

Pan London framework for adult patients who self-monitor their INR

Rationale

This document aims to outline the process for delivering self-monitoring of International Normalisation Ratio (INR) in clinical practice. It is intended to guide commissioners in developing local service specifications for anticoagulant service providers delivering patient self-monitoring of INR. The document was initially developed by the South London Cardiovascular Medicines Working Group but has been ratified by the pan London Atrial Fibrillation (AF) group for use across London.

Aims

This document aims to ensure patients who are self-monitoring their INR are appropriately selected, trained and supported throughout treatment, and that governance arrangements are in place between the patient, GP and anticoagulant service provider to deliver a safe, effective and consistent service.

Introduction

Coagulometers are used to monitor blood clotting (INR) in people taking long term oral anticoagulation with vitamin K Antagonists (VKAs), such as warfarin to reduce their risk of blood clots. These tests allow people who are taking anticoagulant drugs to monitor blood clotting themselves. Self-monitoring in this way is an alternative to venous testing, offering more flexibility of INR monitoring.

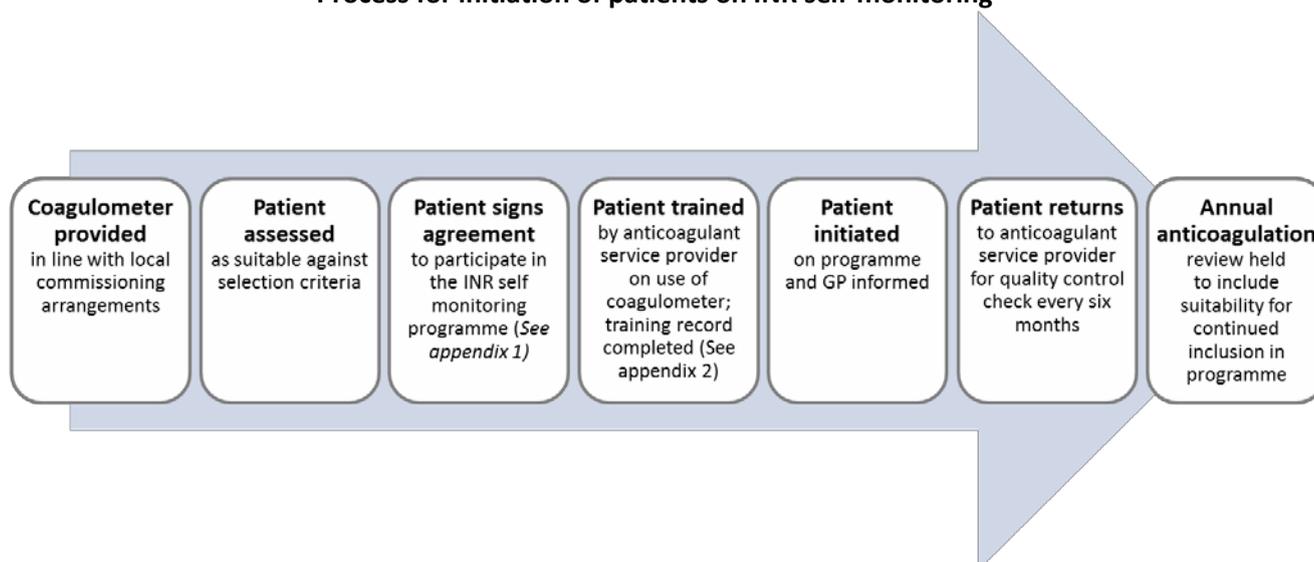
Atrial fibrillation or heart valve disease

The National Institute for Health and Care Excellence (NICE) recommends coagulometers for self-monitoring by people taking long term anticoagulant therapy who have AF or heart valve disease, according to their preference and ability to effectively use this type of monitoring¹.

Venous thromboembolism

Self-monitoring should not routinely be offered to patients receiving fixed duration or short term oral anticoagulation with VKAs for the treatment and secondary prevention of venous thromboembolism (VTE), as the evidence is unclear and it is not cost effective². Although not specifically approved by NICE, those receiving long term (indefinite) secondary prevention of VTE with VKAs may be suitable for a self-monitoring programme.

Process for initiation of patients on INR self-monitoring



The patient is responsible for self-monitoring their INR using capillary sampling using a coagulometer, such as the [CoaguChek XS](#). (**Note:** As of the date of this publication, the CoaguChek XS system is the only NICE-approved coagulometer in the UK.) It remains the responsibility of the anticoagulant service provider with which the patient is registered to provide advice on dosing and frequency of testing. Referrals for self-monitoring will be accepted from patients and healthcare professionals.

In order to participate in self-monitoring the patient must sign the agreement to participate in self-monitoring of INR, and meet the following criteria.

Criteria for selection of patients suitable for self-monitoring

Patients or their nominated carer must:

1. Be orientated and have the mental capacity to manage self-monitoring.
2. Be on long term anticoagulation for atrial fibrillation, heart valve disease or other indication for long term anticoagulation at the discretion of the anticoagulant service provider.
3. Have the manual dexterity and physical capability to operate the coagulometer and components, and adequate eyesight to see the display screen.
4. Have acceptable basic knowledge of what warfarin or similar anticoagulant does and have received initial anticoagulation counselling from the anticoagulant service provider.
5. Understand the self-monitoring protocol and have signed the written agreement to self-monitor (*see Appendix 1*).
6. Be contactable by phone and/or email, as preferred.
7. Be given training in the use of the coagulometer by the anticoagulant service provider and be deemed competent by the trainer (*see Appendix 2*).
8. Be adherent to anticoagulant therapy.

Caution

Patients for whom INR self-monitoring may not be suitable are those at risk of over coagulation or bleeding, or those having problems adhering to treatment. Intravenous drug users, and people with hepatitis B, hepatitis C, or HIV may be referred to a specialist clinic according to local arrangements¹.

Exclusion

Patients with hemochromatosis are unlikely to be suitable.

Initiating patients on self-monitoring of INR

Patients or their nominated carer must:

- Receive written, verbal and visual training on the use of the coagulometer from the anticoagulant service provider and be deemed competent in the use of the machine by the trainer (*see Appendix 2*).
- Sign a written agreement (*see Appendix 1*) to participate in the self-monitoring of INR programme which sets out the responsibilities of the patient/ carer and service provider.
- Depending on local commissioning arrangements, be provided with, or purchase, an approved coagulometer, seeking advice from their local anticoagulant service provider and register with the manufacturer to receive any future quality and safety alerts on the device.
- Check the machine for accuracy by cross checking the results of the first and second INR tests against the results of a venous sample from the anticoagulant service provider, and then six monthly checks throughout treatment.
- Be aware of who to contact at the anticoagulant service provider in the event of any problems or concerns.
- Forward the relevant information to their GP, including a copy of the patient / carer assessment for suitability for self-monitoring of INR, the training record and the protocol for self-monitoring. Where necessary, the patient will be supplied with a customs letter for travel purposes.

Patient / carer training guidelines

- The patient will not commence self-monitoring until they are assessed as competent and have completed the written agreement (*see Appendix 1*).
- Initial patient / carer training must be provided by a trained individual who is competent in the use of the coagulometer and authorised to train in accordance with this policy by the responsible anticoagulant service provider.
- Training will incorporate the theory and practice of self-monitoring. The training framework will be used to teach the patient / carer to self-monitor, and the signed record of training given should be completed

(see Appendix 2). The patient will receive a photocopy for their records. A copy will also be sent to the patient's GP and the original copy will be kept in the patient's medical record.

- Some patients may not demonstrate sufficient competency in the training criteria and may have to be excluded from the self-monitoring programme.
- Once initiated on self-monitoring, the results from the patient's own coagulometer must be compared with the results from the hospital laboratory.
- At initiation of self-monitoring, a venous sample or a professional point of care coagulometer should be used as a comparison to the patient's, (subject to external quality assurance) for a minimum of the first two weekly INR readings. This is to ensure accuracy and reliability of results and allow an assessment of the patient's ability to self-monitor. The results must be within the defined tolerance limits (see *Quality Assurance section*). The patient will need to attend the anticoagulant service provider to allow a direct comparison of results to be made. Clinical discretion should be used to determine if a venous sample is preferred for comparison based on the patient's clinical characteristics.

Procedure for patient self-monitoring

- The patient / carer should perform INR self-monitoring only on the day agreed with the anticoagulant service provider.
- The patient / carer should contact the anticoagulant service provider with the INR result at the agreed date / time and in the manner agreed (eg email, telephone, text).
- An INR should not be self-monitored at intervals other than recommended by the anticoagulant monitoring service provider. If the patient / carer believes there is a new reason to increase the frequency of INR testing (eg initiation of new medication), they should contact the service provider for advice in the usual manner.
- Once the patient / carer has communicated the latest INR result as scheduled, the anticoagulant service provider will advise on the following, as defined by the service provider's protocol for managing patients on VKA anticoagulants:
 - Updated VKA anticoagulant dose.
 - Interval until next INR test required.
- The anticoagulant service provider is responsible for the maintenance of treatment records. All patients self-monitoring should continue to receive formal written updates of INR results, VKA doses and recommended next test dates for their records, as defined by the service providers protocol for management of VKA anticoagulated patients and as agreed with the patient / carer.
- The patient / carer should be provided with a method of recording their INR results at the point of testing, such as a National Patient Safety Agency (NPSA) anticoagulant treatment record ("yellow book").
- The patient / carer must continue to inform the anticoagulant service provider, in the usual manner, of any new information that may affect their anticoagulant treatment or any advice pertaining to this, as per the service provider's protocol, such as changes to medication or dietary intake, instances of bleeding, admissions to hospital, episodes of illness or deviations from recommended VKA dose.

Managing out of range INR results or episodes of bleeding

- In the event that a self-monitored INR result meets any of the following criteria, a self-monitored INR must be repeated within 5 to 10 minutes and the result provided to the anticoagulant service provider immediately (or as soon as is practicably possible). Repeat samples must be taken from a different, clean finger using a new lancet and testing strip if:
 - $INR < 2$
 - $INR > 5$
 - Result is unrecordable or displays an errorThe anticoagulant service provider will then provide advice in accordance with their protocol. This may include recalling the patient for a confirmatory venous INR sample.
- All episodes of bleeding must be reported and managed in the usual manner as defined by the service provider's protocol for management of VKA-anticoagulated patients.

Quality assurance

- Coagulometers have internal (on board and automated) quality control.
- The anticoagulant service provider will provide an external quality assurance programme for the patient's own coagulometer.
- Comparative venous INR samples, taken within five minutes of a self-tested INR sample:
 - For a minimum of two weekly INRs at initiation/training of the self-monitoring programme.
 - At a minimum of once every six months throughout treatment
- The INR results from the coagulometer and the clinic sample should be within 0.5 of each other 3,4. If the results are more than 0.5 apart, then the patient should be suspended from the self-monitoring programme until any issues with the equipment or technique have been resolved.
- Follow up appointments for 6-monthly venous INR checks should be made and communicated to the patient by the anticoagulant service provider.
- All patients must receive annual anticoagulant review, including review of their coagulometer results (comparative testing as above) and competency assessment.

Maintenance of patient's own coagulometer

- The patient / carer is responsible for general maintenance of the machine.
- The booklet supplied with the machine should be referred to for care advice. If problems are experienced with the machine, the patient / carer should stop using the machine, contact the manufacturer for advice and inform the anticoagulant service provider. The patient will need to revert to monitoring of INR at the anticoagulation clinic until the issues with the coagulometer are rectified.
- The patient / carer is responsible for ensuring they request sufficient supplies of strips and lancets and for ensuring that any test strips used are within expiry date. The patient / carer should contact the anticoagulant service provider for further supplies where necessary.
- The patient / carer is responsible for ensuring that the device, test strips, lancets and ancillaries are still suitable for use, including within their expiry date and stored appropriately according to the manufacturer's requirements.

Disposal of waste and equipment

- The patient / carer must dispose of needles and other contaminated material safely in a sharps bin. They will be advised how to do so by the anticoagulant service provider.
- Sharps bins will be supplied by the anticoagulant service provider, and should be disposed of in accordance to local arrangements.

Patient / carer responsibilities

- The patient / carer will provide their contact details (telephone and address, email address), including any changes to the details of their registered GP to the anticoagulant service provider supporting them.
- The patient / carer will adhere to the principles laid out in the self-monitoring programme agreement (*see Appendix 2*), including (but not limited to) the training, device/ancillary maintenance requirements, anticoagulant dosing instructions and monitoring frequency as advised by the anticoagulant service provider. Failure to adhere to the agreement may result in withdrawal from the programme.

GP notification and responsibilities

- When the patient / carer has completed the relevant training programme, the anticoagulant service provider will inform the GP that the patient is transferring to the self-monitoring of INR programme with copies of the training record (*see Appendix 2*) and signed patient agreement (*see Appendix 1*). The GP should document 'self-monitoring of INR' on the patient health record and record the relevant read code (for EMIS: 66QE and VISION: 66QE.00).
- The GP will be informed if the patient is withdrawn from the self-monitoring programme (for example, due to failure to comply with the monitoring schedule or not attending quality control checks). The patient will be advised to re-attend the usual anticoagulant service provider for ongoing management.
- The GP will be sent a letter from the anticoagulant service provider detailing the patient's status on the programme on an annual basis.

- As for all patients on anticoagulants requiring INR monitoring, the GP should check the INR control before prescribing ongoing supplies of the anticoagulant by reviewing results online or checking the oral anticoagulant dosing yellow book or yellow slip. Any concerns should be brought to the attention of the anticoagulation service provider as soon as practicably possible.
- The GP can contact the anticoagulant service provider at any time should they have any problems or concerns regarding the self-monitoring of INR programme for a specific patient.

Anticoagulant service provider responsibilities

- The anticoagulant service provider will be contactable by patients on the self-monitoring programme during the service provider's defined operational hours.
- The anticoagulant service provider will maintain a register of all patients on the self-monitoring of INR programme. Typically this will be maintained on the service provider's anticoagulant management software.
- The anticoagulant service provider is responsible for providing advice on the choice of coagulometer the patient should purchase or receive, as per local arrangements.
- The anticoagulant service provider is responsible for supplying the necessary INR test strips, appropriate lancets and sharps bin to the patient / carer.
- The anticoagulant service provider is responsible for providing advice on VKA dosing and frequency of INR testing. Any out of range INRs should be managed in line with the service provider's anticoagulant management protocol(s).
- All events or decisions regarding management should be recorded on the patient's electronic record held by the anticoagulant service provider.
- The anticoagulant service provider will review the ongoing suitability of each patient for the self-monitoring programme on an annual basis and update the patient's GP by letter.
- If a patient on the self-monitoring programme does not submit an INR reading on the scheduled date, the anticoagulant service provider will manage this in accordance with the "did not attend" (DNA) procedures defined in the service provider's anticoagulant management protocols. Failure to adhere to the schedule for INR testing breaches the self-monitoring programme agreement (*see Appendix 1*). The service provider may then withdraw the patient from the self-monitoring programme, at their discretion. The service provider is responsible for transferring the patient to an alternative method of INR monitoring (eg clinic/phlebotomy services).

References

1. National Institute for Health and Care Excellence (2014). Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguCheck XS system and the INRatio 2 PT/INR monitor). Diagnostic Guideline . London: NICE. <https://www.nice.org.uk/guidance/dg14>
2. National Institute for Health and Care Excellence (2012). Venous thromboembolic diseases: diagnosis, management and thrombophilia testing. Clinical guideline 144. London: NICE_ <https://www.nice.org.uk/guidance/cg144/chapter/recommendations>
3. Fitzmaurice DA., Gardiner C, Kitchen S, *et al*. An evidence-based review and guidelines for patient self-monitoring and management of oral anticoagulation. British J Haematology 2005;131(2):156-165_ <http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2141.2005.05739.x/full>
4. Jennings I, Kitchen D, Keeling D. *et al*. Patient self-monitoring and self-management of oral anticoagulation with vitamin K antagonist: guidance from the British Committee for standards in haematology. British Journal of Haematology 2014;167:600-607._ <http://onlinelibrary.wiley.com/doi/10.1111/bjh.13070/full>

Appendix 1

Patient agreement to participate in the INR self-monitoring programme

Patient name: _____ **Date of birth:** _____

NHS number: _____

Anticoagulant service provider: _____

I confirm the following and agree to participate in the INR self-monitoring programme on the following basis:

- ┘ I have purchased a coagulometer as advised by the anticoagulant service provider and this machine has had an initial quality control check with my anticoagulant service provider.
- ┘ I have completed training on the use of the coagulometer.
- ┘ I understand that maintenance of my coagulometer is my responsibility.
- ┘ I understand that it is my responsibility to arrange for supplies of test strips, lancets, and sharps containers from my anticoagulant service provider should I run out of supplies in between visits.
- ┘ I understand that it is my responsibility to dispose of sharps and contaminated waste responsibly and in line with local arrangements.
- ┘ I will inform the anticoagulant service provider if I move out of area and / or change my GP.
- ┘ I will keep all clinic appointments as requested and submit my machine for cross checking at six monthly appointments.
- ┘ I (or my carer where relevant) will undergo an annual review to assess my capability / suitability to remain on the self-monitoring of INR programme.
- ┘ I will only test my INR at the agreed time and date and will accurately inform my anticoagulant service provider of the result and act on the advice given.
- ┘ I will record all INR test results and any dose changes in my yellow anticoagulant book.
- ┘ I will repeat my INR if the initial test result is less than 2 or greater than 5.0 and, if the second result is outside these parameters, I will contact the anticoagulant service provider and follow the advice given.
- ┘ If I experience unexpected bleeding or bruising I will contact my anticoagulant service provider and / or GP.
- ┘ I will inform the anticoagulant clinic and GP of dates I intend to travel abroad.
- ┘ I will contact my anticoagulant service provider and GP if I decide to stop self-monitoring of INR.
- ┘ I will inform my anticoagulant service provider of changes to medication, diet, alcohol, herbal remedies, missed anticoagulant doses, changes in lifestyle, dental or surgical procedures, admissions to hospital, interruptions to warfarin treatment if unwell or have diarrhoea or vomiting.
- ┘ I will provide my anticoagulant service provider with my up to date contact details.
- ┘ **I am aware that if I fail to follow this agreement I will be withdrawn from the INR self-monitoring programme and that my GP will be informed of my withdrawal by the anticoagulant service provider.**
- ┘ **I am also aware that I can be withdrawn from the INR self-monitoring programme if it is deemed in my best interest due to persistent unstable INR readings.**

Patient signature: _____ Carer signature (if required): _____

Provider name: _____ Provider signature: _____

Date agreed: _____

Copy to GP, patient, notes and electronic patient record.

Appendix 2

Record of training on the coagulometer

Patient name: _____ Carer name (if required): _____

NHS number: _____

Trainer: _____

Date: _____

The training session is being carried out to ensure the correct use of the coagulometer. Please check off boxes to confirm the following information has been given, and sign to confirm this:

Criteria	✓
Coagulometer set up	
Installing batteries	
Display check	
Date format / setting	
Time format / setting	
Set test measurement	
Beep tone	
Therapeutic range	
Test strips	
Storage conditions	
Handling test strip	
Calibration code chip	
Onboard quality	
Sample dosing area	

Criteria	✓
Performing a test	
Switch meter on	
Check screen	
Insertion of test strip	
Confirm code lot	
Strip warming	
Operation of lancet device	
Device components	
Removal of protective cap	
Insertion of lancet	
Priming device	
Depth setting	
Firing lancet	
Ejecting lancet	

Criteria	✓
Obtaining a finger prick sample	
Hand washing	
Sites for taking	
Time limits	
Sampling problems	
Recording results	
Anticoagulation record	
Memory	
Retrieving saved results	
Maintenance / troubleshooting	
Cleaning meter	
Common error codes	
Technical support	
<i>To be secured from manufacturer</i>	

I confirm that I have received the information on the above criteria from the above named trainer. I confirm that I should still read the user manual accompanying my coagulometer in conjunction with this training. If I require any further technical information I will ring the manufacturer of the coagulometer or contact the anticoagulant service provider.

Patient signature: _____ Carer signature (if required): _____

Trainer signature: _____

Date completed: _____