GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Caerdydd a'r Fro | Cardiff and Vale University Health Board

HEALTH CARE PROFESSIONALS OVERSEEING PATIENT INR SELF-TESTING SERVICES PRACTICE GUIDELINES

Reference No:	UHB 210	**Version No:**	1.0	**Previous Trust / LHB Ref No:**	n/a

Documents to read alongside this Policy , Procedure etc (delete as necessary)	Point-Of-Care Testing Policy

Classification of document: Clinical

Area for Circulation: UHB Wide

Author/Reviewee: Consultant Haematologist
Primary Care Pharmacist
Point-of-Care Testing Manager

Executive Lead: Medical Director

Group Consulted Via/ Committee: Point-of-Care Testing Group
Bro Taf Local Medical Committee

Approved by: Point-of-Care Testing Group

Date of Approval: 22nd November 2013

Date of Review: 22nd November 2016

Date Published: 17th March 2014

Disclaimer

When using this document please ensure that the version you are using is the most up to date either by checking on the UHB database for any new versions. If the review date has passed please contact the author.

OUT OF DATE POLICY DOCUMENTS MUST NOT BE RELIED ON

Version Number	Date of Review Approved	Date Published	Summary of Amendments
1	22/11/2013	17/03/2014	New Document

CONTENTS

APPENDICES

1.0 INTRODUCTION

This practice guidance has been prepared to support the Healthcare Professional (HCP) overseeing the management of those patients, in whom it has been decided for clinical reasons that self-testing is appropriate. The document provides training and competency for patient International Normalised Ratio (INR) self-testing using a Cardiff and Vale UHB approved device, the Roche Coaguchek meter.

Self-testing refers to a model of care in which a patient prescribed Warfarin medication measures their own International Normalised Ratio (INR) at home, but has to contact Healthcare Professionals for interpretation and dose adjustment. The patient must also have undertaken a training session on how to use the meter, which is overseen by the HCP, prior to commencing self- testing.

Self-testing may be suitable for those patients who are in employment or education, frequently away from home or who find it difficult to access clinics.

(This differs from self-management, which will not be considered as part of this guidance, but which involves the patient interpreting their INR results and adjusting their dosage based on the value obtained and their therapeutic INR range.) Self-testing is integral to both aspects of self- testing and self-management.

2.0 ASSESSING SUITABILITY OF THE PATIENT

Patients and/or their carers must give informed consent to the clinician responsible for their self-testing. Prior to commencement of self-testing, competence to perform an INR test must be assessed and signed off by an experienced and appropriately trained Healthcare Professional (HCP). The trained Healthcare Professional responsible for self-testing must be fully informed and aware of the National Patient Safety Alert (NPSA) number 18 – *"Actions that can make anticoagulant therapy safer"* (March 2007).
Self-testing should not be commenced in patients where treatment compliance is an issue e.g. non-attendance at clinics or failure to take their medication as prescribed.

The HCP responsible for prescribing **must** undertake the following checks before continuing with the training session as listed in the HCP Checklist for Suitability detailed in Appendix 1.

- Assess whether the patient is suitable for INR self-testing. Risk assessment ensures that the patient is both physically and cognitively competent to undertake INR self testing or has adesignated carer who is physically and cognitively competent to do so on their behalf.
- Check patient has maintained good INR control for the preceding 3-6 month period:

  If INR target is 2.5 a range of results between 1.8-3.5 is acceptable
  If INR target is 3.5 a range of results between 2.8- 4.5 is acceptable
- Ensure patient has a clear understanding of why they are prescribed an anticoagulant and the importance of regular self testing and six monthly review.

- Ensure patient has an NPSA “anticoagulant pack” including card and yellow booklet.
- Explain Patient Agreement Plan and obtain patient agreement- see Appendix 2.
- Ensure patient has been issued with Roche Training Pack or given information on how to access training pack.
- Perform baseline measurement of INR and agree follow-up appointment date.
- Provide patient with appropriate Health and Safety information for disposal of sharps.

Once patient agreement has been obtained, a registered HCP/ competency-assessed individual undertakes the following training procedure on the device.

3.0 TRAINING PROCEDURE FOR USE OF THE METER- AIMS AND LEARNING OBJECTIVES

Aim: To attain competence to perform INR testing of anticoagulant therapy using a CoaguChek XS meter.

Learning Objectives: By the end of this training session patients should be competent with the:-

- **Basic principles of Warfarin therapy** - understand the reasons for warfarin therapy, including an outline of the method of action of warfarin and the importance of regular testing - see Appendix 4.
- **Equipment requirements** - for self testing (2.1)
- **Sampling technique** - to control anticoagulant therapy by the INR method on blood obtained directly by finger-prick including sources of error (pre-analytical factors)(2.2)
- **Storage and stability** - Know how to store test strips(2.3)
- **Quality checks** - explanation of internal quality control/ external quality assessment(2.4)
- **Record Keeping** - understand the frequency of testing and know how and where to record the results/ Understand the significance of the results obtained from the INR meter/ abnormal or unexpected results (2.5)
- **Limitation of the device** - Understand the limitations of the device and identify any contraindications- see Appendix 4.
- **Sources of Errors when testing** - calibration procedure- see Appendix 4.
- **Competency assessment** - Trained HCP demonstrates use of meter and undertakes competency assessment of patient to correctly perform an INR test during the session (2.6)
- **Maintenance technique** - demonstrate routine maintenance of the device – see Appendix 4
- **Health and Safety** - demonstrate the correct disposal of the test strip/ understand health and safety issues (2.7)

3.1 Equipment required for Self-Testing

CoaguChek XS Test Strips and corresponding calibration chip
CoaguChek XS self-training Roche video
CoaguChek XS self-training guide(*test procedure also appended in Appendix 4)*
Hand washing facility or alternative
Lancets
Sharps container
Test strips

3.2 Sampling Technique

- Capillary whole blood is used and at least 10µl is required.
  Hints for achieving a good blood flow:
  Wash hands with warm soapy water
  Let the hand hang down next to the body (or at least be below heart level)
  Massage hands
- Sampling site/Obtaining sample:
  Use the side of the finger
  Firmly press the lancet against the side of the finger and then activate it. Massage finger until a large drop of blood has formed. DO NOT press or squeeze the finger
  Apply the first drop of blood to the test strip
- Application of blood onto test strip:
  Correct application of blood is very important
  The FIRST drop of blood must be used
  The blood MUST be applied to the test strip within 15 seconds of lancing the fingertip
  The blood must cover the entire sample application area
- Sources of Error with sampling techniques
  Insufficient sample
  Blood not applied within 15 seconds
  First drop of blood not used
  Finger pressed or squeezed or excess pressure applied

3.3 Storage and Stability

CoaguChek XS PT Test Strips

- CoaguChek XS PT test strips- can be kept at room temperature (18 – 30 degrees) until their expiry date on the box.
- After removal of a test strip from the container, ensure the stopper is replaced immediately to prevent deterioration of the remaining test strips
- Test strips MUST be used within 10 minutes of removing from the container
- Blood must be applied to the test strip within 15 seconds of lancing the finger

3.4 Quality Checks- Internal Quality Control (IQC) and External Quality Assessment (EQA) Internal Quality Control (IQC)

IQC is used to ensure the day-to-day reliability of INR results. The patient meter has an in-built electronic IQC check.

Internal quality control (IQC) should be performed in accordance with the individual manufacturer's recommendations-

- When a new batch of strips is introduced
- If there is any doubt about the storage conditions of the strips
- If machine is accidentally dropped
- If results are unexpected

Note to HCP- *For HCP meters, built- in quality control on the test strips is* ***not*** *sufficient and QC material provided by the manufacturer (liquid IQC) should be run. IQC should be run at least once a month, pending clinic frequency or prior to start of clinic.*

External Quality Assessment (EQA)

EQA can be performed in one of the following ways:

1. The HCP overseeing the INR testing service should itself participate satisfactorily in an accredited external quality assessment (EQA) programme e.g. WEQAS. The WEQAS EQA INR Scheme distributes samples six times per year, which involves the HCP quality-testing their own meter. When patients attend their six-monthly follow-up appointment a simultaneous blood measurement check should be carried out on both the HCP meter and the patient's own. (Split sample analysis)

An INR deviation of +/-10% between patient's own and HCP meter is acceptable. This serves as a parallel quality- check and ongoing competency assessment.

2. Alternatively, EQA can be performed by taking a venous sample collected at the same time as the patient self-testing sample is taken and analysed in an appropriate hospital laboratory, which has satisfactory EQA performance for INR. However, it is important to note that INR measurements may deviate according to the technique used for measurement. If the measured POCT INR is >± 0.5 of the laboratory INR then the test should be repeated.

An INR deviation of ±0.5 has been considered acceptable for clinical purposes

- If there is a persistent discrepancy the manufactures should be contacted and the machine not used until declared fit by manufacturer.
- The results of these quality control tests should be recorded and a log kept.

3.5 Record Keeping

The process for record keeping of results is as follows:-

- Patient checks INR

- Patient telephones practice with INR result.
- HCP calculates dose and notifies patient – patient confirms dose and also confirms next testing date. If there is any doubt about the validity of a reading then patient repeats the test. If on repeat testing there are still doubts about the result discuss with the HCP.
- Practice records dose centrally from patient result
- Patient records dose in yellow book
- HCP undertakes an annual review of patient results in quality control record keeping book, versus telephoned results. Including quality control record book review and EQA participation as part of ongoing competency assessment
- Recall system in place as per Local Enhanced Service (LES)/ practice policy.

Under **NO** circumstances should the patient alter their dose except on the advice of the HCP managing their therapy.

If a result >4.5 is obtained, the patient must contact the HCP immediately and may be asked to attend the hospital/surgery for a venous sample to be collected.

Source of error of record keeping- Incorrect transcription/ communication of results

Note to HCP- *HCP should be aware of limitations of POCT device – see Appendix 4.*

3.6 Practice Session and Competency Assessment

Patients should complete a competency assessment, with the purpose of assessing the patient's technique and knowledge to the satisfaction of the trainer - see Appendix 3.

3.7 Health and Safety - Collection of patients own sharps

- A referral form has to be completed by either the Clinic Manager or Nurse responsible for the patients care. The Home Collection Service(SRCL) will not accept a request for a collection based on a telephone call from a patient.

- The telephone number for the collection of sharps from their homes is 0333 240 4009 (SRCL). If this number is busy or there is no one in the office the call will be diverted to the main SRCL customer service department who will deal with the request.

4.0 EQUALITY

We have undertaken an Equality Impact Assessment and received feedback on this policy and the way it operates. We wanted to know of any possible or actual impact that this policy may have on any groups in respect of gender, race, disability, sexual orientation, Welsh language, religion or belief, transgender, age or other protected characteristics. The assessment found that there was no impact to the equality groups mentioned. Where appropriate will make plans for the necessary actions required to minimise any stated impact to ensure that we meet our responsibilities under the equalities legislation.

Appendix 1 - HCP Checklist for Assessing the Suitability

The HCP responsible for prescribing **must** undertake the following checks before continuing with the training session –

Checklist	**Tick box when checked and outcome satisfactory**
Consider/ risk assess if the patient is suitable for INR self-testing. Risk assessment must ensure that the patient is both physically and cognitively competent to undertake INR self testing or have a designated carer who is physically and cognitively competent to do so on their behalf.	☐
Check patient has maintained good control for 3-6 month period- If INR target is 2.5 good control between 1.8-3.5 is acceptable If INR target is 3.5 good control between 2.8- 4.5 is acceptable	☐
Ensure patient has a clear understanding of why they are prescribed an anticoagulant and the importance of regular self testing and six monthly review.	☐
Ensure patient has an NPSA “anticoagulant pack” including card and yellow booklet.	☐
Explain Patient Agreement Plan and obtain patient agreement- see Appendix 2.	☐
Ensure patient been issued with Roche Training Pack or given information on how to access training pack.	☐
Perform baseline measurement of INR and agrees follow-up appointment date	☐
Provide patient with appropriate Health and Safety information for disposal of sharps.	☐

Date of completion of Checklist	Completed by	Signature	Contact number

Appendix 2 - Patient Agreement Plan For Self-Testing of INR Measurement

Patient Name: **Address:** **Preferred Contact Number:** **Alternative Contact Number:**
Registered GP: **GP Contact Details:**
Responsible Clinician: **Address:** **Contact Number:**

XXXXXXXXX is the trained Healthcare Professional responsible for ensuring the above named patient is a suitable candidate for self-testing of INR whilst on anticoagulant (warfarin) therapy.	☐

I, (patients name) agree to:-	Initial in box
1. – have read and understood the basic principles of warfarin therapy	☐
2. -always follow the procedures which were agreed in my training sessions.	☐
3. -seek immediate advice/ help about any matter arising from the training or performing the INR test with regards to my technique, from the health care professional responsible for my INR.	☐
4. –maintain accurate records in the yellow book, detailing all INR results, the date of testing, and the dose advised by my health care practitioner. I will also record any other significant events in the yellow book eg starting new medication, stopping medication. This will allow a complete review to be performed every 6 months.	☐
5. -continue to telephone every result to the appropriate person/clinic at the agreed time and date, even if the INR is with the specified range.	☐
6. – to re-test and immediately seek advice from the appropriate health care professional or INR clinic if the result is out of the desired range	☐
7. – to order test strips on prescription from my GP and be responsible for ensuring they are in date, stored correctly and that I do not run out.	☐

8. -comply with the SRCL(patient clinical waste collection service) contaminated waste disposal according to local health and safety policy.	☐
9. -comply with any review or recommendations made by my health care professional, that suggests that I should no longer self-test	☐
10. - to remain in **regular** contact with the named responsible clinician. This may involve an agreement to contact the responsible clinician with the INR result on a specified day of the week or as a pre-arranged telephone appointment. (All contacts details should be documented as part of the agreement and updated accordingly.)	☐
11. – to have access to a recommended coagulometer and understand how to perform the appropriate internal quality control tests as recommended by the manufacturer.	☐
12. - to attend the appropriate setting e.g. community clinic, GP surgery every six months for external quality control to be carried out either via comparison of the result from my monitor with the clinic's monitor or comparison of a venous INR result with the result from my monitor.	☐
13. - to receive further training and support if there are quality-control issues regarding my meter	☐
14. – to contact my health care practitioner of any manufacturer product alerts/ device changes for further information	☐

Signature of Clinician Responsible: **Date**:

_____ _____

Signature of Patient: **Date:**

_____ _____

Appendix 3 – Competency Assessment

Patient Training Record

Patient Name: _____

Trainer Name: _____

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

Criteria	✓
Meter Set Up	
Batteries	
Display check	
Date Format	
Date Setting	
Time Format	
Time Setting	
Set Test Measurement	
Beep Tone	
Therapeutic Range	
CoaguChek XS Test Strips	
Storage conditions	
Handling test strip	
Calibration Code Chip	
Changing Code Chip	
Onboard Quality Control	
Sample dosing area	

I confirm that I have received the information

Criteria	✓
Obtaining a Finger Prick Sample	
Hand washing	
Sites for taking a sample	
Time limits	
Sampling problems	
Recording Results	
Anticoagulation Record	
Memory	
Retrieving saved results	
Maintenance & Troubleshooting	
Cleaning meter	
Common error codes	
Technical support	
CoaguChek Patient Care Line: 0808 100 7666	

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

on the above criteria from the above named trainer. I confirm that I should still read the user manual accompanying my CoaguChek XS device in conjunction with this training. If I require any further technical information I will ring the technical support helpline, or refer back to my HCP at the clinic.

Date: _____

Patient Sign: _____

Trainer Sign: _____

Appendix 4 – Patient Information Sheet

Basic Principles of Warfarin Therapy

Clotting factors are required to make the blood clot. Some clotting factors need to be activated in the presence of vitamin K. Warfarin prevents this activation. As a result the blood is less able to clot.

This is important for patients who have suffered a thrombosis in their veins or arteries, as it prevents further blood clot developing and allows the body to break down the existing clot.

Some people with atrial fibrillation are at increased risk of stroke, due to blood clot formed in the heart travelling to the brain. Warfarin prevents the formation of these clots.

The effects of warfarin may be reversed using vitamin K, or by infusing clotting factors that have been affected by warfarin.

Certain foods and medicines can affect the action of warfarin – some increase it and some reduce its effect. Care must be taken when starting or stopping medicines and when making alterations to dietary intake.

In particular, alcohol can increase the effect of warfarin, but also make an individual more prone to accidental injury, and thus of bleeding. Certain anti-inflammatory drugs, eg aspirin, ibuprofen, diclofenac, interfere with other aspects of the blood's ability to clot, and therefore increase the tendency to bleed when used in association with warfarin.

Also,the action of warfarin can be increased or weakened when other drugs are taken simultaneously (e.g., antibiotics, but also over-the-counter drugs such as pain relievers and cold and flu' remedies). This, in turn, can also lead to either an increase or decrease in prothrombin time (INR). Additional drugs should only be taken if prescribed by your GP.

Inform the pharmacist/ doctor that you are taking warfarin if prescribed or buy any new medication.

Performing an INR Test

i. Place the monitor on a level, vibration-free surface or hold it in your hand so it is roughly horizontal. Turn the monitor on by pressing the On/Off button.
ii. Check that all of the display symbols are displayed properly as shown in training instructions. Results may be misread if a segment is missing.
iii. Check the battery level. If there are no bars left in the battery icon, you cannot perform any more tests.
iv. Check the date and time are correct and correct if wrong (see CoaguChek XS Operators Manual – Monitor Setup/Setting the date).
v. The flashing test strip icon prompts you to insert a test strip. Remove a test strip from its container. Immediately after removing a test strip close the container again with the stopper.
vi. Hold the test strip so the lettering 'CoaguChek XS PT' is facing upward.
vii. Slide the test strip into the test strip guide in the direction indicated by the arrows. Slide the test strip in as far as it will go. A beep indicates that the monitor has detected the test strip. The code number of the code chip inserted in the monitor flashes in the display. Make sure that this number is identical with the code number printed on the test strip container. If the two numbers are identical, confirm by pressing the M button. The code number stops flashing. If the code numbers are not identical, remove the wrong code chip and insert the one that was supplied with the test strips that are being used.
viii. The hourglass icon shows that the test strip is warming up. When the warming-up process is complete, a further beep indicates that you can now apply blood.

ix. The blood drop icon flashes to indicate that the monitor is ready to perform the test and is waiting for blood to be applied. At the same time a 120 second countdown begins. You MUST apply the drop of blood to the test strip within this time otherwise you will receive an error message.
x. Lance the side of the fingertip with the lancing device. Massage the lanced finger until a drop of blood is formed. DO NOT press or squeeze the finger. Apply the first drop of blood from the finger.
xi. Apply the blood directly from the finger to the semicircular, transparent sample application area of the test strip or alternatively touch the blood drop against the side of the sample application area where the blood will be drawn up by capillary action. During this process you must hold the blood drop to the test strip until the flashing blood drop icon has disappeared and the monitor beeps.
xii. The blood MUST be applied to the test strip within 15 seconds of lancing the fingertip. Applying blood after this period of time would falsify the result as the coagulation process would already have begun.
xiii. When applied from above, the blood must cover the entire sample application area. A beep tone will sound when enough blood has been applied. DO NOT add more blood. DO NOT touch the test strip until the result is displayed.
xiv. The monitor performs an automatic QC test on the test strip before it displays the test result. 'QC' appears in the display. Following a successful outcome of the QC test, a tick appears after 'QC'. It is at this point that the coagulation measurement begins. The hourglass flashes until the monitor has the result.
xv. Record result, remove the test strip from the measurement chamber and turn the monitor off.
xvi. Dispose of the used lancet and test strip in accordance with the disposal policy of your medical practice.
xvii. Clean the monitor if this becomes necessary

Limitations of the Device

- The blood drop must be a minimum of 10µl. Low sample volume will cause an error message to appear.
- The valid measuring range for CoaguChek XS PT test strips is 0.8 – 8.0 units. Results that are outside this range are indicated by the symbols < (less than) or > (greater than). Refer to test limitations and known interferences in the package insert supplied with the test strips and repeat the test
- The monitor must only be used at room temperature (18-32°C)

  Strong electromagnetic fields may interfere with the proper operation of the monitor. DO NOT use the monitor near strong electromagnetic fields.
- Anti-phospholipid antibodies (APLS) such as Lupus antibodies may falsely prolong coagulation times i.e., they may cause false high INR values. Where APLS are known to be present, a baseline Prothrombin time/INR should be performed in an accredited laboratory. If the INR is >1.4 then the appropriateness of a coaguchek should be discussed with a haematologist

Sources of Error when performing Calibration Procedure

- Each box of test strips contains a code chip. This code chip contains lot specific information about the test strips, including calibration data that allows the correct results to be calculated, and the expiry date for the test strips.
- The code chip also provides the monitor with important information that it needs to perform the coagulation test.

- Each code chip belongs to a particular lot of test strips. The chip is required when a new test strip container is opened.
- Make sure that the number on the code chip matches the number on the label of the test strip container. On opening a new pack of CoaguChek XS PT test strips replace the code chip from the old pack (if still in the monitor) with the one supplied in the new pack.
- Every time a test strip is inserted the monitor display shows the number of the code chip that is inserted. At this point, the code number on the display must be compared with the number that is printed on the test strip container. The two numbers must be identical. Using the wrong code chip can produce incorrect results. Only remove the code chip when testing with test strips taken from a new pack (with a new code chip).
- To insert the code chip:
    - Remove the old code chip, if one is inserted in the monitor. Dispose of the code chip with household waste
    - Always make sure that the number on the code chip matches the number on the label of the test strip container
    - Slide the new code chip into the slot on the side of the monitor until it snaps into place.

Sources of Error when testing

This is not an exhaustive list, see manufacturers instructions:-

- Incorrect calibration chip
- Strips used beyond expiry date
- Tests strips not used within 10 minutes of being removed from the container
- Blood not applied to the test strip within 15 seconds
- Stopper not replaced on container after use
- Defective LCD
- Low battery

Demonstration of Routine Maintenance

Cleaning the Plastic Housing

Clean the monitor whenever it becomes dirty. Turn off the monitor before cleaning it. Use only the following items for cleaning:

- Ordinary lint-free swabs
- Warm water with or without washing-up liquid
- Soft lint-free moistened cloth or cotton bud.
- **DO NOT** use sprays of any sort, as these may enter the monitor and damage it.
- Clean the outside of the monitor with a lightly moistened cloth
- Then dry the monitor with a fresh cloth.

Cleaning the Test Strip Guide

Check the test strip guide regularly for signs of soiling. If the test strip guide has become soiled with blood or any other material you MUST clean this area. This procedure must be carried out at least once a month.

- Remove the measurement chamber cover by pressing upwards from the front (e.g., using your thumbnail). The measurement chamber cover must be removed (separately from the monitor) and rinsed with water.
- Clean the easily accessible white areas with a lint-free swab or a moistened cotton bud. Make sure that NO liquid enters the monitor. DO NOT insert any objects in the test strip guide. Doing so may damage the electrical contacts behind the test strip guide.
- Let the inside of the test strip guide dry for about 10 minutes.
- After this time, re-attach the measurement chamber cover to the housing. Make sure that the cover is properly closed, it will snap into place.

SRCL®
Protecting People. Reducing Risk.™

Home Patient Clinical Waste Collection Request Form

Referrer:		**Telephone No:**		**Date:**	

Patient Name:	

Collection Address: *please use block capitals*		
	Post Code:	

Contact Telephone Number(s):			

Date Collections Required From:	

Collection Frequency: *please tick relevent box*

Monthly:	☐	**Fortnightly**	☐	**Weekly**	☐
Quarterly:	☐	**Adhoc**	☐		

Category of Waste: *please tick relevent box*

Orange Bag:	☐	**Sharps Bin:**	☐

Please return completed form to SRCL by fax only to :

Fax:	**0113 2700 347**

For queries only (no patient details by email)

Email:	HomePatients@srcl.com

SRCL Contact:		**Leanna Hamilton**	**Telephone:**	**0333 240 4009**

Contract Admin use only:

Customer ID:		Site ID:	
Collection Day:		1st Collection Date:	