

The use of self-test INR Machines and self-management of warfarin in BNSSG – Position Statement

Prescribers should satisfy themselves that a patient is suitable for INR self-testing or monitoring and documented procedures are in place for follow-up.

Introduction

INR (International Normalised Ratio) monitoring is a vital part of warfarin treatment. The preferred option for most patients is to have their INR checked in the surgery/anticoagulation INR clinic, followed by advice on dose changes if necessary.

- In Bristol Venous INR tests are taken at the GP surgery and INR monitoring is provided by the anticoagulation clinic at UHBW/NBT
- In North Somerset INR monitoring is undertaken by the GP using INR Star
- In South Gloucestershire Venous INR tests are taken at the GP surgery and INR monitoring is provided by the anticoagulation clinic at NBT

N.B. Paediatric patients across BNSSG (and across the Southwest) are managed by the Paediatric Cardiac Nurse Specialists, based at Bristol Children's Hospital (BCH).

A small number of patients taking warfarin may request to test their INR level themselves at home using an INR machine/coagulometer (INR machine brands include Coaguchek XS meter or similar devices) and then contact their Anticoagulation Service Provider (i.e. GP surgery or INR/anticoagulation clinic (such as one of the acute hospitals)) for dosage advice that may be needed (*self-testing*). There is evidence that self-testing can lead to good INR control in patients who are motivated and well trained.

A move to self-testing remains the exception rather than routine practice in BNSSG.

The INR machine/coagulometer comprises of a meter and specifically designed test strips that can analyse the blood sample and calculate the prothrombin time and INR. The testing strips are **nonformulary** in BNSSG and should only really be prescribed on an **individual case by case basis** for those patients who their GP and INR/anticoagulation clinic feel that self-checking may be clinically appropriate. See below those circumstances where it would be deemed clinically appropriate for the patient to self-test or self-monitor, where there is a clinician that can interpret the results, where patients can seek help when needed and can confirm when the INR machine needs to be calibrated. GPs prescribing the test strips must check that they are compatible with the meter being used by the patient.

In order to consider self-monitoring or self-testing, the patient needs to discuss the process and associated practical issues in detail with their GP practice and anticoagulation clinic <u>before</u> the patient purchases a machine and <u>before</u> any anticoagulation testing strips are prescribed.

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Useful contact details for further advice:

- UHBW Anticoagulant Clinic 0117 3423874 (or ending 3568 for HCP only) or warfarin.helpline@uhbw.nhs.uk
- North Bristol NHS Trust Anticoagulant clinic 0117 4148405 (additional mobile for HCPs only 07718 575 471) or email ams@nbt.nhs.uk

Glossary

- Self-testing refers to the user doing the INR test themselves and then contacting their healthcare professional with the reading for advice on any change to the dosage of the anticoagulant that may be needed.
- **Self-managing** refers to the user doing the INR test themselves and then self-adjusting the dosage of their anticoagulant medication.
- Self-monitoring a combination of these methods of care (self-testing and self-managing).

Recommended Actions

The clinicians managing the patient's anticoagulation should have a written/documented **agreement** drafted (INR Self-testing & Self-monitoring: Patient & Anticoagulation Service Provider Agreement Form) between the Anticoagulation Service Provider and the patient regarding initiation of INR self-monitoring. The patient will need to have a clear understanding of what they need to do in relation to self-testing or self-monitoring and responsibilities of the clinicians (GP or anticoagulation team) involved in this process.

It may be more practical for patients to discuss and sign the contract with their GP practice e.g. when they go to the GP for their venous INR to have their INR machine/meter calibrated/quality control checked.

The following questions should be answered and clearly documented in the GP practice patient notes.

Patient considerations:

- Why is the patient requesting self-monitoring or self-management?
- Is this a valid clinical reason (e.g. long-distance driving/travelling)?
- Can the practice or INR clinic provide support and reviews?
- Is the patient suitable and competent to manage INR self-testing? Patients should have the physical (e.g. good eyesight, dexterous) and mental capacity to undertake INR self-testing and be able to adhere to treatment.
- For those patients at risk of over-anticoagulation, those at risk of bleeding, those new patients with anti- phospholipid syndrome (positive lupus anticoagulant) or with haemochromatosis, these patients must be discussed with Haematology to ascertain potential suitability for INR self-testing or whether venous INRs are best for them.

Information to discuss with patients:

If you and your patient agree that they may monitor their own INR, they must:-

• Purchase the INR machine (coagulometer) and any quality control solutions needed themselves as the machines are **not reimbursable on the NHS**. All warfarinised paediatric patients are

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provided with their own home testing devices whilst in hospital. Some patients may be able to apply for funding from a charity e.g. congenital heart disease patients. Self-testing devices cost from £400 to £800. The consumables i.e. **test strips, lancets** and **sharps bin** can be prescribed on repeat prescription on an FP10 by the patient's GP.

- Calibrate the machine regularly according to the manufacturer's instructions.
- NBT and UHBW warfarin clinics are *currently* unable to do training on the INR machines with patients face to face or virtually, but patients should be provided with information and video links on how to use an INR machine. These can be found on the manufacturer website e.g. <u>Roche website</u> or on YouTube.
- Agree the parameters for testing frequency and approximate number of strips to be used. To avoid over-testing, determine minimum and maximum number of boxes of test strips and lancets required per year. Once weekly is a common frequency for many self-testing patients this frequency may increase in high-risk times or may decrease when their INR is more stable.
- Report their results to GP or anticoagulation clinic at an agreed frequency.
- Have their INR readings cross-checked (a comparison test with a venous INR) at an agreed frequency. The venous and the INR machine reading must be taken within 1 hour of each other. Some anticoagulant clinics may advise these are checked every 6 months, at a time when the INR is stable.
 - $\circ~$ If the INR machine and venous INRs are within 0.5 of each other, the next check can be in a further 6 months
 - $\circ~$ If the difference is > 0.5 of each other a repeat comparison test will be needed in the following few weeks
 - $\circ~$ If >0.5 upon repeating the comparison, the patient will need to speak to the manufacturer of the coagulometer
 - If the results do not agree, you may ask the patient to stop self-monitoring as per the INR Self-testing Agreement Form that they have signed.

Suggested practice Standard Operating Procedure content:

- Has the patient signed the INR Self-testing Agreement Form?
- Is there a protocol in place to ensure monitoring is done appropriately (at the right time with a correctly maintained & calibrated machine)?
- How frequently should they be testing (to avoid over-testing)? Determine minimum and maximum number of boxes of test strips and lancets required per year.
- How should the results be reported?
- Who is going to record the results?
- Who interprets the results and decides dosing?
- How is the dose communicated to patient?
- What machine will be used? (See specific manufacturer info for calibration details, like Coaguchek)

BNSSG ICB Cost Impact

The <u>cost</u> of the Roche Coaguchek XS PT Testing Strips is **£75.80 / 24 strips** (as per July 2024).

References

- 1. CKS Oral Anticoagulation 2020 http://cks.nice.org.uk/anticoagulation-oral#!scenariobasis:40
- Fitzmaurice et al "An evidence-based review and guidelines for patients self-testing and management of oral anticoagulation" <u>http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2141.2005.05739.x/epdf</u>

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3. NICE (DG14) Coaguchek meters available from https://www.nice.org.uk/guidance/dg14

Please also refer to BNSSG DOAC guidelines: <u>https://remedy.bnssgccg.nhs.uk/formulary-adult/local-guidelines/2-</u> cardiovascular-system-guidelines/

For information on the Management of High INRs in the Community see: <u>https://remedy.bnssg.icb.nhs.uk/formulary-adult/local-guidelines/2-cardiovascular-system-guidelines/</u>

For information in relation to accessing vitamin K via the Community Pharmacy Specialist Medicines LES see: <u>https://remedy.bnssg.icb.nhs.uk/formulary-adult/local-guidelines/16-palliative-care-guidelines/</u>