The NICE diagnostics guidance [DG14] published September 2014 recommends two technologies that enable people on long-term anticoagulation therapy to monitor their blood clotting themselves.

Self-monitoring of coagulation status in adults and children on long-term warfarin therapy who have atrial fibrillation or heart valve disease is recommended as an option if the person prefers this form of testing and the person or their carer is both physically and cognitively able to self-monitor effectively. INR testing for other warfarin indications is not covered by NICE DG14.

The Roche CoaguChek® XS Plus system is used across East Berkshire. Due to clinician experience and familiarity with this system, from a safety and support perspective, patients wishing to self-test are advised to contact the Roche customer care line (telephone 0808 100 7666) in order to purchase a CoaguChek® XS patient self testing system.

What is the difference between self-testing and self-management of anticoagulation?

Self-monitoring can involve either self-testing (where the user performs the INR test themselves and then contacts their health professional for advice on any change to the dosage of anticoagulant that may be required) or self-managing (where the user performs the INR test themselves and then adjusts the dosage of their anticoagulant medication by following an agreed care protocol). The patient is seen by the responsible health professional at agreed intervals to assess INR control and advice.

What are the criteria for accepting patients to self-test/manage?

Suitable patients should be those prescribed warfarin for long-term conditions. Patients must be trained in self-testing or self management of warfarin dosage to a standard acceptable to both the patient and the person with clinical responsibility.

Patient eligibility criteria include sufficient manual dexterity and vision to operate a point of care device (POC) and an assessment of previous treatment adherence, INR control and ability to follow simple instructions. Enthusiasm and personal motivation are, however, as important as physical, visual and cognitive function.

Although contraindications for self monitoring may include previous noncompliance in terms of attendance at clinic or taking of medication, previous INR stability is not necessarily a prerequisite to self testing because unstable patients may benefit from increased autonomy and the possibility of performing the test more frequently.

Who will provide the training?

The manufacturer of the device can provide well-structured training and support materials such as videos via online learning, via a DVD or personalised care over the phone and these can be reinforced by the healthcare professional. Online training is available for both the CoaguChek XS (patient use) and the CoaguChek XS Plus for professional use. People can register and work through the selected training. Each course will include an examination at the end, and upon successful completion, a certificate can be downloaded.
What should the training involve?
If the patient is self-testing, basic training should include a thorough understanding of the device, and an awareness of the effect of diet and medication on warfarin.

If the patient is self-managing, training would also involve understanding how to adjust the warfarin dose by following an agreed care protocol, including when and how to contact the clinician responsible for their care.

How often should the patient see a health professional?
The patient should have a clinical supervisor, such as a practice nurse or GP and have signed a contract to undertake agreed actions (see example in Appendix 1). Follow-up review is agreed on an individual basis, although it is recommended that the patient is seen at least every six months. Once a year the patient should be assessed clinically to ensure he or she is able to undertake self-testing/management in terms of manual dexterity, sight, mental capacity.

What should the patient record?
INR results and dates, quality control results and any problems should be documented accurately. The yellow record book used by anticoagulant clinics can be used by the patient to record INR results and date of next test. Quality control tests and adverse events can be recorded in the comments section.

What internal quality control should the patient perform?
The point of care system has an on-board control built into the test strips; thereby each test automatically receives an internal quality check (IQC) that will provide additional confidence in the INR result. An IQC provided by the manufacturers should be performed and recorded at least every three months, or with every new box of test strips, or if an unusual result is obtained, or there is an unusual occurrence which may affect the result, such as dropping the machine.

What external quality assurance should the patient perform?
Roche recommend the patient comes to the clinic at least once every 6 months for the device to be checked at the clinic. An INR result from a venous sample taken at the practice clinic can be sent to the local laboratory and compared with a capillary sample at the practice using the patient's own system. The INR results should be within 0.5. Alternatively, INR results from the patient POC system can be compared with the result from a quality controlled POC device used in the practice clinic. The INR results should be within 0.5.

How will patients’ self managing know what dose to take?
If patients are self-managing, an agreed algorithm for dosage of warfarin is followed and the clinician responsible contacted for advice if the patient decides to override the algorithm or if the INR result is greater than 5.0. See the dosage chart (see example in Appendix 3) which can be adapted to suit the individual patient.

Who will give the patient advice and support and who is clinically responsible?
Patient advice and support should come from the relevant healthcare professional at the practice. To overcome unnecessary or inappropriate interruptions to practice, a specified weekday and time can be agreed with the patient to give support or advice. The patient's GP is ultimately responsible for their care.

Patients (or their carers) must sign and agree to adhere to the joint care statement (Appendix 1). Competency to perform self-monitoring must be assessed by a trained healthcare professional before a joint care statement can be signed.
How will the CoaguChek testing strips be supplied to the patient?
Later in 2015, practices will obtain test strips direct from Roche. Each test costs £2.84 and each box of 24 test strips costs £68.16 (£133.26/48). These may be supplied to the self-testing patient without the need for a prescription. (When added to prescription, strips may be over ordered by a third party and subject to unnecessary waste.)

Practices must keep a record of supply to self-testing patients in line with good governance. This will also aid practice monitoring of appropriate testing and avoid unnecessary waste. (See an example in appendix 2a & 2b). Practices may also wish to record test strip supplies on the patient electronic records.

How many strips should be supplied to the patient and how often?
Patients within therapeutic range (INR 2-3) will usually need to test no more frequently than every 2 weeks and will require approximately 12 strips every 6 months. The number of strips used since the last appointment should be recorded as part of the review.

Warfarin is a long acting medication, and testing a stable patient more frequently is unnecessary. At the review, if a patient is using many more than 12 strips in one 6 month period they should be reviewed more frequently.

Management of Warfarin Dosage: if patient is self-managing their warfarin, an agreed algorithm for dosage of warfarin is followed and the clinician responsible contacted for advice if patient decided to override algorithm or if the INR result is greater than 5.0 (see Appendix 3). The INR test is performed at a specified weekday and time agreed with the clinician responsible to enable easy access for advice if necessary. All telephone contacts should be recorded in the patient notes. All INR results and dose adjustments must be accurately recorded (together with dates, quality control results and any problems) in the anticoagulant record book provided and be available for the patient review.

Disposal of waste and equipment: Patients to dispose of needles safely in an appropriate container and other contaminated material wrapped up carefully and placed in the usual waste bin. Sharps boxes should be disposed of at point of purchase.

Safety: The trained healthcare professional responsible for assessing and reviewing patients for self-management must be fully informed and aware of the National Patient Safety Agency Alerts concerning anticoagulation, which 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. The NPSA has commissioned e-learning modules on initiating and maintaining anticoagulant therapy which can help practitioners assess their current level of competence and provide training covering knowledge and understanding to promote safe practice. The e-learning modules are available at www.npsa.nhs.uk/health/alerts
How does self-monitoring fit in with patient-centred NHS outcomes?

Not all patients are capable of self-monitoring and some patients may find it unnecessary because of the high-quality care provided by existing anticoagulation clinics. Self-monitoring for all patients is unlikely to be more cost-effective than the current high-quality care provided by specialised anticoagulation clinics and we would encourage the vast majority of patients to attend the centralised services.

However, self management of anticoagulation using warfarin fits into Domain 2 of NHS outcomes framework “Enhancing quality of life for people with long term conditions” where:

- Self-monitoring can improve the quality of patient oral anticoagulation therapy when compared to standard monitoring¹
- Self-monitoring may enhance the quality of life for people who are:
  - Frequently away from home
  - In employment or education
  - Unable to travel to clinics²
- Ensuring that people have a positive experience of care:
  - 77% of people preferred self-monitoring to the usual model of care³
  - Fewer consultations and hospital admissions are required when self-monitoring⁴

The NICE diagnostics guidance [DG14] Key Points

Offering self-monitoring would help to get more patients on anticoagulation medication, improve patients’ INR control and lead to fewer clinic visits and better outcomes.

Apart from the anxiety associated with waiting for the results from an anticoagulation test, the time and cost of attending an anticoagulation clinic can be a significant burden for people on long-term oral anticoagulation therapy and can significantly affect both their working and family life. Because self-monitoring provides almost instant results, self-monitoring can reduce anxiety, provide a sense of control for the patient and remove the need to frequently attend clinics or hospitals.

The option of self testing will benefit patients unwilling/unable to attend practice clinics, those unwilling to try alternative anticoagulants (such as dabigatran, rivaroxaban or apixaban) - particularly people with mechanical heart valves, certain people with renal or liver dysfunction and those taking concurrent drugs that cannot be taken with the non-vitamin K antagonist oral anticoagulants.

Self testing may reduce the frequency of visits to hospital or clinics for patients and enable them to be monitored more regularly. This may improve health outcomes by enabling the dose of therapy to be adjusted more accurately, thereby avoiding adverse events that can result from an over or under dose of long-term vitamin K antagonist therapy, such as stroke and major haemorrhage.

Self-monitoring allows people to visit, or act as a carer for, other family members, without having to worry about attending testing appointments.

Reproduced with kind permission of Professor David Fitzmaurice and Dr Ellen Murray of The National Centre for Anticoagulation Training; Department of Primary care, University of Birmingham

³ Gardiner C et al, Patient self-testing is a reliable and acceptable alternative to laboratory INR monitoring, British Journal of Haematology, 2004
APPENDIX 1: Anticoagulant Patient Self-Monitoring Agreement

Patient name:........................................................................................................................................

Patient address:......................................................................................................................................

Your practice contact is .............................................................who is usually available for advice on

........................................................................ (Day(s)) at ................................... (Time(s))

1) Your regular follow up review will be every……months and you will be responsible for arranging the appointments with
..............................................................................................................................................................

2) INR results and dates, quality control results and any problems will be documented by the patient / carer / clinician (delete as applicable) accurately in the anticoagulant record book provided

3) External quality control will be performed 6 monthly using the following procedure (See Self-Management of Anticoagulation using Warfarin document “What external quality assurance should the patient perform?”)

..............................................................................................................................................................

4) The INR test is performed on........................................ at ...................................................when the clinician responsible is available for advice if necessary

5) If self managing warfarin, the agreed algorithm for dosage of warfarin is followed and

........................................................................................................... contacted for advice if the INR result is greater than 5.0 or if any change from the algorithm is felt necessary.

6) Each supply of test strips will contain 24 strips, will last a stable patient approximately 12 months and are obtained directly from the practice. Patients whose INR results are regularly within range will need to test no more than every 2 weeks because testing a stable patient more frequently is unlikely to provide any additional benefit. The patient will contact .....................................................who will be responsible for arranging and recording the supply. Please allow 48 hours before collection. If you are using many more than 12 strips in one 6 month period you are likely to require a more frequent review.

8) Test strip internal quality control is refrigerated at a temperature between +2 and +8 degrees centigrade (normal refrigerator temperature).(Delete if not appropriate)

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

10)......................................................................................... is informed if the patient is intending to move away or stops self-monitoring so that alternative management arrangements can be made

11) The patient named above will undergo an annual clinical review to assess capability to self test/ manage e.g. manual dexterity, eyesight

Signature of clinician responsible:........................................ Date .........................

Signature of patient:................................................................. Date.............................
Appendix 2a: Individual Patient Record of CoaguChek® Test strip Supply

Each test costs £2.84 and each box of 24 test strips costs £68.16 (£133.26/48)

<table>
<thead>
<tr>
<th>PATIENT NAME</th>
<th>Date self monitoring started</th>
<th>Number of CoaguChek® Test Strips supplied</th>
<th>Date Supplied</th>
<th>Number of strips used</th>
<th>Is a review appointment required? Y/N</th>
<th>Review appointment booked – add date here</th>
</tr>
</thead>
<tbody>
<tr>
<td>eg Mrs Smith</td>
<td>eg 10 Feb 2012</td>
<td>1 x 24</td>
<td>10 Feb 12</td>
<td>New patient</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 x 24</td>
<td>19 Oct 12</td>
<td>24 in 8m</td>
<td>Y</td>
<td>24 Oct 12</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 x 24</td>
<td>8 Sept 13</td>
<td>24 in 11m</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 x 24</td>
<td>24 May 14</td>
<td>24 in 8m</td>
<td>Y</td>
<td>1 Jun 14, INR OK, Problem with machine so used more strips</td>
</tr>
</tbody>
</table>


Appendix 2b: Practice Record of CoaguChek® Test strip Supply to Self Testing Patients

Each test costs £2.84 and each box of 24 test strips costs £68.16 (£133.26/48)

<table>
<thead>
<tr>
<th>PATIENT NAME</th>
<th>Number of CoaguChek® Test Strips supplied</th>
<th>Date Supplied</th>
<th>Is a review appointment required? Y/N</th>
<th>Review appointment booked – add date here</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mrs Brown</td>
<td>1 x 24</td>
<td>1.2.14</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Mr White</td>
<td>1 x 24</td>
<td>4.5.14</td>
<td>Y</td>
<td>4.6.14</td>
</tr>
<tr>
<td>Mr Green</td>
<td>1 x 24</td>
<td>2.6.14</td>
<td>Y</td>
<td>4.7.14</td>
</tr>
</tbody>
</table>
## Appendix 3: Dosage Chart example

<table>
<thead>
<tr>
<th>Name</th>
<th>Indication for warfarin</th>
<th>Therapeutic range</th>
<th>Current warfarin dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Betty Smith</em></td>
<td>Atrial Fibrillation</td>
<td>2-3</td>
<td>3mg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date</th>
<th>INR Result</th>
<th>Warfarin Dose</th>
<th>Next Test due</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/10/10</td>
<td>&lt;1</td>
<td></td>
<td>Contact nurse</td>
</tr>
<tr>
<td></td>
<td>1 – 1.5</td>
<td>4mg</td>
<td>1 week</td>
</tr>
<tr>
<td></td>
<td>1.5 – 2</td>
<td>3.5mg</td>
<td>1 week</td>
</tr>
<tr>
<td></td>
<td>2 – 3</td>
<td>3mg</td>
<td>2 weeks</td>
</tr>
<tr>
<td></td>
<td>3 – 4</td>
<td>2.5mg</td>
<td>1 week</td>
</tr>
<tr>
<td></td>
<td>4 – 5</td>
<td>2mg</td>
<td>1 week</td>
</tr>
<tr>
<td></td>
<td>&gt;5</td>
<td>Stop warfarin</td>
<td>Contact nurse</td>
</tr>
</tbody>
</table>