Buckinghamshire Healthcare NHS Trust

Standard Operating Procedure for Oral Anticoagulation with Vitamin K Antagonists

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Contents

1. Aim

To provide an anticoagulant service in a locally based setting that is easily accessible for the patient and able to deliver a safe, effective integrated anticoagulation service across primary and secondary care. **This must be read in conjunction with appendix 1 (AQP service specification).**

2. Objectives

1. To provide a ONE stop service for patients that is both closer to home and more easily accessible.
2. To receive, manage and ensure consistent appropriate referral of patients who require anticoagulation therapy, either registered or non-registered in the practice, including referrals for consideration of a new oral anticoagulant (NOAC).
3. To ensure a consistent high quality INR monitoring service to patients wherever accessed from.
4. To provide increased capacity in the community to meet the rising demand for anticoagulation.
5. To improve rates of anticoagulation in atrial fibrillation with oral anticoagulants.
6. To improve community access to anticoagulation monitoring services.
7. To ensure consistent outcomes and standards relating to testing, sampling and dosing with vitamin K antagonists (VKA).
8. To have an integrated streamlined service across the anticoagulation pathway.
9. To ensure all patients have a treatment plan reviewed on a regular basis (annually).
10. To identify patients with specific needs, i.e. poor compliance, unstable INR control or frequent non-attenders for review by the NOAC service.
11. To educate newly initiated and long standing patients' understanding of their treatment, in terms of their indication for anticoagulation, target INR, the effects of over and under anticoagulation, diet, lifestyle and drug interactions.
12. To advise on anticoagulant therapy regimen prior to surgery or dental care (BCSH guidelines).
13. To provide optimum care in accordance with the NPSA/NICE guidelines in terms of:
    a. INR control, e.g. 65% of individual patients' INR tests in range at any given time
    b. Identifying and managing clinical events related to anticoagulation therapy
    c. Considering the impact of patient choice (patient satisfaction questionnaire annually e.g. accessibility, waiting time and continuity of care)
14. To ensure safe and accurate recording of all clinical data using the relevant computerised decision support software (CDSS) with relevant back up documentation in case of electrical breakdown.
15. To evaluate the quality of care given through regular audit process, effecting change when required to achieve planned goals.
16. To ensure relevant, complete and accurate documentation of the clinic process.

3. Capacity

All eligible patients aged 16 years and over registered with a GP practice in Buckinghamshire CCG requiring continuation of anticoagulation monitoring and/or non-urgent initiation of oral anticoagulation with a VKA can be referred to the locally based anticoagulation 'one-stop' service. Buckinghamshire Healthcare NHS Trust (BHT) anticoagulant clinics will include arrangements for patients on a VKA requiring domiciliary visits for INR monitoring.

4. Identification and referral of patients

Referrals will be accepted from other anticoagulant clinics e.g. other hospitals and from hospital clinicians and GP practices.

Telephone referrals cannot be accepted unless under exceptional circumstances.

Timely access to anticoagulation therapy is essential. More than 90% of patients referred to the service provider for initiation of warfarin should be seen by the service provider within 2 weeks of receipt of referral (consensus from NICE atrial fibrillation clinical guidelines 180). Systems should also be in place to ensure referral of any existing patients needing transfer from secondary care or moving into area for continuation of anticoagulation can usually be seen within 7 days. All patients referred for oral anticoagulation should have a clear diagnosis /reason for anticoagulation stated on referral.

Where a patient meets the criteria for taking a NOAC in line with local policy, the patient can be referred directly to the NOAC clinic giving reason for referral together with supporting information regarding their anticoagulation management. The patient must however continue to receive appropriate anticoagulation therapy by the service provider until it has been confirmed that the patient has been seen and started on a NOAC.

Patients wishing to transfer to another provider must be referred by their GP or existing provider to ensure a safe transfer. Patients should only be under active monitoring by one community provider at a time.

Referrals to this service provider can be made via the patient's GP, a NOAC clinic or by a clinician from secondary care. All patients seen in secondary care and requiring oral anticoagulation with a NOAC are referred to a NOAC clinic for initiation and follow up. Patients seen in other hospitals may need referring to a NOAC clinic for counselling and further review.

See Appendices 8a, b and c for all referral forms.

All patients will remain the responsibility of the referring centre until the patient is seen in the clinic.

For patients moving to a new practice, hospital clinics will be informed if patients need to be referred back to the hospital clinic. The same referral form will be used attached to a referral letter with a copy to the patient and new GP if known.

5. Identify key personnel

Establish effective routes of communication between some of the following:

- Anticoagulation nurses
- Anticoagulation pharmacists
- Lead consultant anticoagulation haematologists
- Pathology manager
- ICT manager

6. Management of clinic

- Allocate protected time per week for clinic and availability for emergency services other days.
- Train a nurse/pharmacist in anticoagulation management, using the National Patient Safety Agency (NPSA) anticoagulant therapy work competencies (appendix 7), to manage the clinic with support from a designated clinician.
- Measure the INR using a point of care (POC) device.
- Interpret the INR result with the assistance of CDSS.
- Perform internal quality control at the start of each clinic using material supplied by the manufacturer.
- Perform external quality control every three months using samples from an external quality assessment scheme, e.g. NEQAS.
- Adhere to health and safety procedures recommended by laboratory staff to protect both the patient and clinical staff at all times.

7. Risk management

1. Assess risk to both patient and healthcare professional.
2. Implement risk reduction strategies incorporated into the clinic management, e.g.
    a) Patients lost to follow up
    b) Inadequate or lost referrals
    c) Inadequate documentation
    d) Inadequate updated staff training
    e) Point of care failure
    f) Insufficient clinic time/space for appointments education and discussion
    g) Inappropriate dose and monitoring interpretation
    h) System computer network failure
    i) Health and safety, blood spillage, cross contamination
3. Annual review as per AQP anticoagulation management.

Implementation of risk reduction strategies must be done with reference to relevant clinical governance authorities where appropriate.

8. Call and recall

The service provider must have a robust system of call and recall in place and be able to identify and act quickly when a person has failed to attend an appointment to have their INR measured. The provider will implement appropriate and effective policies and strategies for the management and targeting of non-attendees including the facility to alert a patient's GP if a patient fails to attend on 2 or more consecutive occasions or a period of more than 42 days when they have not attended. In the event of a patient failing to attend a routinely arranged single clinic appointment, the service provider should make contact with the patient and reschedule the appointment to be seen within 2 weeks of the missed appointment, appropriate to the patient's clinical need and urgency for INR follow up.

9. Training

The clinic will be managed by trained pharmacist or nurse.

Personnel responsible for the clinic must be aware of professional accountability and undertake the clinic management only if they feel competent to do so.

All staff caring for patients on anticoagulant therapy should have the necessary work competencies and have been assessed against these. See appendix 7 for the NPSA anticoagulant therapy work competencies.

All staff should be trained in using the specific POC device, Roche CoaguChek® Pro, by Roche trainer, or appropriately trained anticoagulation nurse, consultant anticoagulation pharmacist or designated deputy.

Accredited courses are available. Personnel managing the clinic will also be aware of continued professional development and attend regular updates on anticoagulation management.

If independent prescribing by nurses and pharmacists is to be undertaken their names must be annotated on their professional registers to indicate successful completion of recognised prescribing training.

Training should include:

- An introduction to oral anticoagulation therapy, an understanding of the test to be performed, the INR and how it is derived.
- An understanding of specific POC device, Roche CoaguChek® Pro, for deriving INR, setting up and using the device.

- The target INR, how it relates to diagnosis, action if results outside limits.
- Management of vitamin K antagonist therapy based on INR results and management of other anticoagulation therapy.
- Recording of results and quality assurance materials.
- Health and safety - disposal of sharps, control of substances hazardous to health (COSHH) regulation.

10. Indications for warfarin use and target INR

The indications and targets are taken from British Society of Haematology guidelines:
Baglin T, Keeling D, Watson H. Guidelines on oral anticoagulation with warfarin: fourth edition – 2011 update *BJ Haem* 2011; **154**: 311-324

Other targets will be acceptable for named patients after discussion with responsible clinician.

Target INR 2.5	**Target INR 3.5**	**Not indicated**
Pulmonary embolus	Recurrence of venous thromboembolism whilst on warfarin therapy	Ischaemic stroke without AF
Proximal DVT	Mechanical prosthetic valve (or 3.0)	Retinal vein occlusion
Calf vein thrombosis		Peripheral arterial thrombosis and graft
Symptomatic inherited thrombophilia		Coronary artery thrombosis
Recurrence of venous thromboembolism		Coronary artery graft thrombosis
Non-rheumatic atrial fibrillation		Coronary angioplasty & stents
Atrial fibrillation other causes		
Mural thrombus		
Cardiomyopathy		
Symptomatic inherited thrombophilia		
Antiphospholipid syndrome		
Bioprosthetic valve if anticoagulated		
Arterial grafts if anticoagulated		
Mechanical prosthetic aortic valve (or 3.0)		
Cardioversion (or 3.0)		

11. Atrial fibrillation

Anticoagulation is normally advised for patients depending on their stroke risk, which can be assessed using the CHADS-VASc score as below. Patients with a CHADS-VASc score ≥2 and may be considered for patients with a CHADS-VASc score = 1. (Non-valvular AF only)

CHA_2DS_2VASc Score Risk Factors	Score
Congestive heart failure	1
Hypertension	1
Age ≥75	2
Age 65 - 74	1
Diabetes mellitus	1
Stroke/TIA/thromboembolism	2
Vascular disease	1
Sex Female	1

12. Cardioversion

The BCSH recommend anticoagulation for 3 weeks before and for 4 weeks after cardioversion (Keeling, *et al* 2011). However at BHT is it is recommended that patients must adhere to 4 consecutive weeks of INRs which are greater than 2 and less than 4 or a minimum of 4 consecutive weeks of treatment with an alternative drug (apixaban, rivaroxaban, dabigatran or edoxaban) with no missed doses before being allocated a date for DCC. If a patient misses a dose of NOAC or has an INR below <2 then the procedure should be deferred for a further 4 weeks.

13. Endoscopy

See guidelines for Management of Anticoagulation for Gastrointestinal Endoscopic Procedures

14. Dental treatment

Patients are advised to continue with warfarin therapy when attending for dental treatment. However, they will need to check their INR the day before the appointment to ensure the INR is below 4.0. The NPSA, with support from the British Dental Association and BCSH, has produced a useful poster Managing patients who are taking warfarin and undergoing dental treatment.

15. Computerised decision support software (CDSS)

Access to CDSS should be made available for dosing decision support and audit. The dosing component of RAID is the CDSS used for anticoagulation management and must only be used by pharmacists and nurses who are appropriately qualified and trained in interpretation and management of INRs.

As a CDSS is classed as a medical device, as such it must be compliant with all relevant European Medical Device directives and compliant with ISO 13485 standards. In line with BSH Guidelines on oral anticoagulation, RAID has been set up to allow:

- Rapid retrieval of data to screen or printer.
- Data storage in chronological order.
- Dosage recommendations according to algorithm or guidelines approved by clinician in charge of the service - this should include evaluation of results over the full range of INR results.
- An alerting system for patient results which fall outside defined criteria.
- A facility to over-ride computer recommendations.
- Patient recall for testing according to agreed criteria based on previous stability with invalid date alerts.

- An alerting system for non-attendees.
- An alerting system for discontinuation of treatment.
- A prompt system to check for bleeding problems when high INR values are obtained.
- A system to record bleeding/thrombotic event.
- A facility to audit results.

16. Near patient testing devices and quality assurance

Near patient testing (NPT) and laboratory analysers will be used to determine patients' INR levels using only Medicines and Healthcare Products Regulatory Agency (MHRA) approved medical devices and must be compliant with all European Union (EU) medical device directives and compliance with ISO 13485 standards. Details of what devices are being used to monitor INR will be provided.

The Anticoagulation Service will be responsible for all supplies including the test strips, finger prick equipment and internal quality control solution. The NPT equipment should be set up so that the monitor settings allow both operator and patient identifiable data to be entered and the device maintained in accordance with the manufacturer's recommendations.

Sharps should be disposed in line with Control of Substances Hazardous to Health (COSSH) legislation.

Internal Quality Control (IQC) will be performed:

- At the beginning of each clinic.
- Following a series of unexpected results.

The Anticoagulation Service will participate in the UK National External Quality Assessment Scheme (NEQAS) for blood coagulation that monitors the performance of INR NPT devices. Comprehensive records of quality checks to include batch numbers of strips and control samples, time of test and operator must be kept.

Patient testing devices should be reviewed following any failure to produce an acceptable result as a result of the IQC system or if the instrument receives a result outside the consensus from NEQAS. A robust contingency plan needs to be in place in the event of any equipment failure.

17. Domiciliary patients

For domiciliary patients, staff will attend patient's home to monitor INR via NPT testing.

Ensure staff is aware of and familiar with the anticoagulation home visit risk assessment and lone working procedures.

18. Record keeping

A comprehensive treatment record for each patient should be updated at each visit on RAID and includes:

- Patient's INR.
- Dose of anticoagulant.
- Date of next appointment.
- Information from the patient about unusual bleeding or bruising, adherence to treatment, other medication, changes in diet, changes in alcohol or smoking or planned surgery.
- Information from other clinicians looking after aspects of the patients care (where appropriate).
- Any relevant changes in medical history or treatment.

- OTC medication including herbal remedies.
- All patients should be given an individual hand-held record such as NPSA 'yellow book' which states latest INR level, dosing information, date of next test and contact numbers for advice, and which is maintained by the anticoagulant service. Patients are to be encouraged to carry their individual INR treatment record with them at all times and to show it to any health professional whenever they seek medical treatment or advice.

In addition, the following details for all patients under the care of the clinic should be recorded:

- Patient demographic details including date of birth and ethnicity.
- Indication for treatment and start date.
- Planned duration of treatment and stop date if not long term.
- Documented annual review and next annual review date for patients on long term therapy.
- Target INR and INR range.
- Relevant notes supporting dose decision, counselling and self-testing/management.
- Frequency of INR testing and number of DNAs.
- Relevant medical conditions and/or hospital admissions likely to affect anticoagulation status or monitoring requirements.
- Name of initiating clinician.
- Any actions taken other than dosing and retest dates.

19. Clinical governance

All critical or untoward incidents (and near misses) must be reported via the National Reporting and Learning System (NRLS) and the Trust Datix System. Such untoward incidents would include:

- Any patient who had previously been in hospital in the previous 100 days.
- Any equipment or serious communication failure or the issue of an incorrect prescription.
- Any clinical event leading to a major bleed or embolism requiring hospital admission.
- In summary the service provider will be responsible for ensuring that the service is provided according to the service specification. In particular, that:
  - Timely access to treatment is achieved for both new and existing patients.
  - Dose recommendations and recall are made according to approved guidelines.
  - Patient education regarding anticoagulation therapy is provided and the patient hand-held record is kept up-to-date.
  - An annual review is performed.
  - Patients are referred to A&E or secondary care where required.
  - Adverse events are reported.
  - Healthcare professionals involved in delivering anticoagulant service have necessary experience/training and work related competencies and keep professionally up to date.
  - Comprehensive service contingency plans are in place including arrangements for cover annual or sickness leave.
  - All elements of the specification are followed.

20. Clinic procedure for patients receiving warfarin

- Prepare POC device and complete internal quality control procedure. Document control result, batch numbers of strips and controls, user ID.
- Counsel patient regarding clinic process and check for:
  - Bleeding or thrombotic events
  - Tablet compliance and change of medication
  - Lifestyle changes e.g. alcohol binges
- Perform blood test using capillary blood. Venous samples can be taken at patient request or for capillary results greater than POC upper limits.
- Perform INR test using POC device and enter results into the decision support software.
- Follow suggestions given by computer for dosing and recall dates unless clinically inappropriate e.g. patient known to be non-compliant with therapy.
- Complete patient record card and give to patient with verbal instruction regarding dosage and recall.
- Record INR, warfarin dosage and recall date in patient's notes and practice computer.
- The length of time between test dates will vary according to individual patient need. However patients should have an INR check at least every 12 weeks (i.e. a minimum expected number of INR tests per patient per year is 4 unless patient is self-managing). New or less stable patients will require more frequent monitoring.

21. Annual review to be conducted as per AQP service specifications

- Assess condition requiring anticoagulant – risk/benefit - annual specialist or clinician follow up, check recommended period of time on anticoagulant.
- Assess whether anticoagulant therapy is still appropriate e.g. dementia, multiple ADRs.
- Assess haemorrhage risk using the HASBLED scoring system as below:

HASBLED Score Risk Factors	Score
Hypertension	1
Abnormal liver function	1
Abnormal renal function	1
Stroke	1
Bleeding	1
Labile INRs	1
Elderly (Age > 65)	1
Alcohol	1
Drugs	1

- Assess if degree of INR control is more than 65% time in therapeutic range.
- Assess routine blood test to include full blood count and urine and electrolytes.
- Assess patient satisfaction using a questionnaire (appendices 2a, b and c).

22. Patients self-testing and/or self-management

Patients are expected to purchase their POC device but the provision and costs of INR testing strips are the responsibility of the anticoagulation clinic as this is reflected in the tariff paid.

Previous stability of INR is not a pre-requisite to home testing as unstable patients may benefit from increased autonomy. Frequency of INR testing for patients on self-testing/self-management programme should not usually be more than a maximum of once weekly.

Self-testing patients are responsible for testing their INR at home using capillary sampling and a POC device but the dosing of warfarin or other VKA and the frequency of monitoring is determined by a responsible clinician under this service provision. A specified weekday and time should be agreed when the clinician is available for patients self-testing to phone in with their INR result and for follow up INR support and advice. Alternatively, with agreement from the clinicians, an email communications line can be used to relay INR results and a dosing schedule.

Self-management patients must be assessed as capable of testing and dosing according to their INR result at home using a POC INR device. Dosing of warfarin or other VKA and frequency of testing is managed by the patient with support from the responsible clinician according to an agreed signed contract between patient and clinician responsible. The contract should specify the responsibilities of the patient, the agreed algorithm for dosage of warfarin or other VKA and frequency of INR monitoring, and who to contact in the event of INR >5. This should also include agreement to attend clinic regularly for review (every 6 to 12 months once trained to cross check correlation INR results with clinic) and to keep accurate records of their INR results. (See appendix 4)

Recommended criteria for eligibility to self-test anticoagulation status:

- Only patients with long term indications for warfarin or other VKA therapy should be considered for self-testing or self-management using an MHRA approved POC INR monitor with ISI 1.0 designed for patient self-use, e.g. CoaguChek® XS system, INRatio2PT/INR or any other.
- Must have a documented target INR range in line with accepted guidelines and clinical practice.
- Should have demonstrated adherence with taking medication and attending clinic appointments.
- Person or carer is both physically and cognitively able to self-monitor effectively and has been trained and assessed as competent to perform an INR by a suitably qualified healthcare professional prior to allowing home testing.
- In all cases where a patient is self-testing/self-managing the patient's GP must be informed.
- Patients self-testing/self-managing should have a minimum annual assessment of their capability to continue to self-test/manage included as part of their annual clinical review by the service provider.
- Equipment for self-monitoring should be regularly checked using reliable quality control procedures. An acceptable quality assurance method would be for the service provider to simultaneously check correlation of INR clinic result obtained with the patient's INR result obtained using their own monitor and test strips. The INR readings should be within +/- 0.5 units (or +/-15%) of each other.

See appendix 4 for self-testing contract.

23. New patients (see appendices 3a and b for anticoagulant clinic counselling proformas)

- Review treatment plans of all new patients, ensure all patient details are entered and correct in both yellow record book and referral letter and patient is given information sheets and record book.
- Ensure that patient has correct target range, duration of treatment for condition requiring anticoagulant. If not, referring clinician should be consulted.
- Patients should be educated on the following:
  - Name of drug and current dose including tablet colours.
  - Contents of the yellow book or equivalent patient held information.
  - Target INR and range.
  - Reason for and objectives of treatment.

- Anticipated length of treatment.
- What to do in the event of a missed or wrong dose.
- Symptoms of under dose (e.g. progressive worsening of thrombotic signs or new symptoms such as PE) and overdose and what to do if these occur.
- Complications of treatment including side effects and bleeding.
- Drug, alcohol and food interactions and impact on treatment.
- Changes in medication or new medication requiring early monitoring.
- Which medications (e.g. antibiotics) including over the counter (OTC) medications and supplements require particular care.
- What to do if dental treatment or elective surgery or procedure is required.
- Clinic arrangements for monitoring and contact details for the provider in cases of concerns.

24. Clinical guidelines for initiation of warfarin

Patients having warfarin initiated for AF in the community should have a baseline INR performed. Warfarin should only be initiated if the baseline INR is less than 1.3. Any patient with a baseline INR of 1.3 or above should be screened for underlying conditions. Check FBC, U&Es, LFTs (if any reason to suspect abnormal) and clotting screen.

The initiation dose for patients commencing warfarin for AF in the community should be 1 – 3 mg daily, unless exceptional circumstances. Check INR within 2 weeks and dose according to result using CDSS.

Refer to Shared Care Protocol for Oral Anticoagulants When Doses are Adjusted by the Anticoagulation Clinic and prescribed by the General Practitioner.

Over-anticoagulation – stop warfarin and refer to BHT guideline Protocol for Over-anticoagulation with Warfarin and Patient Group Direction Vitamin K_1 (phytomenadione) for Reversal of Vitamin K Antagonists in Anticoagulation Services.

NB. If INR >8.0, with no bleeding, a root cause analysis should be carried out and the patient referred to the NOAC clinic, if the clinical indication for oral anticoagulation is atrial fibrillation or venous thromboembolism.

If major bleeding/life-threatening haemorrhage, stop warfarin, admit to hospital for urgent reversal and discuss with consultant haematologist.

25. Definition of serious and non-serious adverse events

Serious adverse event:

- Bleeding: If admitted to hospital or if surgery was required to stop bleeding and if bleeding led to reduction of Hb of 2 g/dL or more and/or requiring blood transfusion.[1]
- Thrombotic: Transient ischaemic attack (with observed neurological deficit) or stroke, recurrent deep vein thrombosis and pulmonary embolism, systemic embolism.

Non serious:

- All cases of bleeding with no associated costs or medical consequences, e.g. bruising, small epistaxis, microscopic haematuria.

[1] Palareti G, Leali N, Coccheri S, Poggi M, Manotti C, D'Angelo A et al. Bleeding complications of oral anticoagulant treatment: an inception-cohort, prospective collaborative study (ISCOAT). *Lancet 1996; 348: 423 – 428*

26. Guidelines for discontinuing warfarin

To discontinue warfarin at treatment completion, obtain written confirmation from clinical team that commenced warfarin therapy if possible. The end date of treatment should be clarified on original referral form.

27. Administrative tasks

- Perform a weekly computer search for non-attendees to warfarin clinic.
- Contact non-attendees to the clinic with a letter/telephone call and a new appointment.
- Produce and send patient satisfaction questionnaire.
- Undertake referrals to other clinics as necessary.
- Undertake stock control as necessary.
- Arrange protocol and clinical meetings as necessary.
- Ensure training of key personnel is up to date.
- Perform a backup of software at the end of each clinic.

28. Audit (safety indicators)

The CCG will require submission of annual declaration on service provision (see appendix 1) as well as quarterly returns from the service providers giving details on clinical activity and monitoring (see outcomes table below for an overview, and Schedule 4 and Schedule 6 for details). Failure to submit quarterly returns and an annual declaration will result in non-payment.

All service providers are expected to undertake an annual audit of their service that includes a review of clinic service performance and patient satisfaction with service. The audit results will be used to inform local actions needed to continually improve on the safe use of anticoagulants in the community.

	Clinic Service QualityStandards	**Target** *(where applicable)*
1	Number of patients on a VKA currently registered with service provider	**n/a**
2	Percentage of patients have had an INR checked in last 12 weeks	**>95%**
3	Percentage of **new** patients referred to the service during this current quarter seen within 2 weeks	**>90%**
4	Clinic's proportion of patient time in therapeutic range +/- 0.5 target INR or if not available the percentage of INRs +/- 0.5 target INR for last 12 weeks	**>65%**
5	Clinic's proportion of patient +/- 0.75 target INR or if not available the percentage of INRs +/- 0.75 target INR for last 12 weeks	**>80%**
6	Percentage of patients that have had an INR >5 recorded in last 12 weeks	**<5%**
7	Percentage of patients that have had an INRs >8* recorded in last 12 weeks **For every patient with a recorded INR >8 a significant event report giving details of possible cause, management and outcome should be submitted and copied to the commissioner*	**<0.5%**
8	DNA rate as a percentage of clinic appointments in last 12 weeks	**<10%**

29. Clinic procedure for novel anticoagulants

There are currently NICE technology appraisals available for stroke prevention in atrial fibrillation for dabigatran, rivaroxaban, apixaban and edoxaban.

Technology appraisals suggest that they should be made available for patients who require them but that the decision on choice of agent should be undertaken only following an informed discussion with the individual patient.

In addition, rivaroxaban, dabigatran, apixaban and edoxaban are licensed for the treatment and secondary prevention of venous thromboembolism.

Refer to guidelines:
313FM Dabigatran, Rivaroxaban, Edoxaban and Apixaban for Atrial Fibrillation (AF) (amber initiation)
295FM Dabigatran, Rivaroxaban, Apixaban and Edoxaban for Deep Vein Thrombosis and Pulmonary Embolism (amber initiation)

30. Applicable service standards

Applicable national standards (e.g. NICE)

- NICE Commissioning Guide Anticoagulation May 2013. https://www.nursinginpractice.com/sites/default/files/nice/NICE%20Commissioning%20Guide-Anticoag_30.07_LORES.pdf
- NICE clinical guideline on AF CG180 (2014) http://guidance.nice.org.uk/CG36http://www.nice.org.uk/Guidance/CG180
- NICE TA 249 (2012) Dabigatran etexilate for the prevention of stroke and systemic embolism in people with atrial fibrillation with one or more risk factor for stroke https://www.nice.org.uk/guidance/ta249/resources/dabigatran-etexilate-for-the-prevention-of-stroke-and-systemic-embolism-in-atrial-fibrillation-pdf-82600439457733
- NICE TA 256 (2012) Rivaroxaban for the prevention of stroke and systemic embolism in people with atrial fibrillation. https://www.nice.org.uk/guidance/ta256/resources/rivaroxaban-for-the-prevention-of-stroke-and-systemic-embolism-in-people-with-atrial-fibrillation-pdf-82600494885061
- NICE TA 275 (2013) Apixaban for the prevention of stroke and systemic embolism in people with non valvular atrial fibrillation https://www.nice.org.uk/guidance/ta275/resources/apixaban-for-preventing-stroke-and-systemic-embolism-in-people-with-nonvalvular-atrial-fibrillation-pdf-82600614137797
- NICE TA 355 (2015) Edoxaban for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation https://www.nice.org.uk/guidance/ta355
- NICE Clinical Guideline CG144 June 2012 Venous thromboembolic diseases: the management of venous thromboembolic diseases and the role of thrombophilia testing. http://guidance.nice.org.uk/CG144
- Department of Health (DH) Cardiovascular Disease Outcomes Strategy –Improving Outcomes for people with or at risk of cardiovascular disease March 2013 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/217118/9387-2900853-CVD-Outcomes_web1.pdf
- European Society of cardiology (ESC) Guidelines atrial Fibrillation Aug 2010 Camms et al. Eur Heart Journal 2010;12 1360-1420. http://eurheartj.oxfordjournals.org/content/31/19/2369.full
- ESC 2012 Focused Update of ESC Guidelines for management of atrial fibrillation. Eur Heart Journal 2012 33, 2719-2747.
- NICE clinical guideline 76 (2009) Medications Adherence Involving patients in decisions https://www.nice.org.uk/guidance/cg76/resources/medicines-adherence-involving-patients-in-decisions-about-prescribed-medicines-and-supporting-adherence-pdf-975631782085

Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

- National Patient Safety Agency (NPSA) Alert 18; Actions that can make anticoagulation safer (2007) alerts. https://www.sps.nhs.uk/articles/npsa-alert-actions-that-can-make-oral-anticoagulant-therapy-safer-2007/
- British Society Haematology Guidelines on oral anticoagulation with warfarin – 4th edition 2011 British Journal Haematology, 134; 311-324 https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2141.2011.08753.x
- Recommendations from the British Committee for Standards in Haematology and National Patient Safety Agency British Journal of Haematology, 2006; 136, 26–29 https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2141.2006.06379.x
- Royal College of Physicians of Edinburgh (RCPE) UK Consensus Statement on approaching the comprehensive management of atrial fibrillation. Evolution or revolution. March 2012 https://www.rcpe.ac.uk/sites/default/files/documents/pressreleases/rcpe-af-consensus-statement-2012.pdf
- BCSH guidelines on the management of patients on oral anticoagulants requiring dental surgery. http://www.nature.com/bdj/journal/v203/n7/full/bdj.2007.892.html
- MHRA Device Bulletin Management & Use of IVD Point of Care Devices, February 2010
- The International Council for Standardisation in Haematology (ICSH) Guideline for Worldwide Point of Care Testing in HaematologyInt J Haem 2008 30; 105-116. http://islh.org/web/downloads/ICSH_Standards/ICSH_Guideline_for_POCT_in_Haematology_Briggs_April_2008.pdf
- NICE Diagnostics Consultation Document Point of Care coagulometers for self-monitoring coagulation status in patients with AF or heart valve disease on vitamin k therapy. April 2014

Applicable local standards

Available at www.bucksformulary.nhs.uk

- Buckinghamshire CCG Shared Care Agreement for Oral Anticoagulants
- BHT & CCG guidelines: Dabigatran, Rivaroxaban, Apixaban and Edoxaban
- Care Pathways for AF patients and Anticoagulation
- Contraindications to warfarin document

31. Appendices

1. Anticoagulation service specification
2. Patient satisfaction surveys:
    a) Ward 3b anticoagulation clinic patient survey
    b) CCHU anticoagulation clinic patient survey
    c) NOAC led warfarin clinic patient survey
3. Anticoagulant clinic counselling proformas:
    a) Pharmacist led clinic counselling proforma
    b) Anticoagulation nurse led clinic counselling proforma
4. Patient and anticoagulation clinic self-testing agreement
5. Pathway access to phlebotomy services
6. Oral anticoagulation clinics provided by BHT
7. NPSA anticoagulant therapy work competencies:
    a) Initiating anticoagulant therapy
    b) Maintaining oral anticoagulant therapy
    c) Managing anticoagulants in patients requiring dental surgery
    d) Dispensing oral anticoagulants
    e) Reviewing the safety and effectiveness of an anticoagulant service
8. Referral forms:
    a) Oral Anticoagulation Referral Form for patients registered with a Buckinghamshire GP Practice requiring treatment with Warfarin
    b) Referral form to NOAC service for Deep Vein thrombosis (DVT)/ Pulmonary embolism (PE)
    c) Referral form to NOAC service for atrial fibrillation
9. Patient information leaflets

Appendix 1: Anticoagulation Service Specification

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Version	2.0
Service	AQP Anticoagulation Management
Commissioner Lead	Jane Butterworth, Head of Medicines Management, Buckinghamshire Clinical Commissioning Group (CCG)
Provider Lead	
Period	1st April 2015 – 31st March 2018 Contract Extension 1st April 2018 – 31st March 2020
Date of Review	
Date of last Revision	February 2018

1. Population Needs

1.1 National/local context and evidence base

1.1.1 National context:
(From 'Support for Commissioning Anticoagulant Therapy' – National Institute for Health and Care Excellence (NICE) CMG49 May 2013)

Anticoagulation therapy is needed for people with a range of different conditions, who are identified in a range of settings and, in the case of deep vein thrombosis and pulmonary embolism, require urgent intervention.
Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia and if left untreated is a significant risk factor for stroke and other morbidities. It is often only detected after people present with serious complications of AF, such as stroke, thromboembolism or heart failure. People with AF who develop a stroke have greater mortality, more disability, more severe strokes, longer hospital stay and a lower rate of discharge to their own homes compared with people without AF who develop a stroke. Appropriate anticoagulation therapy for people with AF can reduce mortality and morbidity through reduction in incidence of stroke.
Venous thromboembolism (VTE) is a condition in which a blood clot (a thrombus) forms in a vein, most commonly in the deep veins of the legs or pelvis. This is known as deep vein thrombosis, or DVT. The thrombus can dislodge and travel in the blood, particularly to the pulmonary arteries. This is known as pulmonary embolism, or PE.
VTE is treated with anticoagulation therapy and people who have had recurrent VTE or who are at high risk of recurrence may be given prescribed anticoagulants indefinitely to prevent further VTE episodes. There are a number of anticoagulants available, including low molecular weight heparin, fondaparinux, vitamin K antagonists and novel oral anticoagulants (NOACs) also referred to as direct oral anticoagulants (DOACs)

Other conditions needing anticoagulation therapy include Atrial flutter, Chronic rheumatic heart diseases, thrombophilia disorders (such as Antiphospholipid syndrome, factor V Leiden), Dilated Cardiomyopathy and Prosthetic heart valves.

The Topic Advisory Group identified the following key quality issues in the commissioning of anticoagulation therapy:

- Variation in the quality and safety of anticoagulation therapy across the country
- Variation across the country in the activities of anticoagulation services, because there is no standard service model or definition of an anticoagulation service
- Venous thromboembolic diseases (NICE clinical guideline 144 [2012]) and Diagnosis and management of venous thromboembolic diseases (NICE quality standard 29 [2013]), published since the original guide for commissioners, make specific recommendations on anticoagulation therapy for people with VTE.
- A large proportion of people with AF are currently not receiving anticoagulation therapy in line with NICE guidance.

Commissioners should expect providers to collect and act on service user and carer feedback and

comment on anticoagulation services. This should include a number of factors particularly relevant to anticoagulation therapy, including:

- accessibility of venue(s) or domiciliary visits
- availability of convenient appointment times, particularly for working-age adults
- waiting times support and information provided by staff
- choice of anticoagulation therapy.

1.1.2 Local context:

The current situation in Buckinghamshire is that there is a fragmented anticoagulant service pathway with a mixture of delivery models and payment structures. Access to the type of International Normalisation Ratio (INR) testing and consistency in delivery of quality treatment is not equitable across the county and there is also evidence that many patients with AF are either not receiving any treatment or being given sub optimal treatment with antiplatelet therapy which is not as effective as oral anticoagulants. There is a shortage of either auditing or outcomes data of anticoagulant treatment in primary care. The CCGs aim to ensure that capacity issues in secondary care Clinical Haematology services are avoided.

Nationally, Cardiovascular Disease (CVD) accounts for one third of all deaths (CVD Outcomes Strategy, 2013). The prevalence in Buckinghamshire mirrors the national rate, with CVD the cause of 31% of deaths in 2011 (JSNA, 2012/13). Among the main risk factors for CVD, and stroke in particular, is Atrial Fibrillation (AF), which increases the risk of stroke fivefold (AF Association, 2013). AF is most common in elderly patients and its prevalence is increasing (AF Association, 2013), however estimates suggest that 18% of AF is undiagnosed (CVD Outcomes Strategy, 2013). There is a clear link between AF and stroke prevention: according to the CVD Outcomes Strategy (2013), 7000 strokes per year could be prevented through good management of AF, which equates to between three and five strokes per GP practice (AF Association, 2013).

1.1.3 Evidence base:

- Department of Health (2013) Improving cardiovascular outcomes: strategy.
- Department of Health (2011) Innovation Health and wealth: accelerating adoption and diffusion in the NHS.
- Department of Health (2010) Venous thromboembolism (VTE) risk assessment.
- Department of Health (2009) Venous thromboembolism prevention: a patient safety priority.
- Department of Health (2008) Using the commissioning for quality and innovation (CQUIN) payment framework.
- Department of Health (2007) Report of the independent expert working group on the prevention of venous thromboembolism (VTE) in hospitalised patients.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	✓
Domain 2	**Enhancing quality of life for people with long-term conditions**	✓
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	✓
Domain 4	**Ensuring people have a positive experience of care**	✓
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	✓

2.2 Local defined outcomes

To redesign the anticoagulation pathway to reduce stroke and complications of thromboembolism, by improving consistency in the delivery and quality of service, leading to an increase in the uptake and appropriate management of oral anticoagulation. This will be achieved by procuring county-wide provision of near patient testing anticoagulant monitoring (the 'gold standard' of care).

3. Scope

3.1 Aims and objectives of service

To provide 'one stop' anticoagulant clinics in a locally based setting that is easily accessible for the patient and able to deliver a safe, effective integrated anticoagulation service across primary and secondary care within Buckinghamshire.

In particular, the CCG commissioning aims are to:

- Provide a ONE stop service for patients that is both closer to home and more easily accessible;
- Ensure a consistent high quality INR monitoring service to patients wherever accessed from;
- Provide increased capacity in the community to meet the rising demand for anticoagulation;
- Improving rates of anticoagulation in AF with oral anticoagulants
- To improve community access to anticoagulation monitoring services
- Ensure consistent outcomes and standards relating to testing, sampling and dosing across service providers and between primary and secondary services
- Ensure consistent and appropriate referrals for consideration of New Oral Anti-coagulant (NOAC)
- Have an integrated streamlined service across the anticoagulation pathway.

3.2 Service description/care pathway

3.2.1 Service description

The CCGs will commission the provision of 'one stop' locally-based oral anticoagulation management service for appropriate patients aged 16 and over (for exclusions see 3.4) requiring anticoagulation with a Vitamin K Antagonist (VKA) e.g. warfarin that are registered with a GP practice in Chiltern or Aylesbury CCG using near patient testing (NPT) devices for INR monitoring purposes.

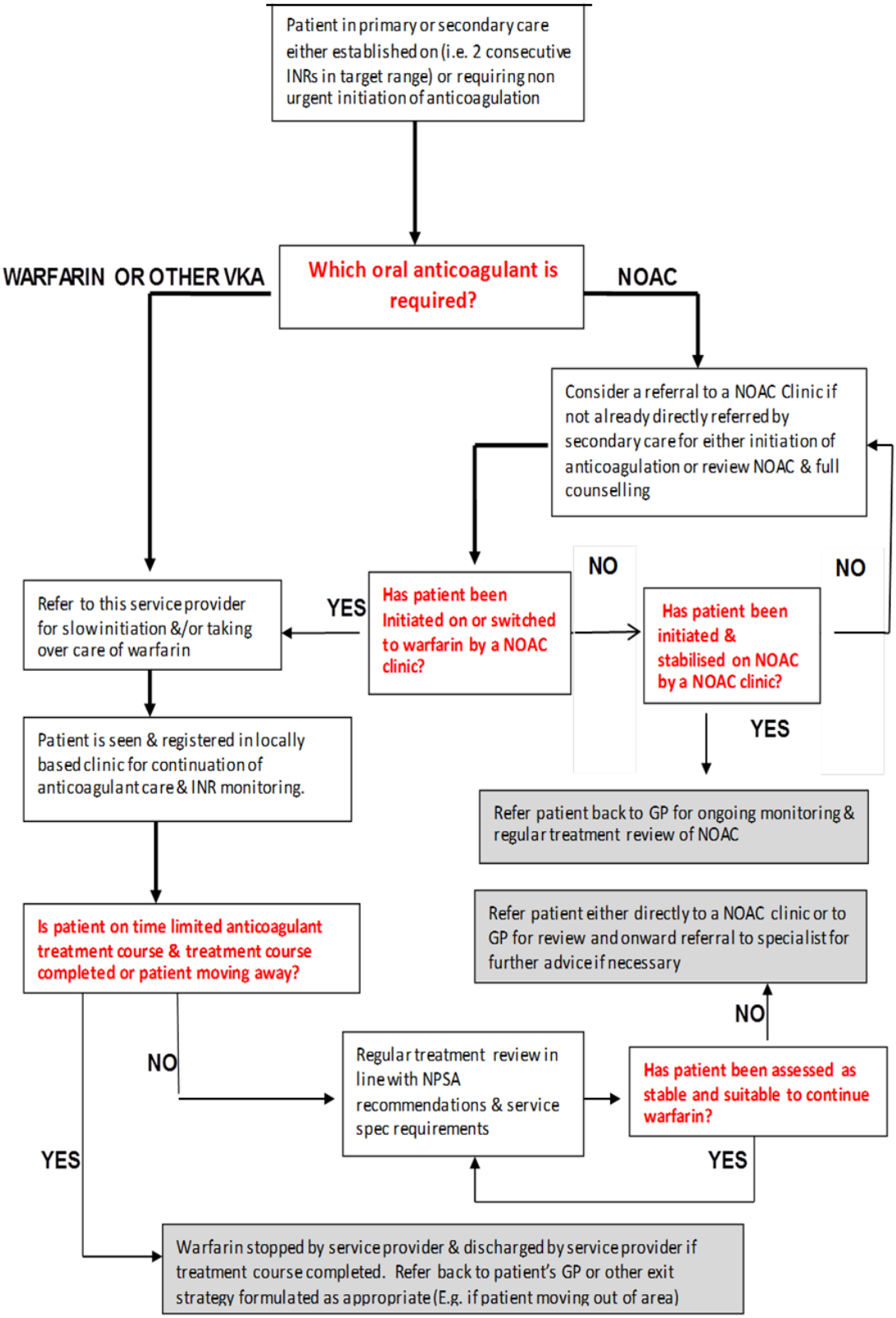
The service will be convenient to patients and have equitable access, ensuring that patients are treated with dignity and respect and are fully informed about their care so that they are able to make informed decisions about their treatment in partnership with healthcare professionals.

Therapy will normally be initiated in secondary care for recognised indications with specified lengths of time except in the case of atrial fibrillation/ atrial flutter where initiation may take place in primary care.

3.2.2 Pathway

Referrals to this service provider can be made directly via the patient's GP, NOAC clinic, by a clinician from secondary care or via A&E or OOH. All patients seen in secondary care and requiring oral anticoagulation with a NOAC are usually referred to a NOAC clinic for initiation.

Pathway Algorithm:



3.2.3 Clinic Service Provision & Standards of Care

Patients can be referred into the service following a formal clinical diagnosis and indication for oral anticoagulation with a VKA (warfarin). The anticoagulation providers should be able to both initiate and stabilise non urgent AF/flutter warfarin naïve patients as well as taking over the care of any patients established on a VKA referred to their service for ongoing INR monitoring and management.
All patients are to be seen in person either in a clinic or at home (if clinically required) by a health professional who has demonstrated clinical expertise &/or undergone accredited or approved anticoagulation training.
Providers must ensure that all staff involved in providing any aspect of care under the scheme has the necessary training and work competencies to undertake their duties.
The service will specifically deliver on:

3.2.4 Nominated Clinical Lead

The service provider is to have a nominated clinical lead(s) who is responsible for ensuring that the service is delivered in line with the service specification and current national standards.

3.2.5 Referral policies

Timely access to anticoagulation therapy is essential. More than 90% of patients referred to the service provider for initiation of warfarin should be seen by the service provider within 2 weeks of receipt of referral (consensus from NICE). Systems should also be in place to ensure referral of any existing patients needing transfer from secondary care or moving into area for continuation of anticoagulation can usually be seen within 7 days. All patients referred for oral anticoagulation should have a clear diagnosis /reason for anticoagulation stated on referral.
Where a patient meets the criteria for taking a NOAC in line with local policy, the patient can be referred directly to the NOAC clinic giving reason for referral together with supporting information regarding their anti-coagulation management. The patient must however continue to receive appropriate anti-coagulation therapy by the service provider until it has been confirmed that the patient has been seen and started on a NOAC.
Patients wishing to transfer to another provider must be referred by their GP to ensure a safe transfer. **Patients can only be registered under one AQP provider at any one time**.

3.2.6 Development & maintenance of a register

The service provider is to set up and maintain an up to date register of all patients being monitored under their care which will include patient identifiable data, indication for and duration of treatment, as well as target INR and review dates.

3.2.7 Professional links

The service provider has responsibility to ensure that robust communication systems are in place with the patient's GP. There should be clear procedures in place which states how information and results are communicated to clinicians & other services within acceptable specified timescales. Each GP practice should receive written confirmation from the service provider when one of their patients has been registered with the service and taken over their anticoagulant care.
All INR results, dosing decisions and next INR test date as well as any significant events are to be communicated electronically to patients GP within 24 hours.

3.2.8 Call and Recall

The service provider must have a robust system of call and recall in place and be able to identify and act quickly when a person has failed to attend an appointment to have their INR measured. The provider will implement appropriate and effective policies and strategies for the management and targeting of non-attendees including the facility to alert a patient's GP if a patient fails to attend on 2 or more consecutive occasions or a period of more than 42 days when they have not attended. In the event of a patient failing to attend a routinely arranged single clinic appointment, the service provider should make contact with the patient and reschedule the appointment to be seen within 2 weeks of the missed appointment, appropriate to the patient's clinical need and urgency for INR follow up.

3.2.9 Clinic Procedures

Providers must have up to date Standard Operating Procedures (SOPs) covering all aspects of the Anticoagulation service that are reviewed at least every 2 years. It is the service providers' responsibility to ensure such clinic procedures are in line with current standards and recommendations issued by British Committee for Standards in Haematology (BCSH) as well as other relevant national regulations and guidelines such as National Patient Safety Agency (NPSA) Written clinic procedures should cover all aspects of anticoagulation management including the

management of DNAs; recall procedures and abnormal INRs.
Specifically, in the event that a patient is found to have an abnormal INR, the service provider must have clear procedures in place for the appropriate assessment and management of the patient, including the administration of oral vitamin K where clinically appropriate. In the event of an INR reading of 8 or more on the NPT device, a repeat INR test should be performed to confirm the INR result. All cases for INRs of 8 and above are to be investigated for identification of the possible cause for such a raised INR and treated as a significant event.
Patients are to be referred directly to secondary care if they have any signs or symptoms of major bleeding or thromboembolism irrespective of their INR reading.

3.2.10 Access to Treatment

All service providers are expected to deliver an INR service that has arrangements in place for access to INR monitoring and advice at least 5 days a week. The number and frequency of routine INR NPT clinics held on a weekly basis will be dependent upon the case load and will be expected to be managed appropriately by each service provider. The provider must provide patients with a suitable date and time of appointment at an accessible and appropriate location. Although the majority of appointments will be clinic based, the service provider is expected to provide an anticoagulant service to care homes and domiciliary patients requiring treatment with warfarin or other VKA. Clinical judgment and/or liaison with the patient's GP should be used to determine whether or not a patient requires a domiciliary visit. In the case of a care home or domiciliary visit, the provider is expected to take all the necessary equipment to provide the full service at this location.
The length of time between test dates will vary according to individual patient need. However patients should have an INR check at least every 12 weeks (i.e. a minimum expected number of INR tests per patient per year is 4 unless patient is self-managing- see section 3.2.17). New or less stable patients will require more frequent INR monitoring.
The service provider shall ensure explicit contingency plans are in place to cover periods of planned and unplanned leave to ensure continuity of high standards of clinical care during periods of staff absence.

3.2.11 Prescribing Responsibilities

Where the service provider is not the patient's GP, the responsibilities for care that are specified in the amber shared care protocol for oral anticoagulation apply.
The service provider should request shared care using the form provided in the local shared care document. Decisions on the duration of treatment should be clearly stated by Haematology or appropriate clinical specialist for time limited courses.
The prescription of anticoagulation therapy will usually be the joint responsibility of the service provider and patient's GP under amber protocol arrangements. If the GP is unwilling to prescribe the on-going prescription for warfarin or other vitamin k antagonist under shared care then the AQP service provider is to provide ongoing prescription for OAC. On the grounds of clinical safety it is imperative that in a patient's GP record has warfarin or other VKA on the repeat medication record so that any potential drug interactions are flagged up.
Decisions on dosing for vitamin k antagonists following an INR test are the clinical responsibility of the AQP service provider. Where a patient is initiated on warfarin or where a dose change warrants a change in prescription of a VKA, the first prescription for 28 days should be issued by the service provider. This is taken in to account and allowance included in the tariff paid.
Good communication links with the patient's GP and AQP provider are essential. Where a GP prescribes a potentially interacting drug, it is the GPs responsibility to notify the provider but the AQP provider must then be able to respond to an additional INR request by the patients GP within a clinically appropriate time frame. It is ultimately the responsibility of the clinician or GP who is prescribing any potentially interacting drug to ensure arrangements are in place for appropriate INR follow up to be done in a timely manner.
When warfarin or VKA is to be stopped for an elective procedure or during a hospital admission, it is the secondary care's responsibility to ensure that appropriate INR monitoring scheduled pre and post procedure and/or following any hospital discharge is in place. The service provider is not responsible for either the decision to stop treatment prior to the procedure or to supply of bridging therapy as this is considered to be part of an episode of scheduled care associated with the procedure itself. (For further information refer to joint bridging therapy guideline.)
The decision to permanently discontinue warfarin or other VKA resides with the referring clinician and patients GP. Confirmation of discontinuation of anticoagulation should be clarified in writing to the service provider if not included on the initial patient referral letter.
A full list of the AQP prescribing responsibilities is included under CCG shared care guidelines for vitamin k antagonists and listed below

1. Confirm receipt of the referral to the referee and the patients GP if not the referee.
2. Initiate and/or take over management of oral anticoagulant treatment
3. Provide written and verbal counselling advice on warfarin. Patients should be provided with patient information and education in an accessible and understandable format that should be provided both at the initiation of oral anticoagulant treatment and reinforced at subsequent patient attendances and/or review as required
4. If the anticoagulation monitoring service is initiating the warfarin to provide the first prescription for warfarin, titrate the dose and establish patient on a stable dose of oral anticoagulant.
5. Where a dose change warrants a change in prescription of warfarin that can't be met with patients existing warfarin supply the anticoagulation monitoring service provider must make the supply.
6. Provide the patient with a patient held yellow oral anticoagulant therapy record book or equivalent with clear details of the reason for anticoagulant therapy, target INR range and duration of therapy in it and issue an oral anticoagulant alert card for them to keep on their person at all times
7. Advise GP of the strengths of tablets to prescribe. (Same day dosing using whole tablets should be prescribed wherever possible - NPSA guidance should be followed.)
8. Provide ongoing monitoring of INRs and appropriate dosing and follow up. **Communicate electronically the INR results, dose prescribed and date of next INR test promptly to the patient and patient's GP within 24 hours**.
9. In cases of over anticoagulation, administer oral vitamin K in accordance with BCSH guidelines and clinic protocols
10. All patients with an INR >5.0 should investigate the cause for the raised INR. For every patient with a recorded INR of 8 or more a significant event report giving details of possible cause, management and outcome is to be completed & GP informed– AQP contract requirement.
11. Where a stop date has been clearly documented by the referrer who is not the patient's GP then the responsibility to discontinue warfarin or other vitamin K antagonist resides with the anticoagulation monitoring service provider and the GP notified OAC has been stopped.
12. Where continuation of OAC is either in doubt or is not in line with national guidance this should be flagged up to the GP or referrer if this is not the patient's GP.
13. The anticoagulation monitoring service provider must actively follow up any patient who does not attend for regular monitoring within the agreed time period as stated in Anticoagulation service specification.
14. If a patient DNAs on 2 or more consecutive occasions or more than 42 days in a DNA period the anticoagulation monitoring service will contact the patient's GP directly.
15. Report adverse events on the yellow card system if appropriate.
16. Ensure clear arrangements for back up advice and support are in place and patient informed
17. Discuss and regularly review benefits and side effects of treatment with the patient. To assess treatment at regular intervals and conduct annual treatment review. To check patient is well controlled (i.e. degree of INR control should be more than 65% of time in therapeutic range in last 6-12 months excluding first 6 weeks of treatment) and no known contraindications to continuing treatment apply or have been identified during monitoring. The outcome of annual review is to be communicated in writing to the patient's GP (see suggested template appendix ii).

3.2.12 Patient Education

The service provider will ensure all patients referred to their service have received standardised written (to be pre-agreed with CCGs) and verbal information (see Appendix iii for patient checklist) about their anticoagulant therapy that is reinforced at regular intervals to ensure the patient is aware of and understands the following:

- Indication / reason and purpose of treatment including patient's understanding of their individual benefits and risks treatment (explained in understandable terms)
- Be able to name drug and current dose including identification individual tablet colours and corresponding strengths
- Contents of the yellow book or equivalent patient held information
- Target INR and range and what that means
- Anticipated length of treatment;
- Importance of medication adherence and what to do in the event of a missed or wrong dose;
- Symptoms of under dose (e.g. progressive worsening of thrombotic signs or new symptoms such as PE) and overdose and what to do if these occur;
- Complications of treatment including side effects and bleeding;
- Drug, alcohol and food interactions and impact on treatment;
- Changes in medication or new medication requiring early monitoring

- Which medications (e.g. antibiotics) including over the counter (OTC) medications and supplements require particular care;
- What to do if dental treatment or elective surgery or procedure is required; what to do for planned holidays especially long haul travel
- Clinic arrangements for monitoring and contact details for the provider in case of concerns.

3.2.13 Annual Individual Patient Review

All service providers are to ensure patients are given at least an annual review of therapy to:

- review the quality of anticoagulation control; checking degree of INR control is more than 65% time in therapeutic range;
- assess issues such as patient adherence and patient's understanding benefits versus risks of continuing treatment.

An annual treatment review is included as part of the tariff paid per patient. A suggested template is given appendix ii.

At annual review the following should be assessed, discussed with the patient and reported to the GP:

- Average TTR in last 12 months and TTR trend for the last 6 months. This should be looked at in the context of monitoring frequency, causes for any deviations in INR stability e.g. planned INR check pre-op or whether unexpected deviation in INR as well as considering overall stability INR trend with the patient (i.e. is INR trend generally stable on same dose with occasional deviation in INR or is the INR trend erratic with frequent swings in INR trend).
- No of INR tests performed in last year/frequency of INR monitoring required – most patients should not need monitoring more frequently than every 4 - 6 weeks on average (i.e. 11 - 13 visits a year) if stable.
- Any unplanned INRs <1.5 or unexplained INRs 5 in last 6 months and possible causes/ reasons identified.
- Assessment of medication adherence, self-reported missed doses and likelihood of possible unintentional non-compliance due to changes in cognitive ability.
- Alcohol status.
- Assessment signs or symptoms excessive bruising/bleeding.

Patients with a TTR less than 65% not due to medication adherence especially with more frequent monitoring and or dose changes should be considered for alternative anticoagulant treatment strategies such as self-management or suitability for a direct oral anticoagulant (DOAC)

As routine blood tests such as full blood count (FBC) and estimate of glomerular filtration rate (eGFR)/creatinine are **not considered mandatory** as part of an anticoagulant annual review for patients on warfarin or other VKA they are **no** longer required to be undertaken under AQP specification provision.

3.2.14 Record Keeping

Every patient should have an individual management plan that is shared with the patient giving the diagnosis or reason for treatment, planned duration and therapeutic range.

Every patient registered with the service and receiving oral anticoagulation must be issued with a completed yellow oral anticoagulation alert card which they must be counselled to keep with them at all times.

Service providers are expected to keep a comprehensive treatment record for each patient that is updated at each visit and includes:

- Patient's INR;
- Dose of anticoagulant;
- Date of next appointment;
- Information from the patient about unusual bleeding or bruising, adherence to treatment, other medication, changes in diet, changes in alcohol or smoking, or planned surgery;
- Information from other clinicians looking after aspects of the patients care (where appropriate);
- Any relevant changes in medical history or treatment.
- OTC medication including herbal remedies
- All patients should be given an individual hand-held record such as NPSA 'yellow book' which states latest INR level, dosing information, date of next test and contact numbers for advice, and which is maintained by the anticoagulant service. Patients are to be encouraged to carry their individual INR treatment record with them at all times and to show it to any health professional whenever they seek medical treatment or advice.

In addition, the service provider is required to keep records of the following for any patient under their care:

- Patient demographic details including date of birth and ethnicity
- Indication for treatment & start date
- Planned duration of treatment & stop date if not long term;
- Documented annual review & date next annual review for patients on long term therapy
- Target INR and INR range;
- Relevant notes supporting dose decision, counselling and self-testing/management;
- Frequency of INR testing & DNA records;
- Relevant medical conditions and/or hospital admissions likely to affect anticoagulation status or monitoring requirements
- Bleeding assessment risk (e.g. 'HAS-BLED' tool risk score) including any bleeding episodes or predisposition to bleeding
- Name of initiating clinician;
- Any actions taken other than dosing and retest dates.

3.2.15 Near patient testing devices and quality assurance

Service providers will provide Near Patient Testing (NPT) and laboratory analysers to determine patients' INR levels using only Medicines and Healthcare Products Regulatory Agency (MHRA) approved medical devices and must be compliant with all European Union (EU) medical device directives and compliance with ISO 13485 standards. Service Providers must provide details of what devices are being used to monitor INR.

Service providers will be responsible for all supplies including the test strips, finger prick equipment and internal quality control solution. The NPT equipment should be set up so that the monitor settings allow both operator and patient identifiable data to be entered and the device maintained in accordance with the manufacturer's recommendations.

Sharps should be disposed in line with Control of Substances Hazardous to Health (COSSH) legislation.

Internal Quality Control (IQC) are expected to be performed by the service provider:

- At the beginning of each clinic, otherwise;
- Each time a new box of strips is started or a new batch is used;
- Following a series of unexpected results.

Service providers must also register and participate in the UK National External Quality Assessment Scheme (NEQAS) or other equivalent registered scheme for blood coagulation that monitors the performance of INR NPT devices. Comprehensive records of quality checks to include batch numbers of strips and control samples, time of test and operator must be kept.

Patient testing devices should be reviewed following any failure to produce an acceptable result as a result of the IQC system or if the instrument receives a result outside the consensus from NEQAS. A robust contingency plan needs to be in place in the event of any equipment failure.

3.2.16 Computerised decision support software (CDSS)

Access to computerised Decision Support Software is to be made available for dosing decision support and audit to healthcare professionals providing anticoagulant clinic service CDSS is designed to be used only by clinical staff appropriately trained and qualified in interpretation and management of INRs.

As a CDSS is classed as a medical device, as such it must be compliant with all relevant European Medical Device directives and compliance with ISO 13485 standards. In line with BSH Guidelines on oral anticoagulation, the CDSS should be set up as follows:

- Rapid retrieval of data to screen or printer;
- Data storage in chronological order;
- Dosage recommendations according to algorithm or guidelines approved by clinician in charge of the service - this should include evaluation of results over the full range of INR results;
- An alerting system for patient results which fall outside defined criteria;
- A facility to over-ride computer recommendations;
- Patient recall for testing according to agreed criteria based on previous stability with invalid date alerts;
- An alerting system for non-attendees;
- An alerting system for discontinuation of treatment;
- A prompt system to check for bleeding problems when high INR values are obtained;
- A system to record bleeding/thrombotic event;
- A facility to audit results.

Depending on the CDSS system used some of the above information may be recorded in the patient's own GP or pharmacy system lifelong record.
Any CDSS system must be able to be integrated to commonly used GP clinical systems such as Emis web, System One and Vision and ideally to point of care testing equipment to minimise the risk of any data transcription errors. Providers must be assured of the longevity of the product solution and that there is appropriate support maintenance over the duration of the contract.

3.2.17 Facility for patients self-testing and/or self-management of oral anticoagulation

Arrangements should be in place for those patients expressing an interest to self-test or self-manage their coagulation status. Patients are expected to purchase their NPT device but the provision and costs of INR testing strips are the responsibility of the service provider as this is reflected in the tariff paid.
Previous stability of INR is not a pre-requisite to home testing as unstable patients may benefit from increased autonomy. Frequency of INR testing for patients on self-testing/self-management programme should not usually be more than a maximum of once weekly.
Self-testing patients are responsible for testing their INR at home using capillary sampling and a NPT device but the dosing of warfarin or other VKA and the frequency of monitoring is determined by a responsible clinician under this service provision. A specified weekday and time should be agreed when the clinician is available for patients self-testing to phone in with their INR result and for follow up INR support and advice.
Self-management patients have been assessed as capable of testing and dosing according to their INR result at home using a NPT INR device. Dosing of warfarin or other VKA and frequency of testing is managed by the patient with support from the responsible clinician according to an agreed signed contract between patient and clinician responsible. The contract should specify the responsibilities of the patient, the agreed algorithm for dosage of warfarin or other VKA and frequency of INR monitoring, and who to contact in the event of INR >5. This should also include agreement to attend clinic regularly for review (at least every 6 months once trained to cross check correlation INR results with clinic) and to keep accurate records of their INR results.

Recommended criteria for eligibility to self-test anticoagulation status:

- Only patients with long term indications for warfarin or other VKA therapy should be considered for self-testing or self-management using an MHRA approved NPT INR monitor with ISI 1.0 designed for patient self-use e.g. CoaguChek XS system, INRatio2PT/INR or any other.
- Must have a documented target INR range in line with accepted guidelines and clinical practice.
- Should have demonstrated adherence with taking medication and attending clinic appointments.
- Person or carer is both physically and cognitively able to self-monitor effectively and has been trained and assessed as competent to perform an INR by a suitably qualified healthcare professional prior to allowing home testing.
- In all cases where a patient is self-testing/self-managing the patient's GP must be informed.
- Patients self-testing/ self-managing should have a minimum annual assessment of their capability to continue to self-test/manage included as part of their annual clinical review by the service provider.
- Equipment for self-monitoring should be regularly checked using reliable quality control procedures. An acceptable quality assurance method would be for the service provider to simultaneously check correlation of INR clinic result obtained with the patient's INR result obtained using their own monitor and test strips. The INR readings should be within +/- 0.5 units (or +/-15%) of each other.
- For patients self-managing an agreed algorithm for dosage of warfarin or other VKA that is tailored to the individual patient should be in place and the clinician responsible contacted for advice if INR result is > 5.
- Appendix iv provides a standard document for self-testing contract.

3.2.18 Clinical Governance

The provider is expected to have an incident reporting policy in place or to comply within existing CCG clinical governance framework. All critical or untoward incidents (and near misses) must be reported via the National Reporting and Learning System (NRLS) for all service providers. Such untoward incidents would include:

- Any equipment or serious communication failure or the issue of an incorrect prescription.
- Any clinical event leading to a major bleed or embolism requiring hospital admission
- In summary the service provider will be responsible for ensuring that the service is provided according to the service specification. In particular, that:
- Timely access to treatment is achieved for both new & existing patients
- Dose recommendations and recall are made according to approved guidelines;

- Patient education regarding anticoagulation therapy is provided and the patient hand-held record is kept up-to-date;
- An annual review is performed;
- Patients are referred to A&E or secondary care where required;
- Adverse events are reported;
- Healthcare professionals involved in delivering anticoagulant service have necessary experience / training and work related competencies and keep professionally up to date
- Comprehensive service contingency plans are in place including arrangements for cover annual or sickness leave
- All elements of the specification are followed

3.2.19 Staff Training

It is the Service provider responsibility to ensure all staff or those contracted by the service providers to provide any aspect of care under this service specification have the necessary experience, competencies, and qualifications to do so.
In particular the service provider must ensure that all staff employed in the provision of the service meets the competencies outlined by the NPSA. In addition the provider shall ensure the clinical lead of the service has:

- The ability to safely manage a locally care based anticoagulation clinic using near patient testing for INR estimating, 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 the ability to evaluate which target INR is required when treating different conditions;
- An understanding of the pharmacology of all oral anticoagulants including Warfarin
- The ability to critically analyse all aspects of anticoagulation management and therefore evaluation aspects for safe practice.

All healthcare professionals involved in anticoagulation management should be able to provide evidence of relevant anticoagulation competencies and on-going continued professional development. Costs for any training required by the service provider to deliver services are expected to be borne by the service provider.
Approved training courses that are recognised as meeting the necessary competencies and CPD training requirements include The University of Warwick Anticoagulant Training which has been developed to meet the educational and training needs of all healthcare professionals involved in anticoagulant management and the University of Hertfordshire Anticoagulation for Healthcare professionals.

3.3 Population covered

All eligible patients aged 16 years and over registered with a GP practice within Buckinghamshire CCG requiring continuation of anticoagulation monitoring and/or non-urgent initiation of oral anticoagulation with a VKA can be referred to the locally based anticoagulation 'one-stop' service. The service provider is to include arrangements for patients on a VKA requiring domiciliary visits for INR monitoring.

3.4 Any acceptance and exclusion criteria and thresholds

The service excludes the following patient groups

1. paediatric patients aged up to 16 years ,
2. patients requiring urgent or rapid oral anticoagulation;
3. pregnant patients (up to 6 weeks post-partum),
4. patients requiring dialysis or other complex secondary care input such as. active cancer patients undergoing complex chemotherapy;
5. patients with Anti-phospholipid Syndrome that cannot be monitored satisfactorily using NPT equipment
6. patients requiring initiation or continuation of a NOAC (DOAC).

Patients listed in categories 1-5 should be monitored in secondary care under the supervision of a clinical specialist.
There must be a clinical reason why a patient referred to the secondary care provider would not be accepted.

3.5 Interdependence with other services/providers

Secondary care NOAC clinic and Clinical Haematology department
GP practices

. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

- NICE Commissioning Guide Anticoagulation May 2013. https://www.nursinginpractice.com/sites/default/files/nice/NICE%20Commissioning%20Guide-Anticoag_30.07_LORES.pdf
- NICE clinical guideline on AF CG180 (2014) http://www.nice.org.uk/Guidance/CG180
- NICE TA 249 (2012) Dabigatran etexilate for the prevention of stroke and systemic embolism in people with atrial fibrillation with one or more risk factor for stroke https://www.nice.org.uk/guidance/ta249/resources/dabigatran-etexilate-for-the-prevention-of-stroke-and-systemic-embolism-in-atrial-fibrillation-pdf-82600439457733
- NICE TA 256 (2012) Rivaroxaban for the prevention of stroke and systemic embolism in people with atrial fibrillation. https://www.nice.org.uk/guidance/ta256/chapter/1-guidance
- NICE TA 275 (2013) Apixaban for the prevention of stroke and systemic embolism in people with non valvular atrial fibrillation https://www.nice.org.uk/guidance/ta275
- NICE Clinical Guideline CG144 June 2012 Venous thromboembolic diseases: the management of venous thromboembolic diseases and the role of thrombophilia testing. http://guidance.nice.org.uk/CG144
- Department of Health (DH) Cardiovascular Disease Outcomes Strategy –Improving Outcomes for people with or at risk of cardiovascular disease March 2013 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/217118/9387-2900853-CVD-Outcomes_web1.pdf
- European Society of cardiology (ESC) Guidelines atrial Fibrillation Aug 2010 Camms et al. Eur Heart Journal 2010;12 1360-1420. http://eurheartj.oxfordjournals.org/content/31/19/2369.full
- ESC 2012 Focused Update of ESC Guidelines for management of atrial fibrillation (Eur Heart Journal 2012 33, 2719-2747).

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

- National Patient Safety Agency (NPSA) Alert 18-; Actions that can make anticoagulation safer (2007) alerts. https://www.sps.nhs.uk/articles/npsa-alert-actions-that-can-make-oral-anticoagulant-therapy-safer-2007/
- British Society Haematology Guidelines on oral anticoagulation with warfarin – 4th edition 2011 British Journal Haematology, 134; 311-324 https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2141.2011.08753.x
- Recommendations from the British Committee for Standards in Haematology and National Patient Safety Agency British Journal of Haematology, 2006; 136, 26–29 https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2141.2006.06379.x
- Royal College of Physicians of Edinburgh (RCPE) UK Consensus Statement on approaching the comprehensive management of atrial fibrillation. Evolution or revolution. March 2012 https://www.rcpe.ac.uk/sites/default/files/documents/pressreleases/rcpe-af-consensus-statement-2012.pdf
- BCSH guidelines on the management of patients on oral anticoagulants requiring dental surgery. http://www.nature.com/bdj/journal/v203/n7/full/bdj.2007.892.html
- MHRA Management & Use of IVD Point of Care Devices February 2013 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/371800/In_vitro_diagnostic_point-of-care_test_devices.pdf
- The International Council for Standardisation in Haematology (ICSH) Guideline for Worldwide Point of care Testing in Haematology Int J Haem 2008 30; 105-116. http://islh.org/web/downloads/ICSH_Standards/ICSH_Guideline_for_POCT_in_Haematology_Briggs_April_2008.pdf
- NICE Diagnostics Guidance DG14 Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers Sept 2014 https://www.nice.org.uk/guidance/dg14

4.3 Applicable local standards

Available at www.bucksformulary.nhs.uk

- Buckinghamsire CCG Shared Care Agreement for Oral Anticoagulants
- BHT & CCG Policy documents Dabigatran & Rivaroxaban Apixaban
- Care Pathways for AF Patients & Anticoagulation
- Contraindications to Warfarin document
- Shared Care Protocol for Vitamin K Antagonists

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality Requirements (See Schedule 4 Parts [A-D])

The CCG will require submission of annual declaration on service provision (see Appendix i) as well as quarterly returns from the service providers giving details on clinical activity and monitoring (see outcomes table below for an overview, and Schedule 4 and Schedule 6 for details). Failure to submit quarterly returns and an annual declaration will result in non-payment.

All service providers are expected to undertake an annual audit of their service that includes a review of clinic service performance and patient satisfaction with service. The audit results will be used to inform local actions needed to continually improve on the safe use of anticoagulants in the community.

	Clinic Service Quality Standards	**Target** *(where applicable)*
	Number of patients on a Vitamin K Antagonist currently registered with service provider	**n/a**
1	Percentage of patients that have had an INR checked in last 12 weeks	**>95%**
2	Percentage of new patients either treatment naive or who have recently started oral anticoagulation referred to the service during this current quarter were seen within 1-2 weeks of referral	**>95%**
3	Clinic's proportion of patient time in therapeutic range +/- 0.5 target INR or if not available the percentage of INRs +/- 0.5 target INR for last 13 weeks	**>65%**
4	Clinic's proportion of patient +/- 0.75 target INR or if not available the percentage of INRs +/- 0.75 target INR for last 13 weeks (only required if target 4 above is reported as less than 65%)	**>80%**
5	Percentage of patients that have had an INR > 5 recorded in last 13 weeks	**<5%**
6	Percentage of patients that have had an INRs equal to or greater than 8* recorded in last 13 weeks **For every patient with a recorded INR 8 or more, a significant event report giving details of possible cause, management and outcome should be submitted with the quality standard report and forwarded to the commissioner*	**<0.5%**

6. Location of Provider Premises

The Provider's Premises are located at:

7. Tariff

The tariff is per patient per year. Payment will be made quarterly.

All patients should be appropriately read coded to allow data retrieval. Only patients with a recorded INR in the quarter specified will be entitled to claim a payment. If there is no activity for the patient during that quarter, payment will not be made.

The tariff paid per patient includes provision for at least an annual treatment review and allowance for supplies of warfarin or other VKA to be made by the service provider.

Tariff per patient per annum: **£225.00**

Appendix i

Annual Statement of Compliance to Anticoagulant Service Specification Standards

For Period 1st April 2018 to 31st March 2020

1. Who is the clinical lead responsible for service delivery *(Ref 3.3.1)

   Name……Signature……..
   Title/ Professional Status & any relevant Qualifications……

   ……
   Contact Base Details ……
   Contact telephone No…….

   - .**** It is the responsibility of the Service Provider to notify the CCG if nominated clinical lead changes during this period.***

2. Please state the full names, professional status and role of any individuals involved in delivering anticoagulant service?

Name	Professional Status	Role/ Duties within Anticoagulant Service
……..	……	……
……..	……	……
……	……	
……	……	
……	…….	
……	……	
…… ….	……	
…… ….	……	

   The CCG reserves the right to request to see individual anticoagulant competencies

   Any changes

3. What IT decision support system is being used to support in the running and management of the anticoagulant clinic service?.

   ……

4. What are the NPT INR devices, serial or model nos and how many are currently in use for INR monitoring under this service specification?

   ……

   ……

5. What is/are your site UK NEQAS registration no (s)

   …… …….. ……

   …….. …… ……..

Please submit copy(ies) of all current certificate(s) of registration with UK NEQAS. Each NPT device used in monitoring INR under this service specification is required to be registered with UK NEQAS.

I can confirm the above information is correct and that service provision complies with the service specification requirements.

Name Service Provider Lead …….

Service Provider Lead Signature……

Date of Declaration…….....

Appendix ii: Suggested Template for Treatment/Annual Review of Patients On Oral Anticoagulants as Vitamin K Antagonist

AQP Provider details……. Date of Tx /Annual Review……..

Patient Details	
Patient Full Name	
Date of Birth	
Patients Address	
Registered GP Name & Surgery Address	
Indication for oral anticoagulation	
Target INR Range	
Date oral anticoagulation initiated	
Treatment duration /Treatment stop date	

Reason for review – Annual Review / End of Treatment Review/ Other

Clinical Review Details	Results	Comments
Average time INR in therapeutic range (TTR) in the last 12 months if on long-term treatment		Assess reasons if poor INR control & provide supporting info if any reasons identified for poor TTR control (TTR <65%) &/or measures taken to improve TTR
INR Time in therapeutic range (TTR) in the latest 6 months (ex 1st 6 weeks tx)		
Average frequency of INR monitoring (excluding 1st 6 weeks of initiation of treatment)	□ self testing/management pt □ 8-12 weekly □ 6-8 weekly □ 4-6 weekly □ < 4weekly	Stable pts should not need more frequent monitoring than every 4-6 weeks
Assessment of medication adherence. / dosing history	□ Never or rarely missed doses. □ Occasionally reported missed doses □ Frequently missed doses reported □ No reported missed doses but erratic or unintentional non- compliance suspected	*Document if any evidence of unintentional non-compliance if poor INR control (also consider adherence with other meds being prescribed if can affect INR control)*
Has there been any **unintentional** INRs ≤1.5 recorded in last 6 months?	Yes/No. If yes how many?	Unintentional includes INRs < 1.5 not due to warfarin being stopped deliberately eg prior to surgery
Has there been any documented INRs > 5 recorded in last 6 months?	Yes /No If yes how many?	*Provide supporting info on circumstances for cause raised INR*
Has patient failed to attend for INR follow up on more than 1 occasion in last 6 months	Yes /No Give details if yes	Record action taken
Is patient taking any other known drugs increasing his bleeding risk as OTCs or supplements	e.g. aspirin containing products, oral NSAIDs; dietary supplements known to increase bleeding risk/ affect INR control	Medicines optimisation key including use OTC to optimising INR control & minimising bleeding risk
Does patient drink alcohol?	Yes/No if yes record No units /week	Ensure pt aware risks binge drinking & effects INR control
Has there been any evidence spontaneous bruising or bleeding reported by the patient in last 6 months?	Yes /No If yes give details	Ensure patients are aware to have regular BP checks (min 6 monthly)
Have any other risks during monitoring of anticoagulant treatment or any factors affecting INR control been identified since last review?	Yes / No. If yes give details	Give details if yes e.g. is patient prone to significant bruising; erratic swings in INR trend etc
Would patient benefit from alternative OAC strategy e.g. self monitoring or consideration DOAC	Yes /No	Give reasons for decision
Has patient or carer have clear understanding indication & benefits & risks of treatment	Yes /No Check patient has yellow OAT card and record any healthcare advice given including signposting to other networks /organisations for further advice/support	The annual review is an opportunity to reinforce key messages & check their understanding of treatment and importance of drug adherance.

RECOMMENDATION by AQP PROVIDER

☐ Warfarin well controlled/ No safety concerns identified. No further action required by GP

☐ Warfarin poorly controlled/ safety concerns identified. Further follow up & review by GP required .

Appendix iii: Anticoagulant Clinic Counselling Checklist Template

Patient Name _____ Clinic ID No: _____

***Explain*:**	***Points to cover***
□ What is the drug?	Ensure knows / recognises name of tablet. Ensure able to identify Tablet colours and strengths and how to make up the correct dose
□ What does it do/how it works?	Delays clotting by affecting level of production of vitamin k dependent clotting factors made in the blood
□ Why is needed?	Discuss individual indication for treatment and benefits
□ How long it is needed for	Discuss duration of therapy. For dvts /pe establish if first event, pmh or family hx of clots.
□ How much is needed and what can affect INR control	Amount can vary from time to time due to changes in patients diet, lifestyle, smoking status as well as due to changes in co-morbidities Patients also differ in how much they need due to individual differences in the way they handle metabolism of drugs and type of medicines prescribed
□ When should it be taken?	Approximately same time each day Stress the importance of taking it daily even if it's not at the same time but as soon as remember -(better to take it even 8 hours later than not at all – consider staggering dose the following day if taken more than 8-10 hours later from usual time average warfarin half life is 36 hours)
□ Need for regular blood tests	Discuss purpose, frequency, interpretation and importance of regular monitoring
□ Significance of INR & target INR	Discuss acceptable limits for individual; what low and high INRs mean and implications to in terms risk to individual (e.g. INR 1.8. is more concern than an INR 3.2 in a patient high risk stroke & lower bleeding risk)
□ Importance of drug adherence & what to do if miss a dose	Discuss the importance of long term adherence to treatment risks of not taking treatment . Discuss what to do and what not to do e.g. Not to double dose, but to take as soon as remember if same day;
□ Discuss possible interactions with warfarin and other medicines and what to do	Always check. Remind pts to tell GPs dentists and other health professionals on warfarin. Avoid self-medication with aspirin and oral NSAIDs. Use prn paracetamol for headache. Always inform clinic of any medicine changes. Review existing medication including any OTC products with patient.
□ Discuss potential side effects & what to look out for especially with regards to bleeding	Explain will bruise and bleed more easily Discuss ways to prevent signs bruising, signs of bleeding and when to seek further medical advice
□ Discuss effect of diet and alcohol on warfarin	Cover importance of balanced diet, safe limits alcohol & effect lifestyle changes can have on warfarin e.g. crash diets, smoking, illness, stress. Give AFA factsheet on warfarin & diet
□ Contraception & pregnancy advice	Give If relevant to all women of child bearing age
□ What to do if have acute illness	See GP if not warfarin related. If warfarin come to clinic sooner or see GP or contact 111 if out of hours or A&E if emergency
□ What happens in the clinic?	Supply patient information leaflet on service. Explain clinic arrangements and appointment times available. Provide contact details of who to contact in an emergency and What to do if can't attend clinic
□ What to do before dental & surgical procedures & when planning to go on holiday	Discuss issues relating to holidays / travel. Explain usual procedure if any elective surgery or dental work needed.

Counselling completed: Patient signature…….. Date……..

Clinician signature…….. Date……..

Appendix iv

TEMPLATE for PATIENT AND ANTICOAGULATION CLINIC AGREEMENT FOR THE USE OF A [NAME OF DEVICE] INSTRUMENT FOR SELF TESTING INR

1) This is an agreement for self testing between:

(Patient's Name) ……*NHS No*……

(Address) ……
(Date of Birth) …… (*Telephone Number)* …….
and ……. Anticoagulation Clinic, *(insert address and contact details*)
……

2) Patient undertaking

I have a [name of device] monitor. To ensure my own safety I agree to work in partnership with

…… Anticoagulation Clinic.

I confirm I have been trained in the use of the instrument.

I have trained …… *(insert patient's name)* in the use of the [name of device] INR monitor and consider he/she to be competent to perform finger-prick INR testing.

(Trainer's name) …… *Date* ……

- I will perform INR tests at mutually agreed intervals and will inform the Anticoagulation Clinic of the results by …… *(insert agreed date time and contact details)* and record the results in my anticoagulant Yellow Book
- I will repeat any test if the result is less than 1.8 (or less than 2.5 if for a mechanical heart valve replacement) or greater than 5.0 or if there is an unusual occurrence which might affect the test strips or the machine e.g. incorrect storage temperature, accidental damage or spills.and contact clinic for advice if necessary
- I will act on the advice given by the Anticoagulation clinic with regard to dosage and test interval.
- I will record the dosage I am given and the next test date in my anticoagulant Yellow Book. I understand the maximum permitted interval for INR tests is 12 weekly (6 weekly if for mechanical valve replacements)
- I understand that it is my responsibility to order supplies of test strips and finger-prick lancets from the service provider.
- I will be responsible for the correct storage of test strips and will dispose of used lancets, other sharps and contaminated waste carefully.
- I will attend the Anticoagulation Clinic for an annual review every 12 months, and bring my Yellow Book, [name of device] monitor and test strips currently in use.
- I will inform the Anticoagulation Clinic if I intend to travel abroad or been, if there is any change to my medical condition or treatment or requiring any surgical or elective procedure that may impact on monitoring requirements
- I will inform the Anticoagulation Clinic if I decide to stop self-testing or move house to a different area so that arrangements can be made for alternative management of my treatment.
- I understand that if I fail to comply with any of the above the Anticoagulation Clinic cannot support me with self-testing and the self-testing agreement will be withdrawn.

Patient's signature …… *Date* ……..

3) Clinic undertaking

The Anticoagulation Clinic agrees to support the above named patient with his/her self-testing provided that the conditions listed above are met. The Anticoagulation clinic will be available, during normal working hours, for help and advice. After the patient has contacted the Anticoagulant clinic with a result, advice on dosing will be given. This advice will be confirmed by letter.

The Anticoagulation Clinic will provide an External Quality Assurance by comparative testing of patient's capillary blood INR by the patient's own [name of device] and by the Anticoagulation Clinic method every 6-12 months. Patients will be sent appointments for annual review in the self-testing clinic every 6 months.

In the event that the conditions are not met the Anticoagulation Clinic will offer the patient a normal

clinic service without any regard to self-testing.

The Anticoagulation Clinic will inform the patient's General Practitioner of his/her intention to start self-testing, stop self-testing or of any failure to comply with this agreement.
Name & Signature …… Date……..
(on behalf of the Anticoagulation Clinic)
ONE copy of signed agreement is to be given to patient and ONE copy kept for service provider records (to be scanned in to patient's records).

4) Additional Notes

Self-testing

In self-testing the patient is responsible for testing his/her INR. The patient is not responsible for dosing unless agreed patient can self-manage. Dosing of warfarin/sinthrome ultimately remains the responsibility of the Anticoagulation Clinic.
Maintenance and storage of the [name of device] is the responsibility of the patient.
External Quality Control will be offered locally by the Anticoagulation Clinic. This requires comparative testing of capillary blood from the patient using both the system used in the Anticoagulation Clinic and the patient's [name of device] - see section External Quality Assurance below.

Criteria for accepting patients to self-test

- Patients must be on long term anticoagulation.
- Patients must have a [name of device] instrument and be competent in its use.
- Patients must have a telephone or mobile telephone for contacting the Clinic.
- Patients must sign up to the 'Patient and Anticoagulation Clinic agreement for the use of a [name of device] INR monitor'.

Equipment needed for self-testing

- [name of device] INR monitor
- Finger pricking device and lancets.
- Test strips

Clinic attendance

Follow-up review is essential. The patient must attend the Anticoagulation Clinic at least every 6 months or sooner if required or requested by the anticoagulant clinic.

Documentation

Test results, quality assurance checks and any problems must be documented accurately. The Yellow Book is the preferred place for the patient to keep these records. The Anticoagulation Clinic will also keep all such records.

Quality Assurance Checks

There are a number of possible approaches to External Quality Assurance.

The preferred method is for the Anticoagulation Clinic to compare the INR result obtained by the patient on his/her own [name of device] with a simultaneous INR result taken by a member of the Clinic staff on the Clinic test system . This is recommended to take place as a minimum standard of care every 6 months.

Contacting the Anticoagulant Clinic

A specified weekday and time should be agreed when the clinician is available for patients self-testing to phone in with their INR result and for follow up INR support and advice.

Advice and support

The INR test must be done on a weekday, at agreed intervals, and the Anticoagulation clinic informed of the result. For patients self-testing, the Anticoagulation clinic will adjust the dose of anticoagulant and will inform the patient accordingly. The anticoagulant clinic will keep a record of all contacts and enter the results and dosing decisions into the Clinic computer system.

Ending the agreement

The patient should inform the clinic if he/she intends to move to another area or chooses to stop self-testing. The clinic will consider this agreement to have finished if the patient fails to comply with the terms of the agreement. If the patient repeatedly fails to attend for review, self-testing agreement will be withdrawn and the GP informed.

Appendix 2a: Ward 3b Anticoagulant Clinic Patient Survey

Buckinghamshire Healthcare NHS Trust

Anticoagulation Clinic Survey (Ward 3b)

We should be grateful if you could complete this questionnaire about your Anticoagulation Clinic appointment. We are always trying to improve our service and your views would be invaluable to us. Thank you.

1. When you booked in at reception did you find the reception staff helpful?

☐ Yes definitely ☐ Yes, to some extent ☐ No, not really
☐ Not applicable.

2. Were you satisfied with the waiting area and the facilities available there?

☐ Yes definitely ☐ Yes, to some extent ☐ No, not really

If there is any aspect of the waiting area/reception that you feel could be improved please comment.

3. How long after the stated appointment time did the appointment start?

☐ Seen on time or early ☐ Waited up to 10 minutes ☐ Waited 11 to 20 minutes
☐ Waited 21 to 30 minutes ☐ Waited 31 to 60 minutes ☐ Waited more than 1 hour

4. If you had to wait more than 10 minutes were you told how long you would have to wait?

☐ Yes, but the wait was shorter ☐ Yes, and I had to wait about as long as I was told
☐ Yes, but the wait was longer ☐ No, I was not told how long the wait would be
☐ Not applicable. Did not wait more than 10 minutes

5. Did the nurse introduce themselves?

☐ Yes ☐ No ☐ I had met them before

6. Were you satisfied with the way your blood test was done?

☐ Yes definitely ☐ Yes, to some extent ☐ No, not really

If No, in what way could we improve this?

7. Were you given the opportunity to ask questions?

☐ Yes definitely ☐ Yes, to some extent ☐ No, not really

8. Were your questions answered in a way you could understand?

☐ Yes definitely ☐ Yes, to some extent ☐ No, not really

☐ I did not ask any questions

9. Were the anticoagulation instructions in your 'yellow book' easy to understand?

☐ Yes definitely ☐ Yes, to some extent ☐ No, not really

If No, in what way could we improve this?

10. Did you have confidence and trust in the nurse?

☐ Yes definitely ☐ Yes, to some extent ☐ No, not really

11. If there are any other comments you would like to make about the nurse, please do so here

12. Overall, did you feel you were treated with respect and dignity while in the clinic?

☐ Yes definitely ☐ Yes, to some extent ☐ No

13. Overall, how would you rate the service you received in the Anticoagulation Clinic?

☐ Excellent ☐ Very good ☐ Good ☐ Fair ☐ Poor

14. If there are any other comments you would like to make about the Anticoagulation Clinic please do so here

Thank you for taking the time to complete this questionnaire.

Once completed, please give this form to the clinic receptionist or volunteer.

Clinic Site: Level 3B, WH Date of clinic:

Appendix 2b: CCHU Anticoagulant Clinic Patient Survey

NHS
Buckinghamshire Healthcare
NHS Trust

CCHU Anticoagulation Clinic Survey

We should be grateful if you could complete this questionnaire about your Anticoagulation Clinic appointment. We are always trying to improve our service and your views would be invaluable to us. Thank you.

1. **Are you happy with the system whereby you leave your warfarin booklet in the yellow basket when you arrive at the clinic?**

☐ Yes definitely ☐ Yes, to some extent ☐ No, not really

2. **Were you satisfied with the waiting area and the facilities available there?**

☐ Yes definitely ☐ Yes, to some extent ☐ No, not really

If there is any aspect of the waiting area/reception that you feel could be improved please comment.

3. **How long after the stated appointment time did the appointment start?**

☐ Seen on time or early ☐ Waited up to 10 minutes ☐ Waited 11 to 20 minutes
☐ Waited 21 to 30 minutes ☐ Waited 31 to 60 minutes ☐ Waited more than 1 hour

4. **If you had to wait more than 10 minutes were you told how long you would have to wait?**

☐ Yes, but the wait was shorter ☐ Yes, and I had to wait about as long as I was told
☐ Yes, but the wait was longer ☐ No, I was not told how long the wait would be
☐ Not applicable. Did not wait more than 10 minutes

5. **Did the nurse introduce themselves?**

☐ Yes ☐ No ☐ I had met them before

6. **Were you satisfied with the way your blood test was done?**

☐ Yes definitely ☐ Yes, to some extent ☐ No, not really

If No, in what way could we improve this?

7. **Were you given the opportunity to ask questions?**

☐ Yes definitely ☐ Yes, to some extent ☐ No, not really

8. Were your questions answered in a way you could understand?

☐ Yes definitely ☐ Yes, to some extent ☐ No, not really
☐ I did not ask any questions

9. Were the anticoagulation instructions in your 'yellow book' easy to understand?

☐ Yes definitely ☐ Yes, to some extent ☐ No, not really

If No, in what way could we improve this?

10. Did you have confidence and trust in the nurse?

☐ Yes definitely ☐ Yes, to some extent ☐ No, not really

11. If there are any other comments you would like to make about the nurse or pharmacist, please do so here

12. Overall, did you feel you were treated with respect and dignity while in the clinic?

☐ Yes definitely ☐ Yes, to some extent ☐ No

13. Overall, how would you rate the service you received in the Anticoagulation Clinic?

☐ Excellent ☐ Very good ☐ Good ☐ Fair ☐ Poor

14. If there are any other comments you would like to make about the Anticoagulation Clinic please do so here

Thank you for taking the time to complete this questionnaire.

Once completed, please place in the box provided.

Clinic Site: Date of clinic:

Appendix 2c: NOAC Led Anticoagulant Clinic Patient Survey

THE NHS FRIENDS AND FAMILY TEST

We would like you to think about your recent experience of our service.
How likely are you to recommend our service to friends and family if they needed similar care or treatment?

Extremely Likely	Likely	Neither Likely or Unlikely	Unlikely	Extremely Unlikely	Don't Know
☐	☐	☐	☐	☐	☐
☺ ⟷ ☹					?

Thinking about your response to this question, what is the main reason why you feel this way?

A Little Bit about you:

Are you?	
Male	☐
Female	☐

What age are you?	
□ 0-15	□ 55-64
□ 16-24	□ 65-74
□ 25-34	□ 75-84
□ 35-44	□ 85+
□ 45-54	

Do you consider yourself to have a disability?
Yes □ No □
Details:

Which of the following best describes your ethnic background?

White
□ British
□ Irish
□ Other white background

Asian or Asian British
□ Indian
□ Pakistani
□ Bangladeshi
□ Chinese
□ Other Asian Background

Mixed
□ White and Black Caribbean
□ White and Black African
□ White and Asian
□ Other Mixed Background

Black or Black British
□ Caribbean
□ African
□ Other Black Background

Other
□ Anything Else
□ I would rather not say

Are you?
□ The patient □ The parent or carer □ The patient and parent/carer

Thank you for completing the card and providing us with feedback to improve our services.

If you DO NOT wish your anonymous comments to be shared then please tick here: ☐

Appendix 3a: Pharmacist Led Clinic Counselling Proforma

Pharmacist led Anticoagulant Clinic Counselling Checklist

Patient Explanation	Tick and Comments
Condition/Purpose of medicine/Duration	
How to takeand frequency	
Support with adherence	Administered by: self / carer prompts / carer administers Dosette:No / Yes Filled by :Self /Pharm /Carer
Compliance	
Action if missed dose	
Acutely unwell/vomiting/diarrhoea	
Alert Card	
Importance of telling healthcare professionals (surgery/dental/injections/ pregnancy	
Interactions	
Pain killers /OTC medicines	
Side-effects/Warning signs/Emergency	
Alcohol /Diet	
Follow up	

Appendix 3b: Anticoagulation Nurse Led Clinic Counselling Proforma

BUCKINGHAMSHIRE HEALTHCARE NHS TRUST
PRIVATE AND CONFIDENTIAL ANTICOAGULATION SERVICE REGISTRATION AND COUNSELLING PROFORMA

PATIENT STICKER OR PATIENT DETAILS AND CONTACT NUMBERS

DATE …….

REGISTERED ☐

REFERRED BY ……

Indications for anticoagulation …….. INR range …….

Duration of anticoagulation……

Relevant medical conditions (Including previous bleeding, VTE events)	Medication Aspirin to continue **Yes / NO**	Has the patient started anticoagulation therapy? **If yes, please enter most recent results and doses below**
		Date INR Dose

BLOODS	Date dd/mm/yy	Normal	Mild abnormal	Major abnormality	Comments
U&ES	__/__/__	☐	☐	☐	
FBC	__/__/__	☐	☐	☐	
LFTS	__/__/__	☐	☐	☐	

RISK ASSESSMENT :	NOTES ☐	REFERRAL FORM ☐	LETTER☐	OTHER
	NO EXCESS RISK ☐	ACCEPTABLE EXCESS RISK ☐	UNACCEPTABLE EXCESS RISK ☐	
COMMENTS : Dr ☐☐☐ Nurse☐☐☐ Other ☐☐☐ (please initial) Signature: ……..				

NURSES CHECKLIST FOR NEW PATIENTS COUNSELLING

EXPLANATIONS TO PATIENTS		NPSA AUDIT Safety indications for patient starting oral anticoagulation	
Condition / reason for taking anticoagulant YES:☐ NO:☐	Comments:	Has a loading protocol been followed? YES:☐ NO:☐ N/A:☐	Comments:
Duration of treatment YES:☐ NO:☐	Comments:	INR in range at discharge? YES:☐ NO:☐ N/A:☐	Comments:
Drug interactions YES:☐ NO:☐	Comments:	Was the patient given appropriate info at initiation of therapy? YES:☐ NO:☐ N/A:☐	Comments:
Illness / surgery/ dental procedures / injections/pregnancy YES:☐ NO:☐	Comments:	Were appropriate plans made for follow up at discharge?: YES:☐ NO:☐ N/A:☐	Comments:
Reason for INR test YES:☐ NO:☐	Comments:	Was there bleeding before discharge?: YES:☐ NO:☐ N/A:☐	Comments:
Alcohol / diet YES:☐ NO:☐	Comments:	Incomplete info on referral?: YES:☐ NO:☐ N/A:☐	Comments:
Risk factors YES:☐ NO:☐	Comments:	INR on discharge > 5 YES:☐ NO:☐ N/A:☐	Comments:

WRITTEN INFORMATION TO PATIENT:		PATIENT / CARER UNDERSTANDING:	RELATIVES / CARERS CONTACT DETAILS:
Disease handout YES:☐ NO:☐		GOOD ☐	
Yellow book /pack YES:☐ NO:☐		ADEQUATE ☐	
Fragmin handout YES:☐ NO:☐		POOR ☐	
Clinic info YES:☐ NO:☐	Further comments:		

INR ……. DOSE …… DATE STARTED …… RECALL ……

SIGNED (NURSE)/PHARMACIST…… DATE:……

I have attended and understood. I will take the tablets as instructed. I will inform the clinic if I stop my warfarin or move away from the area.

Patient's signature…… Date……..

Appendix 4: Anticoagulation – Patient Self-testing Protocol

See Guideline 831 and letter to GP (overleaf) confirming completion of training

DEPARTMENT OF HAEMATOLOGY
ANTICOAGULATION SERVICE – WARFARIN CLINIC

Wycombe Hospital
Queen Alexandra Road
High Wycombe
Buckinghamshire
HP11 2TT
Tel: 01494 526 161
www.buckshealthcare.nhs.uk

Wycombe Hospital:
Philippa Cook (Team Leader)
Bernadette Mileham
Jane Harmsworth
Louise Dugdale
Lynne Fearn
Maggie Aldersley
Kathryne Spencer

Clinic: 01494 426270 (Mon - Fri)

Stoke Mandeville Hospital:
Verity Hook (Team Leader)
Lucy McDermott
Jackie Sweeney
Liz Buckland
Beverley Thorne

Clinic: 01296 315510 (Mon - Fri)

Clinical Lead for both sites: Dr Renu Riat

Dear Dr

Diagnosis:

This patient has successfully completed the Anticoagulation Services self-testing training programme (using the Coagucheck patient self-test machine) and they have been assessed as competent to self-test and subsequently signed our completion of training. This portable device is designed for patient use and the INR is measured by the use of 'strips' that have an in built quality control. (If you would like more information on the issues covered in training, these can be found on the Trust's website, Guideline 831.)

Patients are required to sign an agreement to confirm the training has taken place and that, if they require further technical information for them to call Roche technical support hotline or else refer back to the Anticoagulation Services.

To ensure compliance with Clinical Governance, the patient is required to attend hospital for six monthly review. At the review, the patient will be reassessed for competency to continue self-testing and a comparison test will be performed between our analyser and the patient's. You will then receive a copy of this six monthly INR in the usual way on ICE.

If the patient fails to attend for the six monthly review, we will write to you to flag this up as per our DNA protocol. They will self-test at regular intervals and inform the clinic of their INR results. These results will not be available on ICE or the Pathology reporting system, they will be documented in the patients yellow book and stored in the memory system of patient's own Coagucheck. They have agreed not to self-dose and that any changes made to warfarin dose will be made by the Anticoagulation Service or an attending physician in hospital or community.

Please be assured that the patient will be still be monitored by our service. The patient should record all INR results in the yellow Anticoagulation Book. If the INR is outside the patient's therapeutic range*, the patient should contact the Anticoagulation Service for further instructions.

I hope this letter has clarified the service, but please do not hesitate to contact the team if you require any further information.

We are able to provide test strips and lancets for testing, patient can request new supplies at clinic comparisons or by ringing our service.

Yours etc

Cc to patient

Appendix 5: Pathway for Access to Phlebotomy Services

If patient requires a venous sample and testing:

1. Complete request form – to be provided initially by BHT.
2. Give completed form to patient and direct to nearest available service:

Location	Address	Tel No	Service Opening Hours
Weekday Services			
Phlebotomy Clinic Wycombe Hospital, ground floor	Wycombe Hospital Queen Alexandra Road High Wycombe Bucks HP11 2TT	01494 425234	9am – 3:30pm Mon-Fri (open access), 8:30am – 11am (appointments bookable)
Phlebotomy Clinic Amersham Hospital	Whielden Street Amersham Buckinghamshire HP7 0JD	01494 424244	8.30am – 3pm Mon – Fri, drop-in
Phlebotomy Clinic Stoke Mandeville Hospital	Mandeville Road Aylesbury Bucks HP21 8AL	01296 315591	9:15am– 4:45pm
Out of Hours Services			
A&E Stoke Mandeville Hospital	Mandeville Road Aylesbury Bucks HP21 8AL	01296 315591	Evening, weekends and emergency contact for out-of-hours

Appendix 6: Oral Anticoagulation Clinics Provided by BHT

Location	Address	Tel No	Service Opening Hours
Amersham Hospital, Outpatients Department	Whielden Street Amersham Buckinghamshire HP7 0JD	01494 426270	Monday, Wednesday and Friday 9am – 1pm New patients as arranged Monday/Friday afternoon
Chalfonts and Gerrards Cross Hospital	Hampden Road Chalfont St Peter Buckinghamshire SL9 9DR	01494 426270	Tuesday 8.30am – 12.30pm
Chinnor	Cross Keys Practice Church Road Chinnor Oxon OX39 4PG	01494 426270	Tuesday 12.30am – 12.55pm
Highfield Surgery, Hazlemere	32 Highfield Way Hazlemere High Wycombe Buckinghamshire HP15 7UW	01494 426270	Every other Friday 9am – 11:30am
Hughenden Valley Surgery	Valley Road Hughenden High Wycombe Buckinghamshire HP14 4LG	01296 315510	Alternate Fridays 9.30am – 12.30pm
Ivers Medical Practice (NOAC clinic led)	High Street Iver Bucks SL0 9NU	01494 425590	Thursday 9am – 11.30am
John Hampden Surgery, Prestwood	97 High Street Prestwood Buckinghamshire HP16 9EU	01296 315510	Alternate Fridays 9.30am–11.55am
Marlow Health Centre, Glade Road	Victoria Rd Marlow Buckinghamshire SL7 1DJ	01494 426270	Monday and Wednesday 9am – 1pm
Orchard Surgery, Bourne End	Station Road Bourne End Buckinghamshire SL8 5QE	01494 426270	Wednesday 9am – 12pm
Princes Risborough, Cross Keys Surgery (held at Lincoln House Princes Risborough)	60 High Street Princes Risborough Buckinghamshire HP27 0AX	01494 426270	Tuesday 8.30am – 11.10am
Southmead Surgery (NOAC clinic led)	Blackpond Lane Farnham Common Buckinghamshire SL2 3ER	01494 425590	Wednesday 9am – 11.30am
Stokenchurch Medical Centre	Oxford Road Stokenchurch Buckinghamshire HP14 3SX	01494 426270	Alternate Friday 9am – 11.30am

Location	Address	Tel No	Service Opening Hours
Stoke Mandeville Hospital, Cancer Care and Haematology Unit	Mandeville Road Aylesbury Buckinghamshire HP21 8AL	01296 315510	Tuesday 9am – 4pm Wednesday 2pm – 4pm Thursday 9am – 4pm New patients as arranged Monday/Friday afternoon
Threeways Surgery (NOAC clinic led)	Pennylets Green, Stoke Poges, Buckinghamshire SL2 4AZ	01494 425590	Friday 9am – 11.30am
Wycombe Hospital – Near Point Testing, Ward 3b	Queen Alexandra Road High Wycombe Buckinghamshire HP11 2TT	01494 426270	Tuesday: 1.30 – 3.30pm Thursday: 8am – 12pm, 1.30 – 3.30pm New patients as arranged Monday/Friday afternoon
Wycombe General Hospital – Postal	Queen Alexandra Road High Wycombe Buckinghamshire HP11 2TT	01494 426270	Monday – Thursday (Venous Samples)

Appendix 7: NPSA Anticoagulant Therapy Work Competencies

a) Initiating anticoagulant therapy
b) Maintaining oral anticoagulant therapy
c) Managing anticoagulants in patients requiring dental surgery
d) Dispensing oral anticoagulants
e) Reviewing the safety and effectiveness of an anticoagulant service

Appendix 8a: Referral Form GP to Oral Anticoagulation Clinic

NHS
Buckinghamshire
Clinical Commissioning Group

Oral Anticoagulation Referral Form
For patients registered with a Buckinghamshire GP Practice requiring treatment with Warfarin

Please complete ALL sections

1. Patient Details			
Title:	First Name:	Surname:	
NHS Number:	Date of Birth:	Gender:	Age:
Address:			
Postcode:	Email:		
Telephone Home:		Mobile:	Other:

2. Referral Details	
Date of Referral:	Form completed by: Referring GP (if form completed on GP's behalf):
Surgery:	National Practice Code:
Address:	Telephone:
Email:	Fax: tel:

3. Patient Eligibility Criteria

IMPORTANT: If the patient meets any of the following criteria below, they must be referred to outpatient haematology services. Patients are suitable for referral to an approved Near Patient Testing (NPT) 'one-stop' oral anticoagulation clinic service ONLY if none of the exclusion criteria below apply.

Please indicate if the patient has/is:

• A condition requiring urgent or rapid anticoagulation	☐ Yes	☐ No
• Aged less than 16 years old	☐ Yes	☐ No
• Active cancer currently (or about to start) invasive chemotherapy	☐ Yes	☐ No
• Cancer associated VTE requiring low molecular weight heparin (LMWH)	☐ Yes	☐ No
• Pregnant or up to 6 weeks postpartum	☐ Yes	☐ No
• On dialysis	☐ Yes	☐ No
• Antiphospholipid syndrome not satisfactorily monitored using NPT equipment	☐ Yes	☐ No
• Requiring initiation or switching to an oral anticoagulant drug other than Warfarin	☐ Yes	☐ No

4. Contra-indications to Oral Anticoagulation with Warfarin

☐ **Tick here to confirm that <u>none</u> of the exclusion criteria below apply to this patient and that they are suitable for referral to anticoagulation clinic in primary care.**

- Known large oesophageal varices
- Significant thrombocytopenia (platelet count <50 x 10^9/L)
- Acute gastro-intestinal bleed within last 3 months or major extracranial bleed within the last 6 months
  where the cause has been identified or treated
- Decompensated liver disease or deranged baseline clotting screen (INR>1.4)
- Previous history intracranial bleed
- Dementia or marked cognitive impairment with poor medicines compliance & no access to carer support
- Chronic alcohol abuse associated with binge drinking

5. Reason for Anticoagulation

State the clinical indication for anticoagulation:

☐ Atrial Fibrillation (AF) ☐ Atrial Flutter

☐ Mitral MVR ☐ Aortic MVR ☐ Dilated cardiomyopathy

☐ Isolated calf vein DVT ☐ Proximal DVT / PE* (provoked) ☐ Proximal DVT / PE* (unprovoked)

☐ Other indication, please state:

If indication is for AF, is patient being considered for a cardioversion / cardiac ablation? ☐ Yes ☐ No

** Delete as appropriate*

IMPORTANT: Patients can only be referred for initiation of Warfarin if for atrial fibrillation or atrial flutter.
In all other cases patients should only be referred once they have been initiated on treatment with Warfarin.

For patients who have atrial fibrillation, please calculate CHA_2DS_2-VASc score:

Female Gender	1 point	☐		
Aged 65 - 74	1 point	☐	2 points	Aged 75 or older
		or ☐		
History of Congestive Heart Failure	1 point	☐		
History of Hypertension	1 point	☐		
History of Diabetes	1 point	☐		
History of Vascular Disease	1 point	☐		
		☐	2 points	History of Stroke, TIA or Thromboembolism

Total CHA_2DS_2-VASc score: /9

6. Target INR required

The usual target INR for patients with atrial fibrillation is 2.5:

☐ Target INR of 2.5 (range 2.0-3.0)

☐ Target INR of 3.0 (range 2.5-3.5)

☐ Target INR of 3.5 (range 3.0-4.0)

☐ Other target INR required*, please state Target INR = and give:

Reason*:

**Please indicate reason and provide any supporting information if target INR differs from current BCSH recommendations.*

7. Proposed Duration of Therapy

Indicate duration of therapy required:

☐ 6 weeks ☐ 3 months ☐ 6 months ☐ Long term

☐ Other, please state Duration: **weeks** and Treatment stop date:

8. Current Anticoagulation Status

Indicate current anticoagulation status.

Please note that patients who were usually under the care of a hospital anticoagulation service prior to admission should be referred back to the hospital service.

☐ Not currently on anticoagulation - requires initiation

☐ Existing patient already stabilised on Warfarin*

* For existing patients please state current Warfarin dose and date when next routine INR appointment due if known:

Current Warfarin dose: **Next INR follow-up due date:**

IMPORTANT: Patients should be advised to continue attending their existing service provider for INR monitoring until contacted and arranged to be seen by new service provider.

9. Current Antiplatelet Therapy

Please indicate below if the patient is on concomitant aspirin or other platelet therapy and if this can be stopped upon initiation of Warfarin.

IMPORTANT: Patients receiving an antiplatelet as primary prophylaxis for CVD, peripheral arterial disease, second prophylaxis for stable ischaemic heart disease or previous ischaemic stroke should stop the antiplatelet once Warfarin is commenced (Grade 1B evidence).

Is the patient currently taking aspirin, clopidogrel or other antiplatelet therapy?

☐ No - go to Section 10

☐ Yes, please state Antiplatelet: and Indication:

Is aspirin / clopidogrel* to be stopped on initiation of Warfarin?

☐ Yes ☐ No

If no, is aspirin / clopidogrel* to be stopped at a future date?

☐ Yes, please give Date:

☐ No, please give Reason:

** delete as appropriate*

10. Further Patient Information

Please provide a patient summary / supporting information which details:

- Allergies; current and past medical history; current repeat medication

Merge Allergies, Problems, Medical History and Medication tables here

- Latest blood pressure reading (must be within the last 3 months)

Merge latest blood pressure here with date and value

- Latest blood tests, i.e. FBC, UEs, LFTs including clotting screen (must be within last 3 months)

Full blood count

Merge latest FBC here - date and additional text

Percentage basophils:	Merge value & units	Basophil count:
Percentage eosinophils:		Eosinophil count:
Percentage monocytes:		Monocyte count:
Percentage lymphocytes:		Lymphocyte count:
Percentage neutrophils:		Neutrophil count:

Red blood cell distribution width:
Mean corpuscular haemoglobin concentration (MCHC):
Mean corpuscular haemoglobin (MCH):
Mean corpuscular volume (MCV):
Haematocrit:
Red blood cell (RBC) count:
Platelet count:
Total white cell count:
Haemoglobin estimation:

Urea & Electrolytes

Merge latest U&E here - date and additional text

GFR calculated abbreviated MDRD:
Plasma urea level:
Serum creatinine:
Plasma bicarbonate level:
Plasma potassium level:
Plasma sodium level:

Liver Function Test

Merge latest LFT here - date and additional text

Serum albumin:
Serum alkaline phosphatase:
Serum alanine aminotransferase level:
Serum total bilirubin level:
Plasma alkaline phosphatase level:
Plasma total bilirubin level:
Plasma globulin level:
Plasma albumin level:
Plasma total protein:

INR

Merge latest INR here - date and additional text

Clotting screening test:	Merge additional text only
APTT:	
Fibrinogen level:	
Thrombin time:	
Prothrombin time:	
International normalised ratio:	

IMPORTANT: Blood pressure & blood test results MUST be NO MORE than 3 months old. Referrals cannot be accepted without this information.

11. Additional patient Needs

Patients may be contacted by telephone or letter and an appointment made. Please indicate if they are housebound or have learning, cognitive, communication or other difficulties and where known, how best the need can be met.

☐ Housebound - domiciliary visit required
☐ Learning disability
☐ Unable to communicate in English
State preferred language and dialect if translator is required:
☐ Other difficulty with communication
Please describe (e.g. deafness):
Please advise how the service might meet these needs:

Notes to the Referrer - General Information

Patient should be referred to any AQP anticoagulation provider using their published email address for referrals unless they meet the exclusion criteria detailed above in which case they should be referred to the outpatient hospital haematology services in the usual way.

Appendix 8b: Referral Form for DVT/PE NOAC Service

Buckinghamshire Healthcare NHS Trust

REFERRAL FORM FOR DVT/PE NOAC SERVICE

Patient name: DoB: Gender:	GP:
NHS No: Address & Postcode: Tel (daytime): Tel (mobile): Patient requires transport: **Y** **N** Language: Ethnicity:	Practice name: Practice code: Address & Postcode: Tel: Fax:

	Yes	No
1) Is this a new patient? Tick or cross one that applies: ☐ ✓ ☐		
2) Current anticoagulant a) Warfarin/traditional anticoagulant If known % time in range …….. b) NOAC c) LMW heparin, e.g. Fragmin d) Nothing	Which letter applies?	
3) Indication for NOAC for DVT/PE The only agreed indications for rivaroxaban treatment in DVT/PE are listed below; indicate which criteria fits in the box to the right: a) IV drug user b) Alcohol intake quantity or pattern likely to significantly impair INR control c) Medical co-morbidities, instability or polypharmacy likely to significantly impair INR control d) Practical considerations rendering regular attendance for INR checks excessively burdensome e) Psychological or social considerations rendering adherence to variable dosing regimens impractical f) Persistent severe symptoms due to non-resolving thrombus g) Persisting unacceptably poor INR control (TTR <60%, INR >4 x2, or >7 x1, persistent low INR not due to compliance) h) Warfarin intolerance or allergy i) Adverse events whilst taking warfarin	Which letter applies?	

4) Weight	**Date:**	kg
5) Creatinine (ideally within 3 months of referral)	**Date:**	umol/L

6) Patient summary or hospital discharge letter or clinic letter attached detailing allergies, current medication, PMH, recent BP and FBC or insert details below:

a) Allergies	
b) Current medication	
c) Past medical history	
d) BP	Date:
e) FBC	Date:

7) The following may make the patient higher risk for anticoagulation:

Binge drinking		Indicate which and give details and any other relevant information, including bleeding history and any abnormal ALTs/INR:
Poor cognition		
Poor compliance		

Signed ..... (GP) **Print** …… **Date** ……..

Preferred clinic (please circle): Amersham Wycombe Stoke Mandeville

TELEPHONE NUMBER: 01494 425590

For NOAC Clinic use only: **Triaged by ……**

Appendix 8c: Referral Form to NOAC Service for Atrial Fibrillation

Buckinghamshire Healthcare NHS Trust

GP Referral to New Oral Anticoagulant Service at BHNHST
Atrial Fibrillation

Patient name: Sex: DoB:	GP Name:
NHS No:	Address:
Address:	
Postcode:	
Tel (day): Tel (mobile): Patient email:	Postcode:
Patient requires transport: ☐	Practice code:
Patient needs interpreter: ☐ Language: Ethnicity:	Tel:

Reason for referral: …….

On warfarin ☐ **Time in range** **OR warfarin naive** ☐

Renal function info must be supplied:
Date **creatinine** **and weight** **kg**

Known history of poor compliance? **Give details:**

In addition please provide a **Patient Summary** which details:

- Allergies, PMH, current medication and recent past medication, alcohol use if known, recent BP, FBC.
- LFTs and INR (if any reason to suspect may be abnormal from history)

Please ring the scores for your patient:

		Points
C	LVF/LVD dysfunction	1
H	Hypertension	1
A_2	>75 years	2
D	Diabetes mellitus	1
S_2	Prior stroke or TIA	2
V	Vascular disease	1
A	Age 64 – 74	1
Sc	Female	1
	Total	

	Clinical Characteristic	Points
H	Hypertension	1
A	Renal or LFTs abnormal	1 or 2
S	Stroke	1
B	Bleeding	1
L	Labile INRs	1
E	>65 years	1
D	Drugs or alcohol >8 U/week	1 or 2
	Total	

Signed..... (GP) Print…… Date……

Preferred clinic: Amersham Wycombe Stoke Mandeville
(please circle)

TELEPHONE NUMBER: 01494 425590.

Appendix 9: Patient Information Leaflets

a) Compression stockings information
b) What you should know about your warfarin tablets
c) Deep vein thrombosis
d) Domiciliary visits for warfarin clinic patients
e) Warfarin clinic and anticoagulation department