**1. What should I learn from this topic?**

The aim of this topic is to give you an understanding of the important operational issues of an anticoagulant and stroke prevention service. This topic does not offer a step-by-step approach to commissioning and establishing a new anticoagulant service. Instead, it aims to highlight the main operational considerations in delivering a safe service, including the quality clinical governance of an anticoagulation monitoring and stroke prevention service.

By the end of this topic you should be able to:

1. List some of the different models of anticoagulant and stroke prevention monitoring
2. Identify the policies and protocols needed to support a safe anticoagulant clinic
3. Identify good practice in transferring patients to and from primary and secondary care
4. Describe self-monitoring of oral anticoagulation
5. Summarise the benefits of self-monitoring
6. Assess if self-monitoring may be right for an individual patient
7. Demonstrate how to set up a coagulometer and perform an INR test
8. Demonstrate how to perform a quality assurance test
9. Apply the recommendations of the National Patient Safety Agency (now transferred to the NHS Commissioning Board Special Health Authority) to your own anticoagulant service
10. Summarise audit standards for anticoagulation management

**2. What are the models of anticoagulant monitoring?**

There is no standard service model or definition of an anticoagulant and stroke prevention service. Consequently, there are a number of ways to deliver anticoagulant monitoring at a local level.

Service models include the following:

* Outpatient clinics in secondary care. These are usually nurse or pharmacist-led.
* Outreach clinics delivered by hospital staff in primary care
* Primary care clinics in GP surgeries
* Primary care clinics in community pharmacies
* Domiciliary care services where patients are visited at home
* Patients self-monitoring – self-testing or self-management - in their own homes

POINTS TO PONDER …

What do you consider to be the pros and cons of each of these service models? Do you feel that different models suit different patient populations?

**WHAT HAPPENS NEAR ME?**

**This exercise will result in the generation of a clinic information template to describe to patients the services that you offer. You may wish to use this and develop it further.**

Please answer the following questions:

1. Describe the staff working in your anticoagulation service

(name / profession or role)

2. Services offered

(secondary care clinics / outreach clinics / GP clinics / community pharmacy clinics / self-testing service / self-management service)

3. Contact details for your service

(postal address / tel no. / email)

4. Clinic opening hours

5. Clinic process for patients (how does the system work?)

**3. Defining your patient population**

It is important to define your patient population. For example, some services do not manage those under the age of 18.

Primary care services may exclude those with labile INRs and high-risk patients or those with complex pathologies. For example, whilst someone with controlled heart failure may be suitable for management in primary care, it may be better to retain someone with decompensated heart failure within the secondary care service

Those attending anticoagulant clinics in primary care may also need to be able to travel to clinic of own accord … i.e. not dependent on transport services.

**4. How is stability defined?**

(*Image – balance.svg)*

Many primary care services will manage those who have relatively stable INRs. Therefore, a working definition of stability may be necessary**.** Stability is difficult to define but some criteria are needed for practical purposes. For example:

* Three consecutive INRs in target range
* INR testing no more frequent than every 4 weeks

**5. Defining clinic protocols and procedures**

Written procedures and clinical protocols should be in place to support safe practice. Staff should have easy access to, and be trained in, these protocols and procedures. At Whittington Health these are available as a series of standard operating procedures. These are available in paper form and also on HeliconHeart, the information and advisory system.

Oral Anticoagulant Perioperative guidance

Vitamin K for Elevated INRs in Patients on Warfarin

Sickness and Absence management

Hand Hygiene Procedure

Blood Spillages Procedure

Resuscitation Policy and Procedures

Destroying Confidential Information

Adverse event monitoring and reporting

Error and complaint reporting

Sharps Bins, Clinical Waste and Sharps Injury

Lone working

**Examples of clinic protocols and procedures at Whittington Health**

**WHAT HAPPENS NEAR ME?**

Now check which protocols and procedures are available for your anticoagulant service. Can you identify additional ones that need to be developed?

**6. What information is required for safe transfer of care?**

* Effective communication systems are required when clinical responsibility for anticoagulant therapy is being transferred, for example, on discharge from hospital. Therefore, aminimum data set is required to allow safe management of oral anticoagulation.
* Patient demographic information, including NHS number
* Clinical indication for anticoagulation
* INR target (and reason if it is not an evidence-based INR target for that indication)
* Expected duration of  treatment
* Date treatment started
* Initiating clinician
* Current dose
* Last 4 INRs minimum with associated doses and dates
* Next due INR date
* Concurrent antiplatelet therapy (including if this is to stop or continue after initiation of warfarin)
* If for VTE/mechanical valve replacement, a section required to indicate whether heparin (LMWH) bridging is required and for how long, together with parameters for monitoring (FBC/Platelets) and who should be re-supplying the LMWH
* Other current medication
* Medical history summary
* Previous anticoagulation therapy summary
* Allergies, side effects, contraindication
* Verbal/written information provided to patient
* District nurse input required
* Transport needs
* Translation services required

**Suggested minimum data set for transfer of care for an anticoagulated patient**

**WHAT HAPPENS NEAR ME?**

Take a critical look at the referral form for your anticoagulant clinic. Does it include all of the items in the minimum data set above? Conversely, does it have extra data items?

**6.1 What is needed to ensure safe transfer of patients from secondary to primary care?**

*(Image - patient\_transfer 2 to 1.svg)*

Before accepting patients from secondary care you should receive the minimum dataset as above. Local protocols are needed to define lines of communication between primary and secondary care, and those between the respective services and the patient.

**6.2 What is needed to ensure safe transfer of patients back to secondary care clinics from primary care?**

*(Image - patient\_transfer 1 to 2.svg)*

Equally, effective communication of information is essential to ensure a safe and seamless patient transfer from primary care to secondary care. Communicating directly with the anticoagulant team and confirming details via email will reduce the incidence of patients being lost to follow up. This information should also be recorded in the electronic record system.

A patient may need a review of their anticoagulation by a specialist, for example if they have had erratic/poor INR results or a significant event that prevents the patient from taking their anticoagulation safely. A referral should be made in accordance with local protocol.

* Persistent falls putting patient at risk of bleeds
* Poor INR results (time in therapeutic range (TTR) <50% of time)
* Poor memory – unable to recall dose adjustments
* Poor manual dexterity – patient unable to manage variable warfarin dosing

**Examples of when to refer a patient to a specialist for review of anticoagulation**

POINTS TO PONDER …

Where do you think things might go wrong in transferring patients between primary and secondary care clinics (this might be based on your experience!)? How would you make sure that this transfer of care is safe and smooth?

**7. Documenting results and advice**

* A safe system for documenting results and advice is required. Many services now use an electronic patient record (e.g. HeliconHeart).

*(patientsummary.png)*

**8. Annual clinical review of patients on oral anticoagulation**

*(image - 118\_MP900309636.JPG)*

An annual review of every patient taking an oral anticoagulant is necessary. This expectation has been clearly defined in the 2014 NICE Guidance on atrial fibrillation.

The need for an annual review has become even more important because of the changing characteristics of patients now being anticoagulated. A higher proportion are older and they may have more than one long-term-condition and will be on several medications for these.

As a result an annual review needs to be conducted by the GP; this review may also include the other conditions such as atrial fibrillation, heart failure or diabetes that the patient may suffer from in order to assess that the patient continues to receive the best treatment for all the conditions.

The results of this review must be documented so that all the practitioners involved in the care of the patient are aware of any changes.

* **9. Discontinuation of anticoagulant therapy**

*(image - 115\_MP900448683.JPG)*

When the patient is first started on warfarin, or other vitamin K antagonist there will be a treatment plan in place. There may be an intent to stop the warfarin in 3 or 6 months. Alternatively there may be an unexpected need to stop the warfarin because of the changed risk/benefit ratio; for instance the renal function of the patient may have deteriorated badly.

It is important to ensure that the patient is seen by the clinician responsible for the care of patient and the changed risk/benefit ratio confirmed; or in the example of a planned discontinuation that there is no need to change the plan to stop.

Once the decision to stop has been confirmed there are several measures to take. Firstly the patient needs to be informed and assured that the responsible clinician has confirmed the decision. There may be a need to start some other treatment, for instance aspirin, and this needs to be communicated to the patient. The warfarin can then be stopped on an agreed date; there is no need to phase the reduction in drug dose. Finally the GP needs to be informed and will then stop prescribing the warfarin. Usually all these decisions are committed to paper in a discontinuation form.

**10. I have heard that some hospital clinics do not see every patient face-to-face. How does that work?**

To relieve congestion and to reduce waiting times for patients, many clinics that use venous INR sampling offer a telephone or mailing service. After blood sampling, the patient does not need to wait to see an anticoagulant practitioner in clinic. Instead, they can leave the hospital and will receive their INR result and warfarin dose by post. If the INR is out of range, or if there are any other issues that need resolving, the practitioner telephones the patient at home.

POINTS TO PONDER …

What do you think are the risks of operating a mailing / telephone service? Are there ways of mitigating these risks? Are there alternative ways of relieving clinic congestion?

**11. How can we safely care for those patients on warfarin who are housebound?**

*(Image - 115\_MC900433918.PNG)*

There are an increasing number of patients who are unable to attend clinic to provide a blood sample, requiring domiciliary care. These tend to be frail, older patients with multiple co-morbidities. However, other patients – for example, acutely unwell patients or those who have had recent surgery - may require a domiciliary service until they are back on their feet.

In the absence of a dedicated domiciliary anticoagulant and stroke prevention service, arrangements will need to be made with **district nursing service** to visit these individuals periodically at home to take blood samples for INR testing. Although near-patient testing can be used, usually venous blood samples are taken and then sent to the local hospital for INR testing.

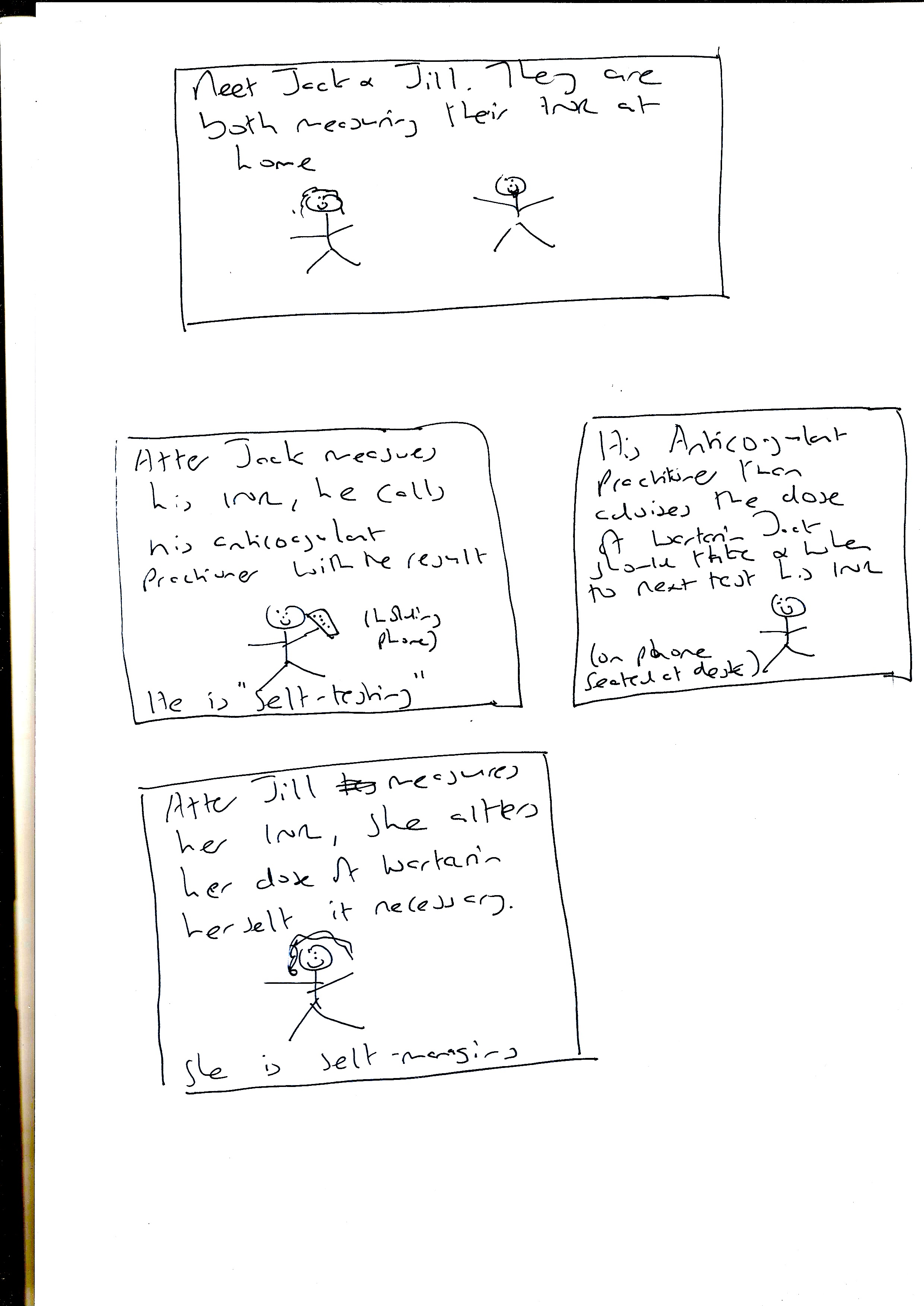
Responsibility for following up the INR result and, once received, for dosing the patient rests with the anticoagulant service managing that patient. In The Whittington service patients managed in primary care who requiring permanent help with district nurse input, are referred back to the secondary care clinics for INR management. For those requiring temporary input by district nurses, it is left up to the primary care anticoagulant practitioner to decide whether to manage the results from the hospital or to refer back to the secondary care clinic for management until fit to return to the community clinics.

It is essential to establish **robust lines of communication** between the district nursing and anticoagulant and stroke prevention services, and to have measures in place to identify patients who are late in having their INR test.

**12. What is patient self-monitoring of oral anticoagulation?**

Those treated with insulin for diabetes have been monitoring their blood glucose at home for some years. Their dose of insulin is then adjusted based on this result. In a similar way, home monitoring of the INR is now possible, using point-of-care testing (POCT) devices known as coagulometers. Point-of-care testing is described further later in this topic

This is known as patient self-monitoring of oral anticoagulation. As an alternative to visiting the anticoagulant clinic for an INR blood test, the patient can measure their INR on a coagulometer at a location convenient to them. After measuring their INR, they then seek dosing advice from a healthcare professional **(patient self-testing).** Alternatively, they can decide on their dose of warfarin based on personal experience, and supported by written or computerised guidance **(patient self-management**). These ways of managing oral anticoagulation are summarised in the short animation below.



In summary:

**Patient self-monitoring.** This is an all-embracing term, suggesting that the patient measures their INR with a POCT device. When self-monitoring, they can either self-test or self-manage.

**Patient self-testing (PST).** The patient measures their own INR, but a healthcare professional will advise them on the dose of warfarin to take.

**Patient self-management (PSM)**. The patient measures their own INR and then interprets the result, altering their warfarin dose as necessary.

If you would like to know a little bit more about the uptake of self-monitoring of oral anticoagulation, please take a look at this *[ to extra content – global uptake]*

**12.1 Is patient self-monitoring of oral anticoagulation safe?**

Published evidence suggests that patient self-monitoring of oral anticoagulation is at least as safe as monitoring in an anticoagulant clinic (‘conventional care’). The INR control of those who were self-monitoring was at least as good as, if not better than, the INRs of those attending an anticoagulant clinic. Those who were self-monitoring their INR were less likely to have a blood clot, and also less likely to suffer from a minor bleed.

If you would like to know a little bit more about the studies that have looked at the safety of patient self-monitoring of oral anticoagulation, please take a look at this *[ to extra content – safety of PSM]*

**12.2 Are there other benefits of patient self-monitoring of oral anticoagulation?**

There may be other advantages arising from self-monitoring in addition to these clinical benefits.

Published studiesare few but do suggest the following benefits:

1. Reduction in “daily hassles”. These “daily hassles” were minor, stressful events
2. Greater confidence in tackling healthcare-related problems (improved self-efficacy).

More information on the benefits of self-monitoring is available from unpublished work:

* Greater convenience. For some people, self-monitoring gives them the freedom to travel or spend lengthy periods overseas. For others it simply frees them from attending the anticoagulant clinic.
* The reassurance of being able to check the INR when concerned
* Giving patients the ability to be able to take more control over their health.
* As an alternative to venous blood sampling. For some people, a venous sample is not possible or desirable.

**ACTIVITY**

Now take a look at this video where someone who is self-monitoring her oral anticoagulation describes her experience.

*http://www.youtube.com/watch?v=Hu553aCUh7o&list=PLkKsqqBKDBzDV\_\_r6LLUBNkvfeXVgPbZ4*

**12.3 Are there any criteria to suggest who might be suitable for self-testing of oral anticoagulation?**

Not everybody will be willing, or able, to self-test. There are no clearly defined selection criteria for patient self-testing of oral anticoagulation and no reliable way to predict who will be suitable for PST.

However, there is consensus on broad selection criteria:

1. On long term oral anticoagulation
2. Willing and motivated to accept responsibility for self-testing
3. Physical capability to self -test. This means that the person (or a carer, family member or friend) has the manual dexterity to operate the coagulometer, and has adequate eyesight to see meter’s display screen
4. Cognitive ability to self-test (or a carer, family member or friend with this ability)

Provided that the person meets the above criteria, self-testing should be considered as an option, irrespective of educational background and social status. Also, prior INR stability should not exclude a person from home testing as those with previously erratic INRs may benefit from increased frequency of testing and greater autonomy.

In September 2014, the National Institute for Health and Care Excellence [**(NICE)**](http://www.nice.org.uk/Guidance/DG14)  *(http://www.nice.org.uk/Guidance/DG14)* recommended home testing of INR as a way of monitoring warfarin treatment. Currently, the patient will need to buy the coagulometer and, in some areas, the INR testing strips used with the coagulometer are not available on prescription. The coagulometer currently costs £299.

**12.4 Should someone who has not been adherent with anticoagulant treatment or INR testing be excluded from self-testing?**

This is a contentious area.Some guidance considers previous non-adherence as a contraindication for patient self-testing. However, it is possible that self-testing may improve poor adherence with anticoagulant treatment or monitoring.

**12.5 Patient self-testing in practice**

If you would like to find out how a patient self-testing service operates in practice please go here *(-> extra content – PST process)*

**12.6 Sources of patient information**

There are also some excellent on-line resources for those considering self-monitoring, a few of which are listed below.

**Anticoagulation Europe (ACE)**

[*http://www.anticoagulationeurope.org]*

ACE is a UK registered charity that provides information, education and support to those taking anticoagulation. One of its key activities is supporting people to take a more active part in their own healthcare, including self-monitoring.

**Atrial Fibrillation Association (AFA)**

*[http://www.atrialfibrillation.org.uk]*

AFA is an international charity that provides information, support and access to established, new or innovative treatments for Atrial Fibrillation (AF), including self-monitoring of oral anticoagulation.

**13. What is near-patient testing of INR?**

Near-patient testing (NPT) is when medical testing is done at the point of care. It is also known as point-of-care testing (POCT). The development of small, portable, accurate meters allows us to use NPT to monitor the INR. The main benefits of NPT are that it is quick, and it allows INR monitoring at a convenient location.

NPTmachines to measure the INR are known as coagulometers and are being used in hospital clinics, GP surgeries, community pharmacy clinics and by patients in their own home. A test strip is inserted into the machine, the patient’s finger is pricked and a capillary blood sample is applied to the test strip. The result of the INR test is usually available within a couple of minutes.

When buying a coagulometer, it is important that you make sure that it has been tested and approved by the regulatory authorities in the UK. The coagulometer in widest use by anticoagulant clinics in the UK is the CoaguChek ® XS Plus; other machines are available.

**ADDITIONAL INFORMATION (OPTIONAL)**

For further information on near-patient testing standards, please visit the Institute of Biomedical Science (IBMS) to take a look at its guidance.

http://www.ibms.org/go/media/publications/professional-guidance

**13.1 Setting up the coagulometer and testing the INR**

It is important that you are able to set up and use the coagulometer correctly. Your local mentor will guide you on how to do this*.*

**DEMONSTRATE YOUR SKILL**

It is important that you are able to set up your coagulometer and perform an INR test. Your local mentor will assess how you perform the task.

**13.2 Which factors affect the accuracy of INR readings?**

It is also important that you are aware of some factors that can affect the accuracy of an INR fingerprick test.

A fingerprick sample may give a lower INR reading if you squeeze the finger when trying to get a blood sample. When you do this you may squeeze out clotting factors. If necessary, the finger should be ‘milked’ rather than squeezed to get a blood sample.

Some medical conditions may interfere with the fingerprick INR test. These include cancer, iron deficient anaemia and anti-phospholipid antibodies. The manufacturer provides more comprehensive information with the coagulometer.

**13.3 How are coagulometer quality assured?(QA)**

As a practitioner providing INR results to patients, having confidence that the machines produce the same accurate replicable results as a hospital laboratory is essential. To ensure this, two quality assurance tests – the internal quality assurance (IQA) and the External quality assurance (EQA) – are used.

**13.3.1 Internal QA**

*‘Am I 100% confident that my results are the same today as they were*

*yesterday or the week before?’*

Internal QA measures the precision of the machine. The CoaguChek ® XS Plus strips have an ‘on board’ strip control which reports the quality control result as a pass or a fail which is represented by a tick or an error message respectively. However, for the purposes of strict clinical governance, the IQA needs to be recorded as a quantifiable number using the liquid control (IQA solution) purchased from the manufacturer. Further information and a demonstration of IQA use will be provided to you by your local mentor.

**DEMONSTRATE YOUR SKILL**

It is important that you are able to perform an IQA test. Your local mentor will guide you on how to do this and will assess how you perform the task.

**13.3.2 How often should I perform IQA?**

There is no fixed rule. This will often be stipulated in local policy or in the service level agreement between the Clinical Commissioning Group and your service. You should clarify this before initiating anticoagulation clinics if this is not stated or clear.

Roche has suggested the following protocol for practitioners using the their Coaguchek ® devices. The frequency of IQA will depend on the volume of patients (and this equates to the number of strips used per clinic) attending over a given period i.e. a week/month.

- If a box of test strips (i.e. 48 strips) is used up in one anticoagulation clinic session, then the IQA needs to be performed before each clinic session.

- If a box of test strips is used in one week of clinic sessions i.e. 48 tests per week, then the IQA needs to be done weekly

- If a box of test strips is used in one month of clinic sessions i.e. 48 tests per month, then the IQA needs to be done monthly.

- If it takes longer than a month to use up a box of strips, then the IQA still needs to be done on a monthly basis as a minimum.

Other times when IQA needs to be performed are as follows: on changing to a new batch of strips, in the event that the machine may be damaged e.g. by a fall or water damage, and most importantly, in the event that you get an unusual INR result.

**13.4 External QA**

‘*Are my results the same as other centres doing the same test on the same machines?’*

External QA measures the accuracy of the machine. As a number of errors can occur in determining the INR in the laboratory, a National External Quality Assessment Scheme (NEQAS)is in place to monitor laboratory performance in order to reinforce standardisation. NEQAS is active in the near-patient testing field, and their services are offered to clinics. Quality control materials are available from the manufacturer to check instrument performance on a more frequent basis. NEQAS compares your result with many other users of the same machine

INR testing undertaken outside of laboratories utilising POCT devices should apply the same standards of total quality management as practiced in hospital based laboratories. These devices should only be used by trained personnel with support from an external quality assessment scheme such as NEQAS or a local hospital laboratory.

Alternatively, if the clinic is affiliated with a hospital, POCT devices can be externally quality assured through the hospital laboratory, with results collated and passed onto the local POCT testing committee. Check with your local hospital to ascertain whether this service can be provided. Costs will vary.

**13.4.1 What should I do if a machine fails its QA test?**

Prompt action is necessary should the machine fail an IQA or EQA. Failed machines should not be used until they have passed the appropriate test. It is the responsibility of the local clinic to quarantine their machines until repaired or confirmed safe to use. Clinics are advised to have two machines; in the event of one machine failing, the spare machine is available as a back-up.

At Whittington Health, there are standard operating procedures in place, in case such events happen. However, it is rare for a machine to fail and a more likely reason is human error - i.e. inadequate storage of IQC solution or incorrect reconstitution of the samples before performing the tests. The local hospital laboratory to which your practice is connected to can advise in the event of a failure and also the manufacturer of the device you use in practice can advise you, via their dedicated Point of Care testing team who are on hand to help you through problems.

If you are using the Coaguchek ® XS Plus machine, a support telephone line is available. The telephone number is 01444256000.

**POINTS TO PONDER**

Consider the following scenario. Despite your machine failing its QA (either IQA or EQA), you continue to use it in your practice on patients taking warfarin.

What are the implications of your actions? How accurate are the results being produced by your device? Who takes responsibility for the consequences of providing advice on potentially inaccurate INR results?

**13.5 How do I look after my coagulometer and testing strips**

Please refer to the manual supplied with your machine for care advice. The testing strips for both CoaguChek® XS Plus can be stored at room temperature for 12 months.

**14. Why is clinical governance important?**

As an anticoagulation practitioner, you are accountable for continuously improving the quality of your service and for safeguarding high standards of patient care. A robust clinical governance structure is important for the following reasons:

* It supports the delivery of a high quality and effective service.
* It ensures that appropriate staff are recruited and trained to deliver the service
* It ensures that audit is regularly conducted
* It puts in place processes and support to effectively handle adverse incidents
* It enables multidisciplinary working.
* It provides commissioners and managers with evidence of a high quality service
* It encourages a culture where learning from mistakes can thrive and where good practice is celebrated

**Case study: North Central London Anticoagulation and Stroke Prevention services**

The North Central London Anticoagulation and Stroke Prevention Service (NCLASP) comprise services delivered in primary and secondary care. NCLASP is underpinned by a robust clinical governance framework, and has established a Clinical Governance Board.

Membership of this Board includes patients; hospital consultants (haematology and cardiovascular); anticoagulant practitioners from each CCG; senior pharmacists with educational remit; senior pharmacists with governance remit; a commissioner from each CCG; a clinical GP lead from each CCG; an academic health informatist; an academic behavioural scientist and statistician; an academic legal advisor; an IT representative from Whittington Health.

The Clinical Governance Board reports to the Clinical Governance Boards in the hospitals as well as the Medicines Management Boards within the CCGs.

The clinical governance support offered to all clinic sites includes the following:

i) Advice on complying with NPSA guidance in a community setting together with audit.

ii) Access to INR result information by site, by INR range across the whole of North Central London Community sites. The Board receives anonymised INR data across all delivery sites in NC London – this forms a rich perspective of the anticoagulant and stroke prevention service by site, by target INR range and by total service. It helps the declared intent that the service standards should aspire to be the same high quality for the whole of North Central London.

iii) Access to collated information relating to NEQAS results and other quality measures

iv) Access to quality measures of the educational processes

v) Involvement in novel techniques to explore quality in service delivery and benefit from the learning that accrues; these techniques include “Root Cause Analysis”, “Cognitive Work Analysis”.

vi) Access to Clinical Standard Operating Procedures (CSOP) and Site Specific Operating procedures (SSOP).

vii) Optional central clinical monitoring service, for audit and governance, by our anticoagulation experts

viii) Optional clinical support telephone/email service.

ix) Optional site visits to troubleshoot or provide support

**WHAT HAPPENS NEAR ME?**

Do you know the clinical governance arrangements for your local anticoagulant service? What do you consider are the strengths and weaknesses of this approach? How could it be improved?

**14.1 NPSA – Quality standards for anticoagulation therapy**

The National Patient Safety Agency (NPSA) published a report in 2006 ‘Risk Assessment of anticoagulant Therapy.’ The report was developed after reports from hospital and the community highlighted that anticoagulants were a class of medication most commonly associated with fatal medication errors.

The NHS Litigation Authority reported that medication errors involving anticoagulants fell within the top10 causes of claims against NHS Trusts and between 1996 and 2002, there were 480 cases of avoidable patient harm from the use of anticoagulants. In addition, 120 of these were fatal – 77% were related specifically to warfarin use.

A further NPSA guideline followed and was published in 2007 ‘Actions that can make anticoagulant therapy safer – Patient safety alert’. This recommended actions to reduce the risk of avoidable patient harm.

1. Ensure all staff have received appropriate training and have the required work competences
2. Undertake regular service audit; act on audit results to improve anticoagulation service.
3. Review and update written procedures and clinical protocols
4. Be aware of potential interactions and how you should manage patients who take interacting drugs.
5. Ensure patients are educated about anticoagulation at discharge, at the first clinic appointment and throughout treatment course
6. Ensure patients receiving dental treatment are managed in an evidence-based way.
7. Ensure INR is checked before issuing or dispensing anticoagulant prescriptions.
8. Standardised supply/use of 1mg, 3mg, 5mg (some CCGs do not allow routine prescribing of 0.5mg)
9. Promote the use of safe written procedures for the administration of anticoagulants in social care settings

**NPSA – Actions that can make anticoagulation safer**

**Required reading**

Now please review the NPSA’s ‘Actions that can make anticoagulant therapy safer’ available at <http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814>. Note that the NPSA has now transferred to the NHS Commissioning Board Special Health Authority)

**WHAT HAPPENS NEAR ME?**

This NPSA action list should be considered when implementing and reviewing oral anticoagulation services. How does your service comply with these recommendations? Draw up a brief list of action points needed to ensure that your service complies with these recommendations.

**14.2 How do we measure the quality of anticoagulant treatment?**

Ongoing audit of anticoagulation control is essential to ensure the safety of the service. The NPSA (now the National Reporting and Learning System in the NHS Commissioning Board Special Health Authority) has determined audit criteria to assess the quality of anticoagulant treatment.

* Percentage of patients suffering adverse outcomes, categorised by type, e.g. major bleed
* Percentage of INRs >1.0 unit below target
* Percentage of INRs >5.0
* Percentage of INRs >8.0
* Proportion of patient-time in therapeutic range **or** the percentage of INRs in range

**NPSA audit criteria for assessing the quality of anticoagulant treatment**

The British Committee for Standards in Haematology recommend that an individual patient should be in-range **at least 60%** of the time.

For an individual patient, the time in therapeutic range (TTR) is the preferred measure of INR control. This involves linear interpolation of the observed INR values for each patient. TRR is defined as the number of patient days spent in therapeutic range divided by the total number of patient days in same time period period.

1. Plot INR results against time
2. Draw straight lines between INR results in order to calculate an interpolated INR for every day.
3. Pick time interval. Take number of days in range divided by total person-time

**Calculating time in therapeutic range (TRR)**

Although subject to less bias, TTR is not without limitations. This calculation assumes a linear relationship between individual INR results, and the reality is that the INR will fluctuate between tests. In addition, small departures from the target range are treated exactly the same as larger deviations. Whilst the former will have little impact on event rates (i.e. thromboembolism / bleeding), the latter have a potentially greater impact.

The proportion of INRs in range in a given period of time is a satisfactory measure to assess the control of a clinic population. This is derived by dividing the number of INR values in therapeutic range by the number of INR tests (x100).

Of the two methods, the percentage of INR tests in therapeutic range is far more simple to calculate, However, it is easily influenced by the frequency of monitoring.

**WHAT HAPPENS NEAR ME?**

How does your service monitor the quality of INR control for its population? Are the results of these audits acceptable to you?

**14.3 Why is educational governance important?**

Educational preparation for anticoagulation practitioners is essential to ensure safe and effective practice. They need to have a clear understanding of the basics of coagulation / anticoagulation, the pharmacology and pharmacokinetics of oral anticoagulants and operational processes underpinning anticoagulant and stroke prevention services. In addition to these knowledge-based elements, they need to develop skill in responding to INRs and patient symptoms.

**Case study: The approach to educational governance in North Central London**

Over the past 14 years Whittington Health has developed a comprehensive anticoagulation education programme, which forms the basis of the programme offered here by HeliconHealth. This delivers both knowledge and skills-based teaching in a classroom setting, supplemented by practical exercises and case studies.

Pivotal to this learning experience is the subsequent experiential learning, where the student sits in on clinic sessions providing them with the opportunity to practice these skills in a real-life, supervised and supported environment.

The quality of this educational process is ensured by a competency-based OSCE (Objective Structured Clincal Examination), which the student needs to pass before practicing in North Central London.

A reaccreditation process is also in place. Practitioners are required to pass a mini-OSCE every two years to continuing practicing.

**14.4 Are there other safety indicators that should be monitored?**

The NPSA has suggested a number of other indicators that may be used to monitor the safety of an anticoagulant service. These can be viewed by accessing ‘Actions that can make anticoagulation safer’(<http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814>).

Additionally, if near-patient testing is used in your clinic, external and internal QA results for the coagulometer should be audited.

**Optional further reading**

Kaatz S (2008). Determinants and measures of quality in oral anticoagulation therapy. *J Thromb Thrombolysis*, **25**: 61-6.

http://link.springer.com/article/10.1007%2Fs11239-007-0106-9

Rosendaal F, Cannegieter S, Van Der Meer F, Briet E (1993). A method to determine the optimal intensity of oral anticoagulant therapy. *Thromb. Haemostas.*, **69**(3): 236-9.

(not available on-line)

**14.5 How can HeliconHeart support clinical governance?**

Monitoring and performance measurement tools are increasingly critical for providers and purchasers of care. HeliconHeart has a powerful clinical governance tool based on sophisticated analytics.

* It gives anonymised access to INR results at practitioner, site, clinical commissioning group (CCG) and total service level.
* It also gives support and oversight of the quality assurance (QA) assessments of near-patient testing devices on all sites. This enables comparison to be made between sites and encourages an equitable, high-quality service to be developed across multiple sites.
* The real-time data can be queried on a wide range of measures, including therapeutic range, age or date. It can also be compared with historical data from the past 20 years.

*(audit data.ppt)*

HeliconHeart is also able to display the INR control by showing the distribution of INR as a distance from the INR target – this enables a fuller picture of the performance of the site or the service. The narrower the distribution is the better the anticoagulation control – the “tails” need also to be small for a high quality control service.

*Placeholder for a distribution curve coming from heliconheart*