Norfolk and Waveney
Integrated Care Board

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Policy Statement on

Patient Self-Testing of INR for warfarin monitoring

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What is it for?	To ensure warfarin monitoring for those patients who self-test are managed safely in primary care
Evidence base	
Who is it aimed at and which settings?	All Norfolk and Waveney system partner
Consultation	INR anticoagulation transfer group / Prescribing reference group
Impact Assessment:	
Other relevant approved documents	
References:	See document
Monitoring and Evaluation	
Training and competences	
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Policy Statement on Patient Self-Testing of INR for warfarin

International Normalised Ratio (INR) monitoring is a vital part of warfarin treatment. The most common method of monitoring is for patients to have their INR checked and warfarin dosing undertaken by local anticoagulation clinics in primary or secondary care. Within NHS Norfolk and Waveney, there is a small cohort of patients who undertake patient self-testing (PST) of INR monitoring using point-of-care (POC) coagulometer devices.

The NICE diagnostic guidance 14 (DG14) provides an overview of the use of POC coagulometers for patients with atrial fibrillation and heart valve disease.

Definition:

Self-testing refers to a care model in which patients on warfarin, or related vitamin k antagonists, measure their own INR with the result being relayed to a health professional for interpretation and dose adjustment.

Self-management refers to where patients measure their own INR, interpret the results themselves, and adjust their anticoagulation dosage according to the value obtained following an agreed care protocol.

Self-monitoring is where a patient undertakes both self-testing and self-management.

Self-managing or self-monitoring should **NOT** be routinely offered to patients in Norfolk and Waveney ICB due to concerns around lack of clinical oversight.

Not all patients are capable of self-monitoring and some patients find it unnecessary because of high-quality care provided by existing anticoagulation clinics. For carefully selected and successfully trained patients, self-testing is as effective and safe as usual care for long-term oral anticoagulation therapy. Due to the reduced need for face-to-face clinic visits, self-testing may enhance the quality of life for some patients, for example those who are frequently away from home, who are in employment or education, or those who find it difficult to travel to clinics.

Patient self-testing is unlikely to be more cost-effective than the current high-quality care provided by specialised anticoagulation clinics in the UK[1] and we would continue to encourage the vast majority of patients to attend centralised services.

Commissioning statement

1. POC coagulometers are not commissioned by Norfolk and Waveney ICS. Patients expressing a wish to self-monitor will need to fund their own machine (approximate cost £400-£800).

2. Prior to obtaining a machine, patients should be reviewed to ensure they meet the criteria for self-testing.

3. Only portable coagulometers that have undergone acceptable evaluations by an expert body – for example the United Kingdom Medical Devices Agency – should be used for self-testing.

4. Consumables (test strips, lancets and sharps bins) can be prescribed on an FP10 in reasonable quantities. Any patients exceeding the expected usage of test-strips should be reviewed.

5. All patients undertaking self-testing must be appropriately coded to allow recall and audit. The GP practice should undertake an annual audit of all patients self-testing to ensure all criteria is still met.

6. If there are concerns with the patient's ability to self-test, they must be reverted back to usual care of point of care testing within the clinic.

Patient eligibility

7. Only patients with indications for long term warfarin therapy should be considered for self-testing. Generally, patients with short term indications for example, first occurrence of a deep vein thrombosis, would not be suitable for self-testing as it can take 2-3 months before a patient becomes fully accustomed to managing their own treatment[2].

8. Those who may benefit most are those patients who are frequently away from home, are in employment or in education, or find it difficult to travel to clinics.

9. Only patients over the age of 18 are suitable for self-testing and subsequent dosing by primary care.

10. The NICE diagnostic guidance 14 (DG14) states the following criteria should be met before self-testing is considered:

    - the person is both physically and cognitively able to perform the self-monitoring test, or a designated carer is able to do so.

- an adequate supportive educational programme is in place to train the person and/or carers.
- The person's ability to self-test is regularly reviewed.
- The person will have access to appropriately trained healthcare professionals for ongoing advice and support (including if they plan to travel abroad).

11. The following patients are **not** suitable for self-testing
    - Those who fail to attend clinic appointments (unless work, school, or access make it hard to attend clinic, in which case self-testing may be helpful).
    - Those who do not adhere to their dosage instructions.
    - Those who do not wish to do so.

12. Previous stability of INR is not a prerequisite to self-testing, as people with an unstable INR may benefit from the possibility of increased autonomy and frequency of testing.

13. The patient (or their carer) must give informed consent to self-testing, including agreement to record results accurately. An example consent form is included in appendix 1.

14. Patients must agree to report their INR results. This may be via the INRstar Engage app which can be accessed via smart phone, tablet or desktop provided there is an internet connection.

Training and support for patients

15. Prior to commencing INR self-testing, the patient (or carer) must have completed a training package to ensure they are competent to use the machine and have a thorough understanding of warfarin anticoagulation. Training should include:
    - theoretical aspects of anticoagulation management.
    - how to monitor and the frequency of monitoring.
    - interaction between anticoagulants and other medications.
    - influence of diet, alcohol, illness and travel of anticoagulation.
    - recognising and reporting complications, for example bleeding.
    - the target INR for their condition and the importance of maintaining the INR within +/- 0.5 of their target.
    - how to operate the device.
    - how to perform a test, including a quality control test.
    - recording and reporting the results.

16. The manufacturer of the coagulometers devices can provide well-structured training and support materials including via online learning and over the telephone. This training should be reinforced by the appropriate healthcare professional.

17. Those patients using the INRstar Engage must undertake the training on the app. The clinician should review this has been completed.

18. The patient must understand who to contact with their INR readings and how they will be informed of their new warfarin dose. This should ideally via the INRstar Engage app.

19. Where possible, patients should be advised to ensure the INR result is communicated to the GP surgery in the morning to allow adequate time for the health professional to review, dose and communicate any dose changes to the patient.

20. Patients should be encouraged to avoid testing on weekends and bank holidays to avoid delays in communicating dose changes.

21. The patient must have access to an appropriately trained healthcare professional for advice when needed (by telephone, INRstar Engage app or in person). **All** patient contact must be documented in the patient's notes.

22. The patient must have their ability to self-test reviewed at least every 6 months by the responsible clinician. The following points should be discussed and documented:
    - Ability to calibrate the device regularly in accordance with the manufacturer's instructions.
    - Ability of patient (or carer) to use the machine and finger pricking device; consider dexterity and vision.
    - Responsibility for ensuring correct use and correlation of results with those from the laboratory via 6 monthly venous INR tests (or external quality assurance programmes).
    - Agreement in advance what happens if the test results don't correlate e.g. revert to POC testing in the practice.
    - Process of reporting of results and responsibility for dosing.
    - Recording of results and sharing as appropriate.
    - Clinical responsibility remains with the clinician prescribing warfarin even though the patient is self-testing.
    - Correct disposal of waste materials.
    - Results and dosing may be shared with secondary care or out of hours if there is a clinical need, for example the patient is admitted to hospital.

Calibration and Quality Assurance Checks

23. To ensure the device is working correctly, the patient must calibrate the machine via internal quality control checks at regular intervals**.** This should be performed at least once a month or, if testing is less frequent than this, every time the machine is used. It should also be performed with every new box of test strips, if an unusual result is obtained, or there is an unusual occurrence which may affect the result for example dropping the machine.

24. Results of calibration checks should be recorded by the patient along with any issues encountered and must be reviewed at the 6 monthly review.

25. Regular external quality control must be performed to ensure the results are within the expected range. This may be via:
    - Obtaining a contemporaneous venous sample during the 6 month review and sending for laboratory testing.
    - Participating in formal external quality assurance programmes such as UKNEQAS. This service is not commissioned by Norfolk and Waveney NHS.

26. If the external quality control procedure is unsatisfactory on more than one occasion, the patient's technique and device must be assessed by the trained healthcare professional*. If performance in the external quality control procedure is persistently poor, the patient should be withdrawn from the self-testing programme.

* The **trained healthcare professional** responsible for assessing and reviewing patients for self-testing must be fully informed and aware of the National Patient Safety Agency, Patient Safety Alert no 18:

Actions that can make anticoagulation therapy safer – Alert March 2007[4]

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

Point 1 of this document states: Ensure all staff caring for patients on anticoagulation therapy have the necessary work competencies. Any gaps in competence must be addressed through training to ensure that all staff may undertake their duties safely.

All practitioners involved with reviewing patients undertaking self-monitoring must have completed the INRStar online training package and ensure they are competent and maintain these competencies.

† The yellow anticoagulant information book can be obtained electronically here or hard copies ordered here.

REFERENCES:

1. Connock M, Stevens C, Fry-Smith A, Jowett S, Fitzmaurice D, Moore D, et al. Clinical effectiveness and cost-effectiveness of different models of managing long-term oral anticoagulation therapy: a systematic review and economic modeling. Health Technol Assess 2007;11(38).
2. H O'Kane, P Sidhu, Society of Cardiothoracic Surgeons Annual Meeting, Nottingham, 1999
3. NICE Clinical Guideline no. 36: Atrial Fibrillation. www.nice.org.uk/cg36
4. National Patient Safety Agency: Patient Safety Alert no 18; Actions that can make anticoagulant therapy safer. March 2007. www.npsa.nhs.uk/health/alerts.
5. Fitzmaurice D, Murray E. Patient self-testing or management of oral anticoagulation – Discussion Paper. University of Birmingham: (2003).
6. Chelmsford PCT. Policy Statement on Self-Management of Anticoagulation using Warfarin. May 2004

Appendix 1

Self-testing of INR – Patient / Practice agreement (for adaptation by individual practice)

Patient Details	
Name	
Home Address	
Date of Birth	
Telephone Number	
Indication for warfarin	
Therapeutic range	
Target INR	
This is an agreement for self-testing of INR between (Patient named above) and (insert practice name):	
Date:	**Clinician name and role:** **Clinician signature:**

GP practice details	
Address and telephone number	
Suitable times to contact the surgery	
Likely times the surgery will contact the patient about dosing	
Responsible healthcare professional	

Patient agreement	
I have purchased an INR monitor and my GP has agreed to prescribe test strips to enable me to self-test. To ensure my own safety I agree to work in partnership with my GP practice and follow the advice in the **patient responsibilities section**	**Sign and date:**
I have been trained in the use of the instrument by my GP practice or have received training from (please specify)……	**Sign and date:**
If using the INRstar Engage app, I have completed the online training.	**Sign and date:**
I understand how to calibrate my machine and agree to have venous samples at least every 6 months to confirm my machine is working accurately.	**Sign and date:**

Patient Responsibilities:	Please tick
I will repeat any test if the result is less than 2 or greater than 4 (or is reported as < or >). The second result should be reported	
If the INR result is greater than 4.5, I understand that I **MUST** contact my GP practice **immediately.** If outside of opening hours (8am to 6pm) and your machine states greater than 8.0 (or cannot be read), you MUST contact out of hours GP by phoning 111.	
Where possible I will ensure I test in the morning on weekdays to allow dosing on the same day.	
I agree to submit my results via INRstar Engage app (This can be used on a smart phone, tablet or desktop provided it has internet connection).	
I understand that it is my responsibility to submit test results to my GP practice by 1pm and ensure that I am available to receive advice regarding the result and dose via telephone (or app) on the same day.	
I will report any of the following when submitting my INR result: • Any bleeding episodes • Excessive or unexplained bruising • Change I medicines / diet / alcohol intake / herbal remedies • Any missed doses of warfarin • If unwell, any vomiting or diarrhoea. • Recent hospital admission	
I will act on the advice given by my GP practice with regards to dosage and INR testing interval.	
I will record the dosage I am given and the date of my next INR test in my anticoagulant 'Yellow book'.	

I understand the maximum permitted interval for testing is 12 weeks, although this depends upon my INR result so may be more frequent.	
I agree that my results and dose may be shared with the hospital or out of hours if it is clinically appropriate, for example I am admitted to hospital.	
I agree that on occasions, the GP surgery may need to consult with the anticoagulation team at the hospital, for example if I require surgery.	
I will calibrate the machine in accordance to the manufacturer's advice. This is usually once a month or, if testing is less frequent than this, every time the machine is used. It should also be performed with every new box of test strips, if an unusual result is obtained, or there is an unusual occurrence which may affect the result for example dropping the machine	
I will attend the GP practice for review at least every 6 months. This includes having a venous sample to ensure my machine is working correctly I will bring the Yellow Book, INR monitor, calibration results and current test strips to the review appointment.	
I will inform the GP practice if I intend to travel abroad whilst self-testing. I will provide a telephone number and / or email address that I can be contacted on for the duration of my travel or will arrange a suitable time to call for advice.	
I will inform the GP practice if I decide to stop self-testing or move house / GP surgeries.	
I agree to give my GP practice my telephone number (and email if using INRstar Engage app)	
Bleeding For minor bleeding and INR greater than 5.0, I agree to contact my GP practice urgently for advice. For major bleeding, I will dial 999.	
I will store the test strips as advised by the manufacturer. Some may require refrigeration.	
I will replace my machine as advised by the manufacturer.	
I will dispose of all needles in a sharps bin and all other items, including test strips, will be wrapped and disposed of in the usual waste bin. I will return my full sharps bin to the GP practice for disposal.	
I understand it is my responsibility to order tests strips, warfarin tablets and sharps bin in a timely manner.	
I understand if I am no longer deemed to have the ability to self-test (including physical dexterity) or I do not follow this agreement, I will be required to revert to usually method of testing at the GP practice.	

Further information

Self-testing:

In self-testing the patient is responsible for testing their INR. The patient is **not** responsible for dosing of anticoagulation. Anticoagulation dosing remains the responsibility of the GP. The GP will provide advice on dosing and frequency of testing via INRstar. Patient must purchase a NICE recommended INR monitor. Maintenance of the monitor is the responsibility of the patient. The GP will provide prescriptions for test strips, lancets and sharps bins.

Criteria For Accepting Patients To Self-Test:

Patients must be on long term anticoagulation, and have the physical capability to use the machine, including adequate eyesight.

Patients must have a NICE recommended INR monitor, or be willing to purchase one and be competent in its use.

Patients must have a telephone or mobile telephone for contacting the GP practice and for the GP practice to be able to contact them on. If using the INRstar Engage app, patients must also have an email address.

GPs must be willing to prescribe testing strips, lancets and sharps bins.

Patients must sign up to the recommendations within this agreement

Equipment Needed For Self-Testing:

- INR monitor
- Finger pricking device and lancets
- Test strips
- Sharps bin
- Patients must store test strips appropriately. Some test strips require refrigeration.

External Quality Assurance:

At least every 6 months the patient must have a venous blood INR sample taken to compare this result to the result obtained on the patient's machine.

General maintenance of the machine is the responsibility of the patient including appropriate cleaning of the machine and equipment as per manufacturer's instructions. The booklet supplied with the machine should be referred to for advice. If there are problems with the machine then the patient should contact the manufacturer's helpline.

Advice and Support:

The INR test must be done on the advised day, at agreed intervals, and the GP practice informed of the result via the telephone advice line number. The GP will adjust the dose of anticoagulant as appropriate and will inform the patient accordingly.

Patients must report:

- Any bleeding episodes
- Excessive or unexplained bruising
- Changes in medicines/diet/alcohol intake/herbal remedies
- Missed doses of anticoagulation
- If unwell, any vomiting or diarrhoea
- Recent hospital admission

Patients should be prescribed a sharps bin to allow safe disposal of needles and lancets.by the GP practice.

Ending the Agreement:

The patient should inform the GP practice if they intend to move to another area or choose to stop self-testing.

The GP practice will consider this agreement to have finished if the patient fails to comply with the terms of the agreement.

Version	Date	Author	Status	Comment
1.1	Oct 2022	HH, MO Team	Final	New document approved as per ICB Governance process
2.0	Jan 2025	As above	Final	Review date extended to July 2025. Content still current