticoagulant clinic at least every 6 months
- Internal quality assurance must be carried out in accordance with manufacturer's instructions and external testing at least every 6 months by comparing the result from the patient's device to that from the clinic device.

For people who may have difficulty with or who are unable to self-monitor, such as people in residential or nursing care, their carers should be considered to help with self-monitoring.

13.7 Discontinuation of Warfarin

The maximum duration of overall treatment will be documented on the initial referral form and in the patient's yellow warfarin booklet.
Whether treatment should be discontinued (including a risk/benefit comparison) should be reviewed regularly and at least annually by the clinician responsible for INR monitoring.
Responsibility for the decision to discontinue the anticoagulant will reside with the patient's own registered GP.

The anticoagulation provider should raise the issue when appropriate and provide written evidence.
Oral anticoagulants will be discontinued on an agreed defined date and all people involved in the care of that patient will be informed.
If warfarin therapy needs to be discontinued for medical reasons then the GP and the initiating consultant/clinician should be notified ASAP.
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. patients not attending regular monitoring, those unable to follow the dosing regimen.

13.8 Managing Patients Requiring Dental Surgery in Primary Care

Oral anticoagulants should not be discontinued in the majority of patients requiring out-patient dental surgery including dental extraction.
The risk of significant bleeding in patients on oral anticoagulants and with a stable INR in the therapeutic range 2-4 (i.e. <4) is very small and the risk of thrombosis may be increased in patients in whom oral anticoagulants are temporarily discontinued.
For patients stably anticoagulated on warfarin (INR 2-4) and who are prescribed a single dose of antibiotics as prophylaxis against endocarditis, there is no necessity to alter their anticoagulant regimen.
For patients stably anticoagulated on warfarin (INR 2-4) and who are prescribed a single dose of antibiotics as prophylaxis against endocarditis, there is no necessity to alter their anticoagulant regimen.
Patients taking warfarin should not be prescribed non-selective NSAIDs and COX-2 inhibitors as analgesia following dental surgery.

13.9 Managing the Transition to Surgery - Bridging

For some invasive procedures, such as joint injections, cataracts and certain endoscopic procedures, warfarin does not need to be stopped. If anticoagulation has to be stopped for surgery or an invasive procedure, the risk of thrombosis, the consequence of thrombosis, by how much bridging therapy with treatment dose LMWH reduces the risk, the excess bleeding due to pre-operative or post-operative bridging and the consequences of bleeding all need to be considered.
Pre-operative bridging carries a low risk of bleeding but the use of post-operative bridging requires careful consideration due to the high risk of bleeding. It is recommend that post-operative bridging should not be started until at least 48 hours after high bleeding risk surgery.
Patients with VTE more than 3 months earlier can be given prophylactic dose LMWH (or a suitable alternative) rather than bridging therapy.
Patients with low risk AF (no prior stroke or TIA) do not require bridging therapy.
Patients with a bileaflet aortic MHV with no other risk factors do not require bridging.
Patients with a VTE within the previous 3 months, patients with AF and previous stoke or TIA or multiple other risk factors, and patients with a mitral MHV should be considered for bridging therapy

It is the responsibility of secondary care physicians undertaking the surgical procedure to advise patients on their anticoagulant therapy. However, GP practices should check this is happening and facilitate communication from secondary care. Good communications are essential, and the patient must be provided with written information informing them:

- When to stop taking their warfarin
- Whether heparin is necessary and if applicable, arrangements for administration
- When to restart their warfarin and at what dose
- Date of their next INR test

14.0 The New Oral Anticoagulants (NOACS)

New Oral Anticoagulants (NOACs) are now available and indicated for certain conditions. Please see Surrey wide Prescribing Clinical Network recommended treatment pathway for the prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation.
Detail is on the web based Prescribing Advisory Database (PAD) - http://pad.res360.net

15.0 Reporting an Incident or Serious Incident

All serious incidents and Never Events (should it be applicable) should be reported and investigated in line with the NHS England national frameworks

'Serious Incident Framework: Supporting learning to prevent recurrence'
https://www.england.nhs.uk/patientsafety/serious-incident/

Serious incidents must be reported to the individual CCG Commissioner as soon as possible. Local processes for reporting a serious incident are contained within the CCG Serious Incident Policy/ Procedure. Reporting details required for NHS England can be found at **appendix 7**.

Serious Incident

A serious incident is defined as 'an accident or incident when a patient, member of staff, or member of the public suffers serious injury, major permanent harm or unexpected death, (or the risk of death or injury), on hospital, other health service premises or other premises where health care is provided and where actions of health service staff are likely to cause significant public/media concern.'

Examples of serious incidents include:

- Extensive bleeding while taking anticoagulants requiring treatment with blood products or causing significant harm or death
- Patient on anticoagulation therapy experiencing thrombosis or extension of existing thrombosis
- Loss or breach of confidentially where person/patient or service users are identified.

Patient Safety Incidents and Near Misses

Patient safety incidents (also referred to as untoward events) will be reported to the CCG through the NRLS e-form, https://report.nrls.nhs.uk/GP_eForm , including the practice code.
http://www.nrls.nhs.uk/report-a-patient-safety-incident/healthcare-staff-reporting
Adverse drug reactions should also be reported to the Medicines HR Agency (MHRA) using the yellow-card system.

Other incidents

Patient safety and other incidents, such as information governance or health and safety, should be reported, investigated and learning identified in line with the organisation's own incident reporting procedures and statutory requirements where applicable. Numbers, types, themes and learning identified will be reported to the commissioner at a frequency to be agreed.

Examples of an incident:

- Wrong dose prescribed but error identified and little or no harm to patient
- Patient discharged from hospital without correct referral to anticoagulant clinic
- A mixture of providers involved in care causing communication errors to occur
- Defective equipment identified and taken out of use without harm to patients
- Test results recorded in wrong patient record
- INR >5.0 due to interacting drug started without clinic knowledge
- INR > 8.0 or bleeding while on warfarin treated in primary care

16.0 Quality Assurance

General

Quality must be assured across all aspects of the service including INR testing, dosage advice, record keeping, documentation (patient and quality control records), patient education and patient satisfaction.
The GP surgery must complete all relevant documentation pertinent to providing the service and record any action taken which is outside the service protocol.

Internal Quality Control (IQC) of Near Patient Testing (NPT)

Those GP surgeries using near patient testing must perform internal quality control procedures as per the manufacturer's instructions. These are used to establish whether the particular technique is performing consistently over a period of time, to ensure day-to-day consistency and accuracy of the INR readings. Many manufacturers of Near Patient Testing (NPT) monitors and test strips for INR determination have control materials or electronic devices available for the purpose of IQC.

Quality control guidance is summarised below for the CoaguChek XS Plus. Full details will be found in the Standard Operating Procedure for the relevant device.
• IQC is to be performed at least weekly and the results recorded.
• Ensure that any results outside of acceptance limits are investigated - Contact Roche or hospital laboratory for support if required.

Quality Control	Details
CoaguChek XS Plus	Integrity check QC included in every strip/test
Liquid control	An appropriate internal quality control (IQC) process must be in place in accordance with the MHRA guidelines on POCT, 'Management and use of IVD point of care test (POCT) devices. Device bulletin 2010(02) February 2010'. This should take the form of at least a daily "go/no go" control sample (use of a liquid sample) on days when the instrument is in use and also when there is a new batch of strips, any doubt about the storage condition of strips, or unexpected high or low test value. All record keeping on this process should be accurate & contemporaneous. If the IQC result is outside the target range, a new IQC sample should be prepared and tested. If the second result is also out of range, no further clinical tests should be performed on the device until the problem has been identified and corrected.
UK National External Quality Assessment Scheme (NEQAS)	Those GP surgeries using near patient testing equipment will be required to join an External Quality Assessment Scheme (e.g. UK NEQAS). Further information is given at Appendix 8. External Quality Assessment (EQA) is used to identify the degree of agreement between one centre's results and those obtained by other centres. External QA is available through the UK National External Quality Assessment Scheme (UK NEQAS) for blood coagulation and is essential in ensuring the INR recordings from the meter are accurate and reliable. Practices will be sent a sample to test approximately every three months. If the NEQAS result is outside the target range, the problem must be investigated immediately and additional IQC performed on the device. If the IQC continues to give in range results the device can be used whilst the EQA performance is under investigation.
Hospital venous sampling	This needs to be carried out : • Before starting warfarin • If the INR is above 6.0 • If the NPT result is unexpected NB: A second capillary sample and quality control check should be performed before venous sampling. • If EQA is outside range, venous sampling of three patients should be performed to check the NPT results.

Cleaning Procedure
The Near Patient Testing device should be cleaned and maintained as per the manufacturer's guidance.

Managing Clinical Performance of Computer Decision Software System (CDSS)
Practices are encouraged to register for the INRstar CDSS point prevalence feedback service. Point prevalence is a way of performing Internal Quality Control on the warfarin dosing.

There is a feedback service which compares different practices' results every quarter. This is the External Quality Control on the warfarin dosing recommendations given by the CDSS.

17.0 Audit of the anticoagulant monitoring service in primary care

All providers will allow CCG access to INRstar Analytics to monitor the quality of the service in regard to Time in Therapeutic Range and numbers of tests above and below range. The analytics data will inform what local actions are needed to improve the safe use of anticoagulants, and will also be used as part of the performance management process of SDCCG.

Appendix 1 - How to order the yellow books //OAT (oral anti-coagulant therapy) booklets for GPs and Primary Care Clinics

GP practices and Primary Care Clinics can order the OAT booklets free of charge via the PCSE online portal at www.pcse.england.nhs.uk. Click on 'General Practices' and then search in 'Supplies'

Items available: OAT Information Booklet, Alert Card, OAT Record Booklet, Record Sheets

Select the items you require. Your order will then be processed.

NB. Please make sure you have the practice address and code to hand – this information is essential. Should you require any further assistance please call Primary Care Support England on Tel: 0333 0142884 or email at pcse.enquiries@nhs.net

Appendix 2 - Risk Assessment for Anticoagulation

The following points must be considered prior to initiating anticoagulation therapy. When discussing the benefits and risks of anticoagulation, explain to the person that:

- for most people the benefit of anticoagulation outweighs the bleeding risk
- for people with an increased risk of bleeding the benefit of anticoagulation may not always outweigh the bleeding risk, and careful monitoring of bleeding risk is important.

Do not withhold anticoagulation solely because the person is at risk of having a fall.

These points are for guidance only and ticking "yes" in any section is not necessarily a contraindication to anticoagulation, but should help you balance the risks.
The decision to anticoagulate or to continue anticoagulation is the responsibility of the prescriber.

Question	YES	NO	Action/Date	Initials
Age > 65 years				
Hypertension History (Uncontrolled, >160 mmHg systolic)				
Alcohol Usage History ≥ 8 drinks/week				
Liver Disease Cirrhosis, Bilirubin >2x Normal, AST/ALT/AP >3x Normal			Contraindicated	
Prior Major Bleeding or Predisposition to Bleeding			Discuss with Consultant Haematologist	
Medication Usage Predisposing to Bleeding (Antiplatelet agents, NSAIDs)				
Stroke History				
Is the patient being investigated for, or receiving treatment for cancer?				
Does the patient have poor literacy skills?				
If the patient has previously been on anticoagulant therapy, is there any evidence of non-compliance or instability of INR control? (TTR<60%)				
Is there any evidence of Alzheimer's or other dementia?				
Decision to anticoagulate **Yes/ No**			Indication	
Target INR range 2-3 2.5-3.5 other_____			Anticipated duration _____months/ Lifelong	
Name / designation			Sign/ date	

Appendix 3 - Counselling Checklist

Patient Name:

Patient Number:

Warfarin Counselling Record (sheet to be filed in medical records)

Date of Birth:
This patient has been counselled on the following areas of warfarin therapy, by a Doctor, Pharmacist or other appropriately trained Health Care Professional in accordance with the guidance overleaf.

	Counselling point	**Signature**	**Comments**
1	Use of the Anticoagulant Therapy Record (yellow book) and alert card		
2	Standard dispensing labels (*i.e. take strictly as directed by the anticoagulant clinic*		
3	Basic mode of action of warfarin		
4	Indication for therapy		
5	Expected duration of therapy		Specify duration if known …….
6	Tablet identification – colour of the different tablet strengths		
7	Dose: Varied dosing Time of day to take warfarin How to use the different tablets strengths to make up the dose intended Action to take if dose missed; NOT to take extra doses		
8	Compliance and ways of remembering to take the tablets e.g. using a calendar		
9	Monitoring: Target INR Where to go for monitoring (and importance of attendance)		
10	Side effects of warfarin and poor control of anticoagulation (and what to do if experienced) Signs /symptoms of excess anticoagulation: bleeding or bruising **Recurrence of thromboembolism**		
11	Potential for drug interactions: aspirin, ibuprofen (paracetamol is the preferred analgesic), antibiotics , herbal remedies etc		
12	Diet (vitamin K containing foods, importance of avoiding major fluctuations in dietary intake; cranberry juice interaction)		
13	Alcohol intake		
14	Contraception, pregnancy and hormone replacement therapy (if relevant)		
15	Surgical procedures (inc. day surgery/dental treatment & hospital admission)		
16	Acute illness		
17	Hobbies and leisure activities (including flying)		
18	Injections (including immunisation)		
19	How to obtain further supplies of warfarin		
20	Who to contact for advice/further information		

Counselled by: (Signature): ……

Print name and Designation…… Date……

Appendix 4 - Warfarin Counselling Advice

Use of the Anticoagulant Therapy Record/OAT Record (yellow book) and alert card.

Show the patient the yellow book and go through it with them filling in the details on pages 1 & 2 if available. If unsure of any sections, check with the doctor. Explain that the anticoagulant therapy record is the only record of dosing information available for the patient, since (2) the dispensing labels on the warfarin boxes/bottles will be labelled as *"Take as directed by your doctor or anticoagulant clinic".* **Therefore it is important to keep the record book up to date at all times and for the patient to understand the dosing instructions.**

Go through the booklet with the patient, highlighting the information it contains and ensuring that the points below are covered.

Basic mode of action of warfarin – *"reduces the bloods ability to form clots"*

Indication for therapy – explain why the patient is taking warfarin. Common examples (list not exhaustive) and patient explanations include:
DVT/PE – "to prevent the clot getting bigger or returning
AF- "when the heart is not beating regularly the blood will not flow smoothly. Therefore there is a risk of getting a clot which may travel through the body and cause damage e.g. a stroke"
Pre & post DC cardioversion for AF
Heart valves – "there is a risk of getting clots around the valve, which may float through the body and cause damage; also to prevent valve damage"
Some cancer patients who are receiving thalidomide in combination with chemotherapy and dexamethasone – "to reduce the risk of getting a clot which is sometimes associated with this group of patients

Expected duration of therapy (if known) – if unsure, check with Doctor. **Do not assume or guess.**
DVT/PE- may be a short course (3 – 6 months) or life long if recurrent
AF/heart valves – treatment will be lifelong
DC cardioversion – e.g. at least 4 weeks before and 4 weeks after, the latter depending on success of DC cardioversion (may be longer in practice – 8 weeks)
Cancer patient receiving thalidomide in combination with chemotherapy and dexamethasone – until end of treatment

Tablet identification
Explain colour of the different tablet strengths and that they will always be the same colour for each strength even if the supplier is different.
White 500 micrograms/Brown 1mg tablets/Blue 3mg tablets/Pink 5mg tablets. Patients should only **have 2 strengths.**

Dose
Varied dosing according to blood result/INR
Warfarin should be taken at same time of day, every day (which is often around teatime / (6-7pm). If patient decides to take it in the morning, tell patient to inform hospital staff if (s)he is ever admitted to reduce the risk of getting a double dose (since many hospitals prescribe in-patient warfarin at 6pm)
How to use the different tablets strengths to make up the dose intended
If a dose is missed, OK to take on the same day within 6 hours of when dose was due. NEVER double up on a dose but carry on as normal on next day if dose is missed. Make a note of the date the dose was missed in the yellow book and let anticoagulant clinic/doctor know. If unsure then it is better to miss the dose rather than risk taking a double dose

Compliance and ways of remembering to take the tablets, e.g. using a calendar to mark off whether a dose has been taken.

Monitoring
INR is monitored regularly initially (daily/every few days) and gradually less often once dose and INR settles (monthly or up to 12 weekly)
Outpatient monitoring clinics / GP practice (and importance of attendance)/ District Nurse

Side effects of warfarin and poor control of anticoagulation (and what to do if experienced)
Recurrence of thomboembolism: contact GP if original symptoms recur
Signs/symptoms of excess dosing: severe bleeding or multiple bruising with or without high INR is the most common side effect: contact doctor immediately if unusual or severe
Contact GP if these occur: bloody stools or urine, nose bleeds (if lasting for >5mins or if pt does not usually suffer from nose bleeds), bloodshot eye, coughing or vomiting blood, excessive vaginal bleeding, cuts that take longer than 5 mins to stop bleeding • Bleeding from gums (use a soft toothbrush)
Any other side-effects: discuss with GP

Potential for drug interactions: may be affected by many medicines, therefore:
Patient should always let doctor/dentist/pharmacist know that (s)he is on warfarin
Not to take aspirin unless prescribed by doctor. Care with OTC painkillers (e.g., Ibuprofen/aspirin preparations). Paracetamol is preferred
Caution with antibiotics and always check with pharmacist/anticoagulant clinic before taking herbal remedies
Inform GP/anticoagulant clinic of any drugs stopped started or if doses are changed

Diet: some foods contain high levels of vitamin K which may interfere with warfarin action (e.g. broccoli, brussels sprouts, cauliflower, cabbage, chickpeas, kale, spinach, turnip greens, beef liver, pork liver + all pork products) Patient may have these foods in moderation but important to avoid major changes in regular diet or crash diets. Report any major changes in diet to anticoagulant clinic.
Cranberry juice may raise INR – avoid or limit intake of cranberry juice whilst on warfarin.

Alcohol intake: check patient's current alcohol intake and basic LFT's/clotting. If patient a heavy drinker (known alcoholic, or drinks > recommended units/wk), discuss with Dr re plan for alcohol reduction and also warfarin implications/suitability. Ideally keep intake to a minimum. Small to moderate amounts (e.g. 1 glass of wine/ half pint beer/lager per night or 2 – 3 x per week) should not affect warfarin control in otherwise healthy individuals with no liver problems. Avoid binge drinking

Contraception, pregnancy and hormone replacement therapy (if relevant): this should be discussed in detail in the anticoagulant clinic according to separate guidance. Basic points: if patient is still on HRT/OCP then discuss with the clinician re: stopping/appropriate choice (generally avoid oestrogen-containing preparations – progesterone only ones are preferred). Check that there is no possibility of the patient being pregnant at the time of starting warfarin therapy and that she understands the importance of effective contraception.

Pregnancy should be planned following discussion with anticoagulant clinic/GP. **Urgently refer women who may be pregnant and are on warfarin.**

Surgical Procedures (including dental treatment) and hospital admission: patient must inform Doctor/dentist that s/he is on warfarin

Inform treating Doctor (e.g. GP) of acute illness, as more regular INR check may become necessary

Hobbies and leisure activities (including flying): avoid contact sports (e.g. boxing) and other higher risk sports (e.g. skiing and horse riding), as increased risk of bruising/bleeding. Inform Dr/anticoagulant clinic if flying in the near future

Injections (including immunisations): patient must inform GP/practice nurse that s/he is on warfarin

Obtain further supplies of warfarin from your GP. Make sure never to run out of warfarin tablets, especially when on holidays

Further advice/ information GP surgery or patient information leaflets

Appendix 5 – may be replaced by local policy for each CCG/Provider

Policy for the Appropriate Transfer of Patients from Secondary Care Clinics to Primary Care Clinics

1. Existing patients

1.1 The Anticoagulation Clinic in secondary care identifies suitable patients for transfer of care into primary care. The clinic faxes the transfer request form (do we have a form?) with the patient's details to the patient's registered GP.
1.2 On receipt of the transfer request form, the GP surgery will arrange a first appointment for INR monitoring.
1.3 When the primary care monitoring appointment has been arranged, the patient's GP signs the bottom of the transfer request form and faxes this back to the secondary care anticoagulation clinic. The GP takes responsibility for the monitoring arrangements of that patient **from the date that the transfer form is signed**. At this point the patient will be deemed to have been discharged from secondary care.
1.4 If there is a time delay between the secondary care clinic first sending the referral form and the patient being accepted by the GP practice and the patient has attended secondary care for further monitoring, updated documentation on latest dosing and INR results must be sent to the primary care provider.

2. New patients

2.1 The secondary care anticoagulation clinic will transfer all patients as section 1.1 -1.4 above.
2.2 The secondary care anticoagulation clinic may decide to request transfer in situations where the patient's INR is not stable, but where it would be beneficial for the patient to be monitored in primary care.

3 Existing Primary Care Anticoagulation patients - post discharge

3. Patients who were being managed by a primary care anticoagulation service prior to a hospital admission will be referred back to the primary care service post discharge.
3.2 The responsible professional in secondary care will fill in the Anticoagulation Transfer form (do we have one?) . This must be sent to the GP surgery.
3.3 An appointment must be made for the patient for their next INR check.
3.4 Prior to discharge, the patient must have details of their next INR check. However if the patient has left hospital before being given this, the ward staff will be responsible for contacting them about their next appointment.
3.5 Should discharge occur on a weekend, referral to the GP surgery will be made in line with 3.2 above. On Monday morning the GP surgery will arrange an appointment for the patient. If there is sufficient time before the appointment date, the ward will post out a copy of the referral form to the patient; otherwise the ward will contact the patient by phone to give them the appointment details.

Appendix 6 – Common Warfarin Drug Interactions

The drugs in this list are more usually associated with loss of INR control in patients already established on warfarin. This list is not exhaustive - refer to the British National Formulary (BNF) for further information. If any of the drugs below are to be started in these patients then the use of alternatives in the same therapeutic class may be considered. If this is not possible then the patient's INR should be monitored as detailed below. Those drugs highlighted in bold are significant interactions and should be avoided or used with caution.

Drugs marked * are liver enzyme inhibitors and increase the INR. They act very quickly (can be within 24 hours) and if the drug is withdrawn the effect disappears quickly depending on the drug half-life. The INR should if possible be monitored within 72 hours of starting the interacting drug and on withdrawal.
Drugs marked $ are liver enzyme inducers and decrease the INR. They act more slowly (up to a week) with peak effect at 2-3 weeks and can persist for up to 4 weeks after stopping depending on drug half-life. The INR will need checking after 1 week of concurrent therapy.
Drugs with neither have other mechanisms, which affect the INR.

NB. If a patient on warfarin were started on ANY other new medication a repeat INR after 1 week would be sensible.

Drugs that increase the INR and risk of bleed	
Gastrointestinal	**cimetidine*,** omeprazole* esomeprazole
Cardiovascular	**amiodarone*** (liver enzyme inhibition is slow and may persist long after withdrawal requiring weekly monitoring over 4 weeks), **fibrates**, ezetimibe, **propafenone*,** propranolol, statins – no clinically relevant interaction will normally be seen however it is prudent to check INR in the weeks after initiation and at any dose change
CNS	**Entacapone, fluvoxamine***, SNRIs, **SSRIs*, tramadol**
Anti-infectives (anti-infectives in general may cause raised INR"s)	**azole antifungals*** (esp. miconazole including oral gel and vaginal), **co-trimoxazole*, macrolides*** (can be serious but unpredictable), **metronidazole***, **quinolones*** (can be serious but unpredictable), **tetracyclines,** influenza vaccine
Endocrine	**anabolic steroids (and danazol), high dose corticosteroids, glucagon (high dose 50mg+ over 2 days), flutamide, levothyroxine**
NSAIDs	Ibuprofen at lowest effective dose (+/-PPI) is probably safest if NSAID is required **N.B. All NSAIDs can increase the risk of bleeds and should be avoided if possible**
Antiplatelets – increased bleed risk	**Aspirin, clopidogrel and dipyridamole**
Anti-coagulants	**Fondaparinux, heparin; low molecular weight heparin e.g. enoxaparin, tinzaparin; NOACs e.g. apixaban, dabigatran, rivaroxaban**
Cytotoxics	**Erlotinib, etoposide, fluorouracil, gefitinib,** gemcitabine, imetinib, **sorafenib, vemurafenib**
Miscellaneous	Alcohol (acute), **actiretin,** allopurinol*, **benzbromarone*,** colchicine, **disulfiram,** interferon paracetamol (prolonged use at high dose), **sulfinpyrazone**, **tamoxifen**, **topical salicylates**, zafirlucast*
Herbal preparations/Food supplements	Carnitine, chamomile, **cranberry juice***, curbicin, dong quai, fenugreek, fish oils, garlic, gingko biloba**, glucosamine**, grapefruit juice*, lycium*, mango, quilinggao
Drugs that decrease the INR	
Miscellaneous	**Alcohol$ (chronic), azathioprine, barbiturates$,** bosentan$, **carbamazepine$, carbimazole,** **griseofulvin$, mercaptopurine, nevirapine$, OCP/HRT**, **phenobarbital, phenytoin, propylthiouracil,** raloxifene, **rifampicin$(most potent inducer),** trazodone
Herbal preparations etc	Avocado, co-enzyme Q10, green tea, natto, soya beans, **St Johns wort$ (avoid**)
Binding agents	Colestyramine, sucralfate
Warfarin antagonist	**Vitamin K**
Drugs that increase or decrease the INR	
Anti-virals	Atazanavir, **efavirenz, ritonavir, telapravir**
Miscellaneous	Ginseng, phenytoin, quinidine, **tricyclic antidepressants**

Based on original by Julian Holmes, Nottingham University Hospitals Trust, and further adapted by NHS Derbyshire County PCT County PCT Updated by Aiste Baltramaityte and David Anderton Derby Hospitals NHS Foundation Trust Further updates by Dr Jennifer Pickard, Public Health Clinical Effectiveness Team. April 2013.

Appendix 7- NHS England South East (KSS) Serious Incident Guidance

Introduction

This pack is written for providers that do not currently report directly onto STEIS (Strategic Executive Information System).

A good safety culture is one where staff have a constant and vigilant awareness of the potential for things to go wrong, are able to identify and acknowledge mistakes, learn from them, and take action to put things right in order to make patient care safer.

Practices with a strong safety culture are those that engage with patient safety proactively: reporting and learning from incidents (including reporting so that other practices can learn from their experiences).

A strong safety culture requires:

• Leadership – the whole team to show that they believe in a good safety culture and are prepared to take ownership when things go wrong.
• Teamwork – the role of every team member in promoting safety to be recognised and valued.
• Accountability – fair responsibility for your actions and accountability on four levels: professional, legal, ethical and contractual.
• Understanding – moving on from blaming the individual to recognising the role of system factors in patient safety.
• Communication – not assuming staff have understood the importance of patient safety and of recognising risks; remind them and applaud good practice. Make it commonplace and easy for all members of the team to speak up about concerns, taking care to reduce the impact of hierarchical relationships.
• Awareness of workload pressures – when times are busy, risks increase.
• Safety systems – robust systems to be put in place to prevent common errors.

Reporting Serious Incidents (SI), their subsequent investigation and learning is an integral element to a strong safety culture; this pack will support your management of the serious incident.

If you have any queries at all please feel free to contact us on the following e-mail address: ENGLAND.southeastsis@nhs.net

For more detailed guidance please refer to the NHS England Serious Incident Framework attached below:

NHSE Serious Incident Framework 2

What is a Serious Incident:

Serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

The occurrence of a serious incident demonstrates weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the

organisations involved. Serious incidents therefore require investigation in order to identify the factors that contributed towards the incident occurring and the fundamental issues (or root causes) that underpinned these. Serious incidents can be isolated, single events or multiple linked or unlinked events signalling systemic failures within a commissioning or health system.

There is no definitive list of events/incidents that constitute a serious incident and lists should not be created locally as this can lead to inconsistent or inappropriate management of incidents. Where lists are created there is a tendency to not appropriately investigate things that are not on the list even when they should be investigated, and equally a tendency to undertake full investigations of incidents where that may not be warranted simply because they seem to fit a description of an incident on a list.

For a list of definitions describing the circumstances in which a serious incident must be declared please refer to page 14 of the attached Serious Incident Framework.

Reporting a Serious incident:
Serious incidents must be reported by the provider to the commissioner without delay and no later than 2 working days after the incident is identified.

Incidents falling into any of the serious incident categories listed below should be reported immediately to the relevant commissioning organisation upon identification. This should be done by telephone as well as electronically:

- Incidents which activate the NHS Trust or Commissioner Major Incident Plan.
- Incidents which will be of significant public concern:
- Incidents which will give rise to significant media interest or will be of significance to other agencies such as the police or other external agencies:

Out-of-hours, the local on-call management procedures must be followed.

Incidents should be reported using the NHS serious incident reporting system STEIS. However, if your organisation does not have access to STEIS the incident can be reported by completing the form in appendix 1and returning by secure email to ENGLAND.southeastsis@nhs.net where it will be uploaded to the STEIS system for you. The serious incident form must not contain any patient or staff identifiable information (including initials or names) and the description should be clear and concise.

All incidents which meet the definition for a patient safety incident (including serious incidents) should be reported separately to the NRLS for national learning. Organisations with local risk management systems that link to the NRLS can report via their own systems. Organisations without this facility should report using the relevant NRLS e-form which can be found using the following link: http://www.nrls.npsa.nhs.uk/

Appendix 1
SERIOUS INCIDENT REPORTING FORM

REPORTER CONTACT DETAILS:

NAME			
JOB TITLE			
TELEPHONE NO			
EMAIL			
INCIDENT REPORTED TO NRLS	Yes	No	If No please state why:
BOX TICKED TO SHARE WITH NHSE AREA TEAM	Yes	No	If No please state why:

PATIENT DETAILS: (THIS INFORMATION SHOULD ONLY BE SUPPLIED IF THIS FORM IS TRANSMITTED VIA A SECURE NHS.NET EMAIL)

CARE SECTOR	
CLINICAL AREA	
DATE OF BIRTH	
PATIENT GP DETAILS	
TYPE OF PATIENT	
GENDER	
ETHNIC GROUP	
LEGAL STATUS OF PATIENT	

INCIDENT DETAILS:

DATE	
TIME	
SITE	
LOCATION (LOCALITY)	
REASON FOR REPORTING	
TYPE OF INCIDENT	
NEVER EVENT	
WHERE IS PATIENT AT TIME OF REPORTING?	
FAMILY INFORMED	
DESCRIPTION OF WHAT HAPPENED	
IMMEDIATE ACTION TAKEN	

Appendix 8 - Quality control of the CoaguChek

Quality control procedures on the CoaguChek are integral to providing quality assurance for the anticoagulant monitoring service. Quality control data must be recorded after every test, on the form provided, to ensure adequate audit trail.

Internal Quality Control

An appropriate internal quality control (IQC) process must be in place in accordance with the MHRA guidelines on POCT, 'Management and use of IVD point of care test (POCT) devices. Device bulletin 2010(02) February 2010'.

- CoaguChek XS Plus strips – These strips incorporate an on board integrity check. They contain a compound which is sensitive to ambient factors such as light, humidity and temperature, which could cause test strip deterioration. Any resulting chemical changes are detected electrochemically by the CoaguChek XS Plus and patient results will only be displayed if the test strip integrity is intact.

NB: CoaguChek S strips do not have this integrity check.

- Liquid control –This should take the form of at least a daily "go/no go" control sample (use of a liquid sample) on days when the instrument is in use and also when there is a new batch of strips, any doubt about the storage condition of strips, or unexpected high or low test value.
- All record keeping on this process should be accurate & contemporaneous. IQC results should be recorded with the batch number of IQC, and test strips and the identity of the operator. These details will be required as part of the annual audit return to the CCG.
- IQC results should be within a range of 1.0 INR units (not the wider range quoted by the manufacturer) for one particular batch of test strips; i.e. within ±0.5 INR of the mean of the first 5 IQC results.
- If the IQC result is outside the target range, a new IQC sample should be prepared and tested. If the second result is also out of range, no further clinical tests should be performed on the device until the problem has been identified and corrected. The manufacturer should be contacted if there are concerns about the accuracy of the device.
- IQC tests are usually supplied in a box of four vials; each batch number has a different INR range.

External Quality Control

UK NEQAS - U.K. National External Quality Assessment (EQA) Scheme for Near Patient Testing. Every device should be registered with NEQAS.

It may be possible to use the same EQA sample on more than one machine (probably not more than 2 devices due to delays affecting the result) which could save a bit of money.

The scheme

The purpose is to provide external quality assessment as a part of the overall quality assurance for tests of blood coagulation carried out on an instrument designed for near patient or point of care testing whether within or remote from hospital laboratories.

Registration

The participant registered should be the centre responsible for performing the tests. If the daily testing is carried out by a GP surgery then the surgery should be registered. Results and associated data from participants will be treated with strict confidentiality. Each registered participant will be given a unique participation number which should be quoted in all correspondence. Use of this number will assist in maintaining confidentiality in survey correspondence.

Participation

Participating centres will be sent at least four surveys per year each comprising of two samples for

INR determination. The samples will consist of lyophilised human plasma which has been screened for hepatitis B surface antigen (HBsAg), and for antibodies to hepatitis C and human immunodeficiency virus types 1 and 2 (anti-HIV-1+2).

Participants will be provided with instructions on reconstitution and testing of the samples. A closing date for return of the results will be given and results will be analysed and reports sent back to participants approximately one week after the closing date of the survey.

Performance Analysis
Approval has been given by the UK National Quality Assurance Panel for Haematology for the following performance criteria:

A median result will be calculated for each reagent/instrument group, and the percentage deviation of individual laboratories from this median will be determined. The figure will indicate how close to the 'consensus' result individual results are from other users of the test system and performance 'without consensus' is defined as a result greater than 15% deviation from the reagent group median.

If the result is out of range the practice must investigate immediately and notify the CCG and Roche Diagnostics. Reasons for unacceptable EQA results include problems with the QA material, poor operator technique and faulty equipment. Follow up of such results may require additional training sessions, investigation of EQA sample storage/processing or machine maintenance.

An overall report on the operation of the scheme will be distributed on an annual basis. UK NEQAS for blood coagulation and the near patient testing EQA scheme are fully accredited by Clinical Pathology Accreditation (CPA (UK) Ltd) in the EQA Scheme Accreditation programme..

For further details please contact the scheme manager:
UK NEQAS for blood coagulation, Rutledge Mews, 3 Southbourne Road, Sheffield. S10 2QN.
Tel 0114 267 3300. Fax 0114 267 3309.
E-mail: negas@coagega.demon.co.uk

Venous sampling for analysis at the central laboratory.

Venous blood sampling should be undertaken if the CoaguChek result is unexpected. Unexpected results should be verified by performing a liquid quality control and repeating the near patient test before taking the venous sample.
The practice should perform random venous blood sampling to cross check results with the laboratory as part of quality assurance.

Appendix 9 - Contingency Planning

All practices have business continuity plans and these should be followed for situations that arise that are covered by the plan. For the anticoagulation service itself, the following continuity plans should be followed:

Computer decision support software

In the event of INRstar software failing, the following guidance should be followed:

INR	Advice to patient
INR within target range	To continue current dose. To contact patient with any change within 24 hours
INR above target	**Action: To liaise with clinician**
INR below target	**Action: To liaise with clinician**

In the event of INRstar software not being available for more than 24hours:
The practice needs to contact the INRstar support desk.

Coaguchek XS Plus

In the event of the CoaguChek XS Plus meter not working, Roche should be contacted immediately to organise a repair or replacement. The machines have two years warranty (which excludes damage through misuse) and Roche promise to repair or replace the meter normally the next day providing the problem is reported before 3pm Monday to Thursday. All other times, a repair or replacement will be provided within two days.
Details that will need to be provided are:

- Description of the problem
- Serial number of the monitor (located on the back)
- Strip lot number/QC lot number
- Error message (if applicable)
- Contact details if you are calling for the first time

Contingency contact details

Contact Details	
Roche diagnostic for repair of CoaguChek XS Plus	Tel 0808 100 1920
INRstar (available 9.00am to 5.30pm)	Tel 01209 710999

Appendix 10 - Anticoagulation Patient Self-Monitoring Agreement

Patient name: _____

Patient address: _____

1. Follow up review will be every _____months. (minimum 6 monthly)

2. The above patient will be responsible for arranging the appointments with
_____

3. INR results and dates, quality control results and any problems will be documented accurately in the anticoagulant record book provided.

4. External quality control will be performed 6 monthly using the following procedure:
_____
_____

5. If self-managing their warfarin, the agreed algorithm for dosage of warfarin is followed and _____contacted for advice if the INR result is greater than 5.0.or if any change from the algorithm is felt necessary.

6. The INR test is performed on_____at_____ when the clinician responsible is available for advice if necessary.

7. Needles are disposed of safely in an appropriate container and other contaminated material wrapped up carefully and placed in the usual waste bin. Sharps boxes should be disposed of at point of purchase.

8. _____is responsible for ordering supplies of equipment directly from manufacturer or strips from the practice

9. _____is informed if patient is intending to move away or stops self testing/management so that arrangements can be made for alternative management.

10. _____will undergo an annual clinical review to assess capability to self test/manage; e.g.; manual dexterity, eyesight and competence.

Signature of clinician responsible: _____ Date: _____

Signature of patient: _____ Date: _____

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