

**Protocol for Patients on oral Anticoagulants
who wish to perform INR self testing**

**Anticoagulation service – Bolton NHS
Foundation Trust**

April 2017.

Document Control

Document Ref No.	ANTICO05
Title of document	Protocol for Patient's on oral Anticoagulants who wish to perform INR self testing
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Author's job title	Anticoagulant Services Manager
Dept / Service	Integrated community services division
Doc. Status	Version 1
Based on	ANTIC04 from PCT
Signed off by	
Publication Date	April 2017
Next review date	April 2109 or until new evidence is published
Distribution	Trust wide / Internet
Has an Equality & Diversity Impact Assessment been completed?	Yes

Consultation History

Version	Date	Consultation
Draft 0.4	25 4 17	Anticoagulant staff Dr Patalappa Pharmacists RBH CCG meds management
Draft 0.4	5 5 17	Changes accepted

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1.0 Introduction

There are currently over 3100 patients in Bolton under the care of the Anticoagulation service. These patients attend the clinic at intervals of between 1 day to 12 weeks, dependant on individual need. At the clinic they undergo INR testing and dosing of oral anticoagulation therapy. For a group of patients the therapy is life long. There have been a number of studies comparing patients who self test versus clinic based testing and it has been shown that improved INR control can be achieved through self testing (M. Connock et al 2007)

In 2010 we undertook a 12 month pilot study involving 10 existing clinic patients who expressed an interest in and were assessed as competent to be involved in the pilot. The aim of the pilot was to allow us to effectively identify any resource implications, governance issues, patient/staff satisfaction and to evaluate the potential of self testing with a view to ultimately developing a self testing programme in the future whereby the patient purchases a machine and performs a self test INR. Each patient underwent a period of training and comparison of self versus clinic results to ensure competency and signed a contract agreeing to comply with the testing protocol, use the kit effectively and safely, maintain contact with the service and complete regular evaluations. All patients were aware that as normal they should inform us of any changes which might affect Anticoagulant control e.g. new medicines or ill health.

In August 2010 we surveyed the patients and asked for their perspective on self testing. The pilot outcomes were an improvement in patient satisfaction and self control by the patient. Patient satisfaction was high regarding training and support from the Anticoagulant clinic. We ask patients to inform us, by texting or telephoning to a specified telephone number, of all INR's so that all results are documented on the Anticoagulant software package, Dawn AC, more accurately. GP's receive emails for all INR's taken.

In reviewing the outcomes of the pilot self testing it became clear that self testing had positive benefits for appropriate patients but would not be cost effective for all patients on oral Anticoagulants if we had to purchase machines for all patients who could or wished to self test. Self testing is often more frequent than clinic visits and so the numbers of strips used is more and has cost implications for the service. In view of this we have facilitated and supported self testing only for those patients who are willing to purchase a machine and fund strips them selves. Those on the pilot were allowed to continue to loan clinic machines but they would have to purchase a replacement themselves if the machines cease to function. They must also make arrangements to purchase their own strips. Patients wishing to self test must buy them directly from the manufacturer. NICE issued guidance in September 2014 supporting self testing.

2.0 Guidelines for Patient Self Testing Pilot

The guidance has been produced to provide support to staff for those patients who wish to purchase and use a coagulometer for self testing of INR.

Portable coagulometers for self testing are commercially available. They cost approximately £300 each.

The specialist nurses of the Anticoagulant team have been trained to use Coagucheck XS machines manufactured by Roche. They are deemed competent as trainers for patient self testing.

Each patient considering self testing will be individually assessed by the following parameters before they can be considered to be safe to self test or to purchase a machine.

They are required to sign the agreement form in the appendices which lays out our expectations of the patient in this scheme

The patients GP is informed in a standard Dawn AC letter that the patient will be self testing in future. The patient must purchase strips from the manufacturer directly.

2.1 Anticoagulant Issues

Long term indication with a specified target range.

Patients with Antiphospholipid Antibodies are excluded from self testing in line with manufacturers' advice.

2.2 Physical Suitability

Ability to obtain capillary samples (self or carer).

Dexterity and visual accuracy to place a blood drop on correct spot.

Ability to see the monitor display clearly (self or carer).

2.3 Psychological / Personal Issues

Patient is willing to purchase own machine.

Patient is willing to purchase own strips.

No impairment in memory, cognitive skills

Patient agrees to comply with all stipulated conditions for self testing support in a signed agreement.

Patient agrees to attend for required comparison tests as specified below to check validity of their results and checking of machine memory.

2.4 Provision of Test Strips

The patient is willing to purchase their own strips. The GP should not prescribe strips on NHS prescriptions.

2.5 Quality Control Procedures

The machine has internal QC during each test.

Recheck INR reading if 1.0 out of normal range.

Comparisons of self test results are made every 3 months against a clinic INR on the same day. This is considered as an external quality control. Patients are informed in the training sessions that if they wish to register with a separate quality control centre e.g. NEQAS it would have a cost implication for them. Clinic machines are externally quality controlled by NEQAS. If after 12 months the patient has been compliant with all aspects of the agreement then machine checks can be performed every 12 months for as long as compliance / comparisons continue to be acceptable.

Patients self test result must always be within 0.5 of clinic result or self testing will cease until further training is given and self tests are again within consensus.

3.0 Training Programme

Provided by identified members of anticoagulant team.

Diagnostic Training includes the following:

1. Watching DVD / reading manufacturers manual
2. Initial set up of machine
3. Quality Control testing (internal)
4. Obtaining a good capillary sample
5. Performing a test
6. Recording of results
7. Action to take when INR is out of range
8. Care of the machine
9. Test strip codes
10. Storage of test strips.
11. How to perform a test

Training is tailored according to individual requirements based on performance, understanding of basic principles and all issues mentioned above

4.0 Blood Testing and Recording of Results

1. Once the initial training session is completed, the patient is to check INR weekly prior to weekly clinic visit.
2. Patient is to check INR just before attending clinic.
3. Comparison is made between patient Coagucheck reading and clinic results
4. The above process is repeated on at least 3 consecutive occasions.
5. Results must always be within 0.5 of clinic result to be deemed acceptable.
6. If comparisons are not within 0.5 self testing is suspended. Further training is given. The patient is monitored in clinic until such time as INR within consensus on three consecutive occasions. Failure to achieve valid reliable results means they cannot safely self test (see under QC section).

7. Once the results are comparable and when the patient feels confident, then *clinic visits* can be extended to 3 monthly intervals for 4 comparison visits and 12 monthly thereafter for as long as compliance / comparisons continue to be acceptable .
8. Frequency of routine self-testing can be increased gradually from weekly up to 4 weekly minimum intervals if the is INR stable.

INR in range after 1 week - test in 2 weeks

INR in range after 2 week - test in 3 weeks

INR in range after 3 week - test in 4 weeks

9. The patient's dose remains constant unless the INR is out of the range, when the patient must contact the Anticoagulant team for advice.
10. The patient must not change the dose by themselves without instruction from the Anticoagulant team.

This scheme supports self testing only not self management.

11. If the result is out of range the patient must contact the Trust Anticoagulant team for further advice.
12. All results (INR's) must be recorded in the patient's anticoagulant yellow book each time they perform the test.
13. Patients must inform the clinic by text or phone of all INR's for updating of Dawn records
14. CoaguChek comparisons will be recorded by the Anticoagulant staff for audit.

5.0 Actions to be taken when patients are not compliant.

Issues of non compliance may include not taking INR as requested, not recording results, not informing the clinic of normal or out of range INR's, changing Anticoagulant doses themselves or non attendance for comparative checks.

Patients will be contacted by phone or by letter and given the opportunity to discuss any difficulties they may have to prevent them from fulfilling their part in the agreement.

If a non compliant patient agrees to comply with our protocol, this patient will be kept under observation in before allowing regular home testing to recommence and extending the clinic visits.

If a patient chooses not to comply with any part of this protocol, then the home testing programme will be discontinued and the patient's GP will be informed of this decision. If the machine is on loan, the patient will be asked to return the machine to the Anticoagulant clinic. If the patient has purchased their own machine they and their GP are informed we will not consider any readings taken. Under both circumstances the patient will return to their normal Anticoagulant clinic monitoring schedule as before by attending the clinic.

***Clinical effectiveness and cost-effectiveness of different models of managing long-term oral anticoagulation therapy: a systematic review and economic modelling.** M Connock,¹ C Stevens,² A Fry-Smith,¹ S Jowett,³ D Fitzmaurice,⁴ D Moore^{1*} and F Song⁵ *Health Technol Assess* 2007;**11**(38):1–86

NICE recommendation <https://www.nice.org.uk/guidance/DG14/chapter/1-recommendations>

Appendix 1

**Conditions of Patient self testing - supported
by Bolton NHS Foundation Trust Anticoagulant clinic (loan machine).**

The CoaguChek machine belongs to NHS Bolton and is loaned to you on the conditions shown below.

- The equipment must be returned or given up for repair as soon as we ask you to do so.
- It must be kept clean and in good working order.
- It must be protected from damage at all times.
- You must let us know straight away if the equipment is involved in an accident or it is lost or damaged.

The conditions to be included in the programme are:

- Willing and able to undertake training for self testing using a CoaguChek machine.
- To take self tested capillary INR's as directed by the Anticoagulant clinic staff.
- To report any INR out of normal range either low or high for advice by specialist nurses.
- To attend clinic for comparisons as requested by Anticoagulant clinic staff.
- Not to alter Anticoagulant dose without instruction from Anticoagulant clinic staff.
- To document all INR's in the Yellow book.
- To report by text or telephone all INR's for maintenance of accurate records.
- Patient willing to purchase strips independently.
- Will return the machine to Waters Meeting Health Centre promptly if requested
- Understands that the clinic will only accept self test INR's while the patient is currently on the self testing programme. INR's taken if the scheme has been terminated for any reason will not be accepted.

Agreement of conditions

I have read the conditions carefully and agree to the conditions for inclusion in the self testing programme

Signature Name

Address..... Date

.....

Appendix 2

**Conditions of Patient self testing - supported
by Bolton NHS Foundation Trust Anticoagulant clinic (machine purchased
by the patient).**

- Assessed as suitable and capable of self testing.
- Willing and able to undertake training for self testing using a CoaguChek machine.
- To perform self test capillary INR's at time intervals as directed by the Anticoagulant clinic staff.
- To report any INR out of normal range either low or high for advice by specialist nurses.
- To attend clinic for quality control comparisons as requested by Anticoagulant clinic staff.
- Not to alter Anticoagulant dose without instruction from Anticoagulant clinic staff.
- To document all INR's in the Yellow book.
- To report by text or telephone all INR's taken for maintenance of accurate records.
- Patient willing to purchase strips independently.
- Understands that the clinic will only accept self test INR's while the patient is currently on the self testing programme. INR's taken if the scheme has been terminated for any reason will not be accepted.

Agreement of conditions

I have read the conditions carefully and agree to the conditions for inclusion in the self testing programme

Signature Name

Address..... Date

.....

Appendix 3

Self testing summary for self tester / trainer

Anticoagulant staff will

- provide initial and ongoing Coaguchek training and support
- provide dosing support
- monitor patient compliance to the Trust agreement
- keep the patients GP informed as stipulated
- provide a troubleshooting / advice service for patients

Patient reads and understands the conditions for clinic support of self testing.

Patient signs agreement (Appendix 2).

Patient undergoes training.

Patient understands they need to attend weekly to compare clinic and self test INR before we will accept self test readings.

If 3 consecutive results are within 0.5 of clinic comparison we can allow the patient to self test.

- Patient to home test in 1 week.
- If normal INR extend to 2 week
- If normal in 2 week then test in 3 week.
- If normal in 3 week test every 4 weeks.

INR to be taken every 4 weeks as a minimum.

Send Dawn AC preset letter to GP to inform of training and self testing.

Patient is to telephone the Anticoagulant clinic for dose advice if INR out of normal range. Specify desired range clearly for each individual patient.

All INR's to be documented in Yellow book by the patient after each test.

All INR's to be communicated by phone or text to Anticoagulant clinic for update of results after every test including date of test, INR, current dose.

At next clinic visit INR to be done at home before clinic and compare with clinic result.

All INRs recorded in the machine memory are to be checked by staff at each clinic visit and compared to documented INR's in the Yellow book.

Staff are to check at each visit that

- Self test INR and clinic INR documented clearly on Dawn and within 0.5.

- Machine memory shows testing intervals / INR's as expected
- Clinic have been informed of all INR's
- Out of range INR's were reported and actioned
- Patients have not altered the dose themselves without discussion with clinic staff
- Yellow book is updated after every test

If patients are not complying with conditions for self testing staff must document this and discuss with the patient.

Agreed conditions for self testing are to be reiterated to the patient.

A repeated failure to adhere to self testing conditions will result in withdrawal of self testing support and a return to previous clinic monitoring arrangements.

Appendix 4

Initial training checklist for CoaguChek self testing.

	Patient name			
	NHS number			
Training issue	Trainers signature	Date of training	Date of agreed competency	
Has watched DVD and read manual.				
Initial set up of the machine				
Quality control testing				
Obtaining a good capillary sample				
Performing a test				
Recording of results				
Informing clinic by text or phone of all results / doses				
Action to be taken when INR out of range				
Care of the machine				
Test strip code chip / Storage of test strips				
Problem solving				

Trainer signature

Patient signature

Date