



**HEALTHY  
FUTURES**

Better health for all across  
the West Yorkshire region



# Stroke Programme

**Atrial Fibrillation Project**

Anticoagulation Service

Opportunity Assessment

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# 1.0 Background and Context

- AF is a significant stroke risk and West Yorkshire has an anticoagulation treatment gap of 40%;
- Work collaboratively commissioned by the 10cc and the Healthy Futures Programme Board seeks to significantly increase the levels of anticoagulation in West Yorkshire thus reducing the number of strokes;
- There are approximately 15,000 untreated patients to medicate and closing this treatment gap will create significant demand for the existing anticoagulation services;
- This peak in demand will need to be managed and as part of the collaborative project we chose to perform a baseline assessment of the eight existing anticoagulation services to understand both their capacity to deal with this demand and the quality of the services provided;
- The report identified a number of recommendations and opportunities that were summarised into 3 categories, Service Redesign, 10cc Collaboration and Local CCG Implementation;
- The Healthy Futures Programme Board directed the project to explore two specific opportunities further, **Patient Self-Testing** and **Point of Care Testing**;
- This document is the requested output from exploring these two opportunities.

# 2.0 Patient Self-Testing

# Description: Patient Self-Testing

- Patient self-testing allows a patient to test their International Normalised Ratio (INR) themselves at home or at a place and time convenient to them using a simple quick finger-prick test. The number of visits can vary depending on the stability of the patient's INR, but can be up to around 20 times per year;
- Patients perform their own INR tests using portable coagulometers and then either determine their own dose adjusts (self-management) or place a phone call into the anti-coagulation service to provide their results and have it determined for them;
- NICE has recently assessed 2 point-of care coagulometers, the CoaguChek XS system and INRatio2 PT/INR monitor, and recommended them for use by people taking long-term anti-coagulation therapy who have atrial fibrillation (AF). It also states "the accuracy of both monitors are comparable to laboratory-based INR testing";
- The availability of patient point-of care coagulometers presents an opportunity to provide flexible and efficient patient focused care;
- The main advantage is that it gives patients the freedom to carry on with their daily lives, without the restrictions of having to attend anticoagulation clinics, either at their practice or local hospital;
- Self-management allows a person to test their INR at home and then adjust their own warfarin dosage (within set limits). Collectively, self-testing and self-management are known as patient self-monitoring;
- In a 2011 survey, 70% of people on long-term warfarin therapy found regular clinic visits inconvenient (*AntiCoagulation Europe and Roche Diagnostics survey of people on long-term warfarin, AFA*);
- There are more than 1.2 million people in the UK on warfarin therapy, of whom fewer than 2% benefit from self-monitoring of their INR level;
- "Self-management improves the quality of oral anticoagulation. Patients capable of self-monitoring and self-adjusting therapy have fewer thromboembolic events and lower mortality than those who self-monitor alone."  
*Source: Self-monitoring of oral anticoagulation: a systematic review and meta-analysis. Lancet 2006*

# Description: Patient Self-Testing (PST)

- The number of visits can vary depending on the stability of the person's INR, but can be up to around 20 times per year;
- One third (34%) of CCGs allow people to self-test their INR level and 28% of all CCGs allow self-management (which included self-testing);  
*Source: Anti-coagulation services and patient access to INR self-monitoring in the NHS in England: Anti-coagulation Self-Monitoring Alliance, July 2014);*
- CCGs which currently allow self-testing include Oxford, Ashford, Great Yarmouth & Waveney, Bromley, Ealing, Sandwell & West Birmingham, Durham Dales, and Easington & Sedgfield;
- CCGs could consider exploring opportunities to use this technology as it could reduce net service demand, provide greater patient choice and flexibility, and provide a practical alternative to servicing geographically dispersed communities.

## Opportunity Self Assessment: Extract from West Yorkshire AC Clinic Provision Baseline Report

	Bradford	Leeds	N.Kirklees	G. Hudd.	AWC	HaRD	Calderdale	Wakefield	SUMMARY
Patient Home Testing	M	H	M	M	M	M	H	M	M

**L:** Low Degree of Opportunity for Service

**M:** Medium Degree of Opportunity for Service

**H:** High Degree of Opportunity for Service

# Case Studies Summary

## Current State

- Only 28% of CCGs allow patients to self-manage and only 34% allow them to self-monitor;
- There is a disconnect between national Government policies which are supportive of greater self-management and poor implementation of those policies at a local NHS level;
- CCGs policies for the NHS prescription of self-testing strips are inconsistent.

## Future State

- All suitable patients are given the choice to self-monitor their INR levels;
- Consistent availability of prescriptions for self-testing strips across CCGs;
- Provision of accessible clinical dosing support for self testers;
- CCGs working collaboratively to procure self-testing service and deliver economies of scale.

Title	Insights
<b>Self-Testing Based on Long Term Experience</b>	<ul style="list-style-type: none"> <li>• Home monitoring for warfarin therapy shows excellent time in therapeutic range;</li> <li>• Weekly testers achieved TTR of 74% versus 68.9% for variable testers;</li> </ul>
<b>Review &amp; Analysis of Individual Patient Data</b>	<ul style="list-style-type: none"> <li>• Self-monitoring and management of anticoagulation is a safe option for suitable patients of all ages;</li> <li>• Patients should be offered the option to self-manage their disease with suitable health-care support;</li> </ul>
<b>Teaching Patients to Self-Test</b>	<ul style="list-style-type: none"> <li>• At-home coagulation testing among AF patients receiving warfarin led to improved outcomes versus traditional self-testing management as well as enhanced clinical efficiencies and reduced costs;</li> </ul>
<b>Great Western Hospital, Swindon</b>	<ul style="list-style-type: none"> <li>• Hospital run anti-coagulation service supports and enables self-testing;</li> <li>• Delivering faster results, better outcomes and increased patient satisfaction;</li> </ul>
<b>Basildon Hospital: Monitoring Pioneers</b>	<ul style="list-style-type: none"> <li>• Basildon Hospital runs one the biggest self-testing programmes in the country with 270 patients;</li> <li>• Provision of accessible clinical dosing support for self testers via phone or email;</li> </ul>
<b>County Durham FT: Telehealth Solution</b>	<ul style="list-style-type: none"> <li>• A three-way partnership between Roche, providing home testing technology, software company InHealthcare, providing CDSS, and County Durham Foundation Trust.</li> </ul>

# Self-Testing Based on Long Term Experience

Patient self-testing at home achieves high-quality warfarin therapy outside of clinical trials and compares favourably with the results achieved in anticoagulation clinic settings

**Aim:** A retrospective analysis to determine the quality of warfarin therapy as determined by time in therapeutic INR range (TTR) in patients who perform home monitoring outside of a clinical trial setting.

**Approach:** The database (29,457 patients with multiple indications for warfarin therapy) of an independent diagnostic testing facility was retrospectively queried over a 2.5-year period (January 2008-June 2011) and patient TTR was analysed based on frequency of testing, age, gender, indication for therapy, duration of therapy, and critical value occurrence.

**Outcomes:** The mean TTR for the entire group was 69.7%, with weekly testers achieving a TTR of 74% versus 68.9% for variable testers (testing every 2-4 weeks) ( $P < .0001$ ). In all categories analysed (age, indication for anticoagulation, and referral site volume), weekly testers performed significantly better than variable testers. Older individuals had a higher TTR than younger patients. Weekly testers experienced significantly fewer critical values (INR  $< 1.5$  or  $> 5.0$ ) than did variable testers.

## Learning / Critical Success Factors:

- Home monitoring for warfarin therapy shows excellent time in therapeutic range;
- Patients are able to monitor their own warfarin therapy outside of a clinical trial setting;
- For patients self-monitoring, the high rate of time in therapeutic range and limited extreme INR values indicates the potential to reduce adverse events with warfarin therapy;
- The model offers the potential to improve quality of life for patients on warfarin therapy, to reduce physician work, and may ultimately lead to an increase in treatment of patients who are not currently being treated.

*Source: STABLE Results: Warfarin Home Monitoring Achieves Excellent INR Control, The American Journal of Managed Care, 2014, Vol. 20(3)*

# Review & Analysis of Individual Patient Data

Self-monitoring and self-management of oral anticoagulation is a safe option for suitable patients of all ages. Patients should be offered the option to self-manage their disease with suitable health-care support as back-up.

**Aim:** To clarify the value of self-testing and self-monitoring of oral anticoagulation set in a context of inconsistent uptake despite good evidence of their effectiveness.

**Approach:** Searched Ovid versions of Embase (1980–2009) and Medline (1966–2009), limiting searches to randomised trials with a maximally sensitive strategy. Approached all authors and requested individual patient data: primary outcomes were time to death, first major haemorrhage, and first thromboembolic event. Undertook a pre-specified subgroup analyses according to age, type of control-group care (anticoagulation-clinic care vs primary care), self-testing alone versus self-management, and sex. Analysed patients with mechanical heart valves or atrial fibrillation separately. Used a random-effect model method to calculate pooled hazard ratios and did tests for interaction and heterogeneity, and calculated a time-specific number needed to treat. Of 1357 abstracts, 11 trials with data for 6417 participants and 12 800 person-years of follow-up were included.

**Outcomes:** Reported a significant reduction in thromboembolic events in the self-monitoring group but not for major haemorrhagic events or death. Participants younger than 55 years showed a striking reduction in thrombotic events, as did participants with mechanical heart valve. Analysis of major outcomes in the very elderly showed no significant adverse effects of the intervention for all outcomes.

## Learning / Critical Success Factors:

- Provide choice to patients to self-manage their disease with suitable health-care support as back-up;
- Self-monitoring and self-management is a safe option for suitable patients.

*Source: Self-monitoring of oral anticoagulation: systematic review and meta-analysis of individual patient data, Lancet 2012; 379: 322–34*

# Following Protocol: Teaching Patients to Self-Test

At-home coagulation testing among atrial fibrillation patients receiving warfarin led to improved outcomes versus traditional self-testing management, as well as enhanced clinical efficiencies and reduced costs.

**Aim:** To assess the impact on outcomes of undertaking at-home coagulation testing regime using a management by exception protocol for patients with AF receiving warfarin versus traditional self-testing management.

**Approach:** An outpatient “management by exception” protocol was used where patients followed specific clinic-issued, written instructions for managing out-of-range International Normalized Ratio (INR) self-test results within predetermined safety range. With traditional self-testing, clinicians typically call all their patients for re-management regardless of how close they were to their target. Four study centers enrolled (72 patients) with target INR of 2.0 to 3.0 in the 6-month protocol, during which they self-tested weekly and reported their results via telephone. They were contacted by their clinic only if their INR results were less than 1.8 or greater than 4.0. INR. Results were compared with those from each patient’s previous 6 months, during which traditional self-testing testing and follow-up was conducted.

## Outcomes:

- 33% reduction in dangerously low and high INR test results thus dramatically reducing the risk of bleeding and thrombotic events;
- Eliminated the need for 350 telephone outbound calls to patients, which led to improved satisfaction scores among both patients and clinics, and could potentially free up staff to spend more time caring for patients at higher risk;
- Realised a total cost savings of \$2062.50 among the 4 participating clinics during the short 6-month window of the study.

## Learning / Critical Success Factors:

- Management by Exception protocol can effectively automate patient care, without increasing patient or practice risk, while empowering patients to be a partner in their care;
- Self-testing with Management by Exception enhanced the safety of warfarin therapy.

*Source: Burgwinkle P, Pigott V, Liska G, Koshy T. Follow the protocol: teaching patients to self-test. Nursing 2014. 2014;44(3):20–22.*

# Great Western Hospital, Swindon

Delivering faster results, better outcomes and increased patient satisfaction, as more and more patients take control of their own care.

**Summary:** The anticoagulation services has evolved over time to become a dynamic anti-coagulation service. Critical in its development has been the successful pilot and resultant rollout of portable INR testers which take blood to test INR's giving the result within a few minutes. The number of anti-coagulated patients of the clinic has increased over the years, and they now have 3,500 patients on their case load of which 151 patients (4.4%) self-test. The service adopted a pro-active approach to self-testing and became the regional training centre for the South West and a provider of training in the use of the INR tester for its community phlebotomist to facilitate INR sampling for patients who had poor venous access and would normally require patient transport to attend the clinic. They offer a loan scheme as some patients cannot afford the meter.

## Outcomes / Benefits:

- Better warfarin control, with an average increase in their % TTR from 59% to 77% (based on 24 test results);
- Increased patient empowerment;
- Greater convenience and quality of life as patients are able to test their INRs at a place of convenience;
- Reduction in the amount of time and money spent travelling.

## Learning / Critical Success Factors:

- **Assessment of Suitability:** Self testing is not suitable for every patient and ideally this should be agreed between the patient, family or carer and their GP. Patients who are on long-term warfarin will be more likely to invest in a meter.
- **Staged Patient Empowerment:** Adopt a process of asking the patient to suggest their own warfarin doses, and gradually, as their experience and knowledge increases, allow them to self-manage.
- **Appropriate Training:** Once a patient has their INR tester, they should be encouraged to watch the DVD and practice.
- **Accessible Support:** Access to a dedicated care line or the anticoagulation clinic to ensure patients feel reassured that they are dosing correctly.
- **Clear Protocols:** These need to be developed to guide a range of issues from the testing period, reporting procedures and patient actions.

Source: *Anti- Coagulation Self-Monitoring Alliance - NHS Case Studies*

# Basildon Hospital: Blood Monitoring Pioneers

Improving safety and proving patients with greater more independence

**Summary:** Basildon Hospital runs one the biggest self-testing programmes in the country with 6%of the trusts 4,500 warfarin patients taking part in self-testing through the use of pocket sized coagulometers (typical cost of a new meter is £300 per device, and testing strips are £65, which may be prescribed by GPs). The national average for self-testing is two per cent. Patients who self-test measure their clotting levels by applying a pin-prick spot of blood to a testing strip. This is fed into the monitor for a reading, which the patient then telephones or emails to the anticoagulation nurses for dosing.

## Outcomes / Benefits:

- Greater patient independence and reduction in travelling time waiting for blood tests in clinics;
- Increased convenience for patients and patient safety. Patients less likely to miss tests, greater patient compliance as previously many check up appointments would be missed or cancelled due to personal or work commitments.

## Learning/Critical Success Factors:

- **Quality Assurance:** Patients have to attend an appointment every 9 months to have their machine quality assured;
- **Patient Suitability:** Adoption of self testing may not be suitable for patient on warfarin in the short term due to the investment costs;
- **Accessible Support:** Provision of accessible clinical support for self testers.

## Sources

- [www.pacehealthsystems.com/inr\\_intro.html](http://www.pacehealthsystems.com/inr_intro.html)
- [www.basildonandthurrock.nhs.uk/media-centre/1132-basildon-hospital-helping-patients-take-control-of-their-care](http://www.basildonandthurrock.nhs.uk/media-centre/1132-basildon-hospital-helping-patients-take-control-of-their-care)
- [www.thetelegraphandargus.co.uk/news/11775445.Blood\\_monitor\\_pioneers](http://www.thetelegraphandargus.co.uk/news/11775445.Blood_monitor_pioneers),
- [www.echo-news.co.uk/news/11775445.Blood\\_monitor\\_pioneers](http://www.echo-news.co.uk/news/11775445.Blood_monitor_pioneers)

# County Durham FT: Telehealth Solution

Remote monitoring of patients taking warfarin avoids the time, expense and disruption of having to continually attend clinics for tests – and points to a way forward for telehealth for other conditions.

**Summary:** The Trust piloted a telehealth solution for six months, a novel approach that could redefine both how patients on warfarin can take more control of their condition and how we think about telehealth. A partnership was been set up with Roche, which provides home testing technology, and software company InHealthcare. The patient self-tests at home on an agreed date, reports the results/clinical symptoms to an automated system and then waits for an automated call at a time they have chosen. These results are automatically fed to a web portal at the hospital for review by a clinician. It took six months to establish the pilot, designing the operating procedures and clinical governance and starting the recruitment of patients. 100 people were recruited from two main groups, people who worked and had to take time off work to come to clinic and retired people who travelled a lot.

## Outcomes / Benefits:

- Positive feedback from patients and people are queuing up to join;
- A small number dropped out after the first training session, once they understand how it works, and who decide that it is not for them;
- Save patients time and money (less travel expense) and involves less disruption to daily life;
- Increased time in therapeutic range;
- Creation of healthcare professional capacity to see those patients with more complex cases who require face to face care.

## Learning/Critical Success Factors:

- **Patient Suitability:** There are people for whom this system might not work, e.g. people who are hard of hearing might and people who have problems with dexterity and keying numbers into a telephone;
- **Appropriate Training:** Appropriate training needs to be in place so that patients can learn the technique and provide assurance to the providers that they have it correct. Self monitoring should not commence until a patient is deemed competent.

*Source: Innovation Through Technology, HSJ Supplement, July 2013*

# Potential Benefits for West Yorkshire

## Clinical Benefits

- Self-testing with coagulometers is convenient for patients and would reduce the frequency of visits clinics for patients (and associated costs, inconvenience and waiting times for laboratory results) whilst enabling them to more frequently monitor their INR;
- 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 inappropriate dose such as stroke and major haemorrhage;
- Self-monitoring enables people to spend more time within their therapeutic range (TTR). 80% of poorly controlled patients moved into the well-controlled category after starting self monitoring. The average improvement of TTR was 16.8%. *Source: HSJ - Evaluation of self-testing for warfarin patients - Nov 2013;*
- Several studies have shown that patient self-monitoring improves the quality of oral anticoagulant therapy. Those who self manage have fewer thromboembolic events and lower mortality rates. *Source: Self-monitoring of oral anticoagulation: a systematic review and meta-analysis. Lancet 2006;*
- Reduced demand pressures on anticoagulation clinics would allow scarce resources to be prioritised and focussed on the more complex cases;
- Studies show if patients were offered self-testing about 25% of those who are stable would readily take up the self-management approach, *Source: Data on file Atrial Fibrillation Association, AntiCoagulation Europe 2011;*

# Potential Benefits for West Yorkshire

## Patient Benefits

- It has been shown that 77% of people taking warfarin preferred patient self-monitoring\* to the usual model of care and that fewer consultations and hospital admissions are required when self-monitoring. In short, self-monitoring enables:
  - *People taking warfarin to spend greater time in their therapeutic range;*
  - *The ability to test their INR when it is convenient to them;*
  - *Better health outcomes as it reduces the risk of blood clots and bleeding;*
  - *Freedom to travel for business or pleasure;*
  - *People to stay in control of their life;*

*\*Source: Gardiner C et al, Patient self-testing is a reliable and acceptable alternative to laboratory INR monitoring, British Journal of Haematology, 2004*

- Self-testing would also empowers the patient and increases the emphasis on their role and involvement in the active self-management of their condition . This in turn supports the vision set out in the West Yorkshire Atrial Fibrillation Anticoagulation Strategy;

## Financial Benefits

- The capital costs related to the coagulometers and testing strips make self-testing comparatively expensive when compared against laboratory testing. A model typically employed is that the patient pays for the coagulometers with the testing strips on are provided on prescription.

# Patient Voice

**Norman** had his heart valve replaced in 1994, which involved hospital visits every one to two weeks, often having to wait up to two and a half hours at a time. All that changed in 2008 when Norman started self-monitoring his INR levels. This followed a joint decision by Norman, his clinic pharmacist and GP, who throughout the whole process provided fantastic support. The GP has willingly provided test strips, which not all GPs do.

Since he began self-monitoring, Norman feels very much in control of his INR, as he has been in therapeutic range 90% of the time. Self-monitoring has given Norman greater knowledge, which has made him more aware of why there is a need for regular testing and the confidence to challenge medical staff when he thinks things are not quite right. Norman said: “My 20 years’ experience of measuring my INR has shown me that too much time is spent on regulations and not enough on educating INR patients of opportunities and benefits from increased involvement and responsibility to share control”.

**Angela** has an artificial heart valve and has been on warfarin for 26 years. For the last 10 years Angela has been able to self-monitor, which was a life changing experience.

Before self-monitoring Angela was having her INR checked once or twice a week as her INR level was fluctuating so much, which was always making her feel as though she must be ill. While being tested at hospital clinics the regular hospital trips were taking three to four hours, which was having a huge impact on the quality of her life and meant that she was frequently having to take time off work. As a consequence her work colleagues knew about her medical condition. Angela felt powerless as she couldn’t do anything to look after herself, and had to wait until the next day to get her INR results.

Self-monitoring has changed all this as Angela now has a sense of control and confidence, her INR level is more stable, and people she works with don’t know about her medical condition unless she chooses to tell them. Despite self-monitoring for the last 10 years there are still some challenges, particularly with prescription of test strips which is becoming a regular battle with Angela’s surgery due to pressure from her local CCG. Angela said: “Self-monitoring has provided me with a far brighter future as it has allowed me the freedom to do what I want, when I want, rather than having to base my life around hospital appointments”.

# 3.0 Point of Care Testing

# Description: Point of Care Testing (PoCT)

- In respect to anti-coagulation services Point of Care Testing (PoCT) refers to the International Normalised Ratio (INR) testing of patients blood who are receiving warfarin therapy to measure how long it takes to clot. This is performed in the clinical setting by non-laboratory healthcare professional;
- The results are available immediately and can be linked with computer decision support software (CDSS) that automatically recommends the patient's next dose of warfarin and the timeframe for the next test;
- The use of PoCT and dosing reduces both the risk of delays to initiating treatment in patients with extreme INR scores and the risk of dosing errors or mistakes in transmitting results of INR tests to patients;
- Anti-coagulation services can replace laboratory centric testing models and incorporate this into local services thereby reducing risks and improving patient service and outcomes. This can also be combined with exploring the provision of printed dosing instructions to patients at the time of their INR test;
- The National Patient Safety Agency (NPSA) suggests that the likelihood of dosing errors is greatly reduced where patients are given printed dosing instructions at the time of their INR test;
- The use of PoCT outside of acute settings can also significantly reduce patient waiting times;
- The disadvantage with PoCT compared with laboratory testing is the increased cost of each test performed at the PoCT is approximately three times greater than that of conventional laboratory testing.

## Opportunity Self Assessment: Extract from West Yorkshire AC Clinic Provision Baseline Report

	Bradford	Leeds	N.Kirklees	G. Hudd.	AWC	HaRD	Calderdale	Wakefield	SUMMARY
Point of Care Testing	L	L	M	L	H	H	H	M	M

**L:** Low Degree of Opportunity for Service

**M:** Medium Degree of Opportunity for Service

**H:** High Degree of Opportunity for Service

# Case Studies Summary

## Current State

- Patient waiting time of several hours for results or a next day service;
- Significant clinical risk for patients with high or low INR scores leaving clinics untreated;
- Transcription errors made during the communication of INR test results.



## Future State

- Immediate availability of diagnostic INR test results;
- Reduction in transcription errors;
- Additional capacity created in acute settings for the management of complex cases;
- Provision of patient-centric care closer to home.

Title	Insights
Surrey PCT	<ul style="list-style-type: none"><li>• PCT uses non-laboratory staff in primary care settings to deliver PoCT of patient INRs;</li><li>• Combination of Roche Coaguchek XS Plus devices and INRstar CDSS;</li></ul>
Leeds Teaching Hospitals	<ul style="list-style-type: none"><li>• Anti-coagulation service launches PoCT from 1st April 2015 across 12 spoke sites;</li><li>• LTHT improves patient services and significantly reduces the turnaround time for acquiring results;</li></ul>
Plymouth Hospitals	<ul style="list-style-type: none"><li>• Delays in the laboratory processing of patient results overcome through the deployment of PoCT for patient INRs;</li></ul>
Sheffield Community Pharmacy	<ul style="list-style-type: none"><li>• Sheffield establish a network of community pharmacists to provide PoCT of patient INRs;</li><li>• Being locality based rather than practice based ensures a sufficiently high volume to be cost efficient;</li></ul>

# Surrey PCT - Anticoagulation Monitoring

**Aim:** To provide standardised and clinically effective anticoagulation management in GP practices to patients by means of Point of Care Testing (PoCT) and Computerised Decision Support Software (CDSS).

**Summary:** Using the Roche Coaguchek XS Plus device and INRstar software (CDSS providing patient dosing and review period suggestions driven by peer-reviewed maintenance algorithms, as well as TTR analysis and reporting) the anticoagulation service provided non-laboratory staff in primary care settings to deliver PoCT of patient INRs. Patients start anticoagulation in secondary care until such a time as the patients INR is stable (at least 3 consecutive INRs within 0.5 of target INR) and are then transferred into primary care for management.

## Outcomes / Benefits:

- Accessible, safe, effective anticoagulant monitoring at the point of patient care;
- Optimised management of INR control decreasing the risk of a thrombo-embolic events by maintaining patient INRs at optimal levels of therapy without producing an unacceptable risk of haemorrhage;
- Improved primary/secondary care interface resulting in a streamlined service that benefits patients.

## Learning/Critical Success Factors:

- Staff who are to use PoCT equipment needed to be appropriately trained and follow appropriate standard operating protocols for interpreting results and dosage requirements;
- All INR analysis have to be carried out in accordance with national guidelines for PoCT;
- The service is not suitable for all patients and transfers are arranged by request between the GP and the lead clinician for the hospital based service. This allows formal review of the patients AC records before transfer as some patients in high risk or complex case categories may be best served by remaining with the secondary care service;
- Venous blood sampling is undertaken if the Coaguchek result is unexpected. Unexpected results are verified by performing a liquid quality control and repeating the patient test before taking the venous sample. Practices perform random venous blood sampling to cross check results with the laboratory as part of ensuring quality assurance.

# Leeds Teaching Hospitals

**Aims:** To improve patient facing services, significantly reduce the turnaround time for acquiring results, and improve the patient experience and flow through the clinic of the circa 300 sample INR tests performed on clinic days.

**Summary:** The time taken to process laboratory based venous samples means that many patients do not wait and leave the clinic before their results are available. Where patients are identified with high INR scores and require immediate reversal the elapsed time to treatment is often over 14 hours. The increased speed of test results will facilitate reversal within 20 minutes thereby improving patient safety. The service did trial other testing devices but chose the Roche CoaguChek based on both it's reliability, lightweight construction making it easy to use in mobile settings or home visits, and high levels of software integration and interoperability with pre-existing CDSS applications.

## Outcomes / Benefits:

- Increased patient convenience, service accessibility and safety;
- Increased speed of results and interventions where required for patients with high INR scores;
- Ease of use of the CoaguChek testing equipment compared to venous testing equipment thereby enabling the testing to be performed by a broader range of staff (Band 2 Phlebotomists in this instance);
- Dis-benefit – the increased cost of INR test per unit (unit cost of venous sample laboratory based test - £1, unit cost of PoCT - £2.80). This is primarily driven by the cost of the testing strips;

## Learning / Critical Success Factors:

- Roche provide free training to Leeds Teaching Hospital staff on the CoaguChek devices . They will also provide nursing support to train patients in the future who opt for self testing. The hospital now have their own member of staff acting as a key trainer within the service who can complete staff training within an hour;
- Previously the trust was paid by venous sample test activity as recorded through the laboratory system. This meant any service provided through PoCT had no means of being recognised and paid for thereby creating a barrier. Development of an alternative payment mechanism was required to address this;
- External quality assurance is performed on a bi-monthly basis by WEQAS (a UKAS accredited proficiency testing provider) to ensure the accuracy of the PoCT devices.

# Plymouth Hospitals

**Aims:** To create capacity within the hospital laboratory services following unprecedented demand to avoid the resulting delays in reporting and dependant patient treatments.

**Summary:** Carrying out over 800 samples a day the coagulation laboratory was working beyond capacity and samples were being sent to other trusts as far afield as Oxford for processing. This backlog inevitably increased delays in the delivery of patient results and initiation of treatment creating in a serious clinical risk. The service decided to trial near patient testing using NICE approved devices to reduce the demand pressures on the laboratory service.

## Outcomes / Benefits

- Reduced demand pressures on the laboratory service;
- Reducing results processing times and the clinical risk to patients associated with backlogs and delays in the initiation of treatment;
- The service is being extended to include the provision of a community based hub and spoke service;
- Less clinically stable warfarin patients are to be offered self testing devices to support increased frequency of monitoring.

## Learning/Critical Success Factors:

- Appropriate training on the NPT devices for nurses and phlebotomists;
- Developing standing operating procedures and evaluation processes;
- In respect to quality control every 10th INR result from the NPT device is tested in duplicate with the laboratory method from venous sample for comparison;
- In addition to recording INR results, patients yellow anticoagulation record books were used for documenting quality control results associated with the NPT devices;
- All users need to be aware of calibration and quality assurance methodologies for all devices.

# Sheffield - Community Pharmacy INR Tests

**Aims:** To establish a network of suitably trained community pharmacists to ensure adequate local provision of anticoagulant care in Sheffield thereby reducing pressure on hospital clinic staffing. Provide a convenient community based INR testing and dosing service using NPT devices without the patient needing to attend multiple appointments or travel to hospital.

**Summary:** Provide a pharmacist led locality based monitoring of patients on warfarin. Being locality based rather than practice based would ensure a sufficiently high caseload for it to be cost efficient and effective because of the continual development through exposure of the clinical staff involved. The use of community pharmacists would bring them closer to the primary healthcare team to mirror the development of hospital clinic services.

## Outcomes / Benefits:

- A survey of patients attending hospital anticoagulation clinics found the 36% of patient required ambulance transport. The locality service decreased usage of patient transport services to hospital for testing and then again for results and consultation;
- Projected annual savings of approximately £345k based on the reduced demand for patient transport services to hospital settings;
- Increased convenience, decreased appointment durations, and increased service accessibility for patients;
- Reduced hospital admissions and increased capacity of acute appointments to deal with complex cases;

## Learning/Critical Success Factors:

- The community pharmacy approach was selected ahead of other considered options (spoke clinics run hospital staff, patient self testing, clinics in GP surgeries) as it was believed that a 'locality clinic' would have the advantage of a sufficiently high caseload to produce a cost efficient service whilst exposing staff to sufficiently volume / variety that they would develop a high degree of expertise whilst requiring minimal extra training;
- The service reports back to the local haematologist for oversight and quality is overseen by a pathology based near patient testing co-ordinator;
- Regular audits were implemented to ensure best practice is adhered too in accordance to national guidance.

# Potential Benefits for West Yorkshire

## Clinical Benefits

- Immediate availability of diagnostic test results significantly reduces the therapeutic turnaround time;
- Reduction in transcription errors and increased speed of dosage adjustments;
- Reduced demand / attendance in acute secondary care / clinic settings creating capacity for patients with more complex and urgent needs;
- Reduced demand for laboratory services thereby increasing both capacity and responsiveness of the service to provide other test results;
- Entry of up-to-date INR results directly onto electronic patient record systems;
- Elimination of blood collection tubes and centrifugation with fresh whole blood specimen;

## Patient Benefits

- High levels of convenience for patients who receive test results within minutes;
- Provision of patient-centric care closer to home (reducing patients need to travel);
- Fewer emergency hospital admissions for patients significantly out of range;

## Financial Benefits

- Reduction and/or elimination of blood specimen/sample transport;
- Reduction in the demand and cost of patient transport services to anticoagulation services where provided.

# 4.0 Costings

**Self-Testing:** Annual costs for self-testing / monitoring with the CoaguChek XS taken from NICE Costing Statement DG14.

	Setting	Year One Costs	Reoccurring Annual Cost
Self-Testing*	Primary Care	£620	£231
	Secondary Care	£720	£251
Self-Management*	Primary Care	£606	£127
	Secondary Care	£786	£147

\*It was assumed that this would include around 35 tests per year

**Anti-coagulation Service:** Example unit costs taken from existing services.

AC Service	Activity	Unit Cost
Bradford AQP	AC Clinic Visit	£34
	Domiciliary Visit	£50
Leeds THT	Phlebotomy & Dose	£5
	Face to Face Consultation	£36
Mid-Yorks Hospital Trust	Phlebotomy & Dose	£7
	Face to Face Consultation	£29
	Domiciliary Visit	£38

**Self-Testing:** The table below is a detailed breakdown on the simplified costs from the table above.

Self-Testing	Primary Care	Secondary Care
<b>Year One Costs</b>		
Device list price	£299	£299
Training	£90	£170
Initial costs	£389	£469
<b>Total year 1 costs</b>	<b>£620</b>	<b>£720</b>
<b>Annual recurrent costs</b>		
Test strips and lancets	£100	£100
Quality control tests	£28	£48
Phone calls (nurse time)	£104	£104
<b>Annual recurrent costs</b>	<b>£231</b>	<b>£251</b>

Self-Management	Primary Care	Secondary Care
<b>Year One Costs</b>		
Device list price	£299	£299
Training	£180	£340
Initial costs	£479	£639
<b>Total year 1 costs</b>	<b>£606</b>	<b>£786</b>
<b>Annual recurrent costs</b>		
Test strips and lancets	£100	£100
Quality control tests	£28	£48
<b>Annual recurrent costs</b>	<b>£127</b>	<b>£147</b>

**Point of Care Testing:** Example unit costs of venous sample laboratory based test - £1, unit cost of PoCT - £2.80 (example taken from LTHT).

# 5.0 Risks

The key risks associated with the successful implementation of self-testing and PoCT are summarised below. These risks would need to be overcome if either of the opportunities were to be realised:

Risk Description	Implication	Mitigation
<p><b>Accuracy of the Coagulometers:</b> There is a risk that the equipment used to perform self-testing / PoCT is not as sophisticated as the laboratory equipment;</p>	<p>The results produced by the devices may not be accurate and could result in dosing errors placing the patient at risk;</p>	<ul style="list-style-type: none"> <li>• NICE diagnostics guidance [DG14] states that the evidence indicates that the precision and accuracy of both monitors are comparable to laboratory-based INR testing;</li> <li>• Devices used self-testing / PoCT are also currently used in secondary care anticoagulation clinics;</li> <li>• Establish a quality assurance regime.</li> </ul>
<p><b>Unjustifiable Setup Costs:</b> There is a risk that the opportunity costs for developing an anticoagulation service based around self-testing / PoCT for suitable patients would be disproportionate;</p>	<p>CCGs do not believe that there is a convincing business case for supporting self-testing / PoCT and will not commission the service;</p>	<ul style="list-style-type: none"> <li>• Perform a feasibility study accompanied by a financial and economic model to understand the costs involved;</li> <li>• Explore the delivery models utilised in other CCGs that support self-testing / PoCT to inform decision making (CCGs which currently allow self-testing include Oxford, Ashford, Great Yarmouth &amp; Waveney, Bromley, Ealing, Sandwell &amp; West Birmingham, Durham Dales, and Easington &amp; Sedgefield).</li> </ul>
<p><b>Cultural Resistance:</b> There is a risk that CCGs will not support self-monitoring for reasons of clinical safety or because of medico-legal implications if 'something went wrong';</p>	<p>Patients are denied the opportunity, choice and freedom to self-manage their condition;</p>	<ul style="list-style-type: none"> <li>• Develop robust clinical procedures for both patients and healthcare staff to follow when implementing self-monitoring to eliminate potential risks;</li> <li>• Provide nurse training for patients;</li> <li>• Utilise CDSS to automatically monitor and report on patient TTR analysis.</li> </ul>

# 6.0 Dependencies

The successful implementation of each of the opportunities would be dependent on a number of enabling conditions being present at either a local or sub-region level. These conditions are summarised below for reference:

## Patient Self-Testing

- **Self Funding:** Due to the high entry cost of personal testing devices they are often only available to self funding patients;
- **INR Test Strips:** Patients will require access to (and ideally funding of) the test strips through NHS prescription;
- **Clinical Dosage Support Service:** An INR results dosage adjustment service needs to be provided for self-testers;
- **Patient Assessment:** Criteria to assess the suitability of an individual to self-test;
- **Patient & Carer Training:** Training for patients and carers in the effective use of the coagulometers, together with regular reviews of their ability to self monitor;
- **Quality Control:** Reliable quality control procedures for regularly checking patient devices.

## Point of Care Testing

- **Medical Staff Training:** Additional training for medical staff to use the PoCT equipment and perform the tests;
- **Capital Investment:** The availability of funding for the initial procurement of portable PoCT INR testing devices;
- **Budget Investment:** The increased unit costs of PoCT when compared to traditional laboratory testing will require additional budget;
- **External Quality Control and Calibration:** External quality assurance and calibration services would be required to ensure the accuracy of the PoCT devices;
- **Computer Aided Decision Support Software (CDSS):** Testing staff would require access in the field to CDSS for guidance on patient dosing and review periods.

# 7.0 Opportunity Assessment

Having explored both of the opportunities and considered several case studies it is helpful to summarise and contrast the both the arguments for and against implemented each of the proposals. These arguments are summarised below:

## Patient Self-Testing

### Strengths

- Immediate availability of diagnostic test results reducing the therapeutic turnaround time;
- Increased patient convenience and safety;
- Increased TTR for warfarin patients;
- Reduced pressure on acute AC clinic services;
- Empowers the patient and increases the emphasis on their role and involvement in the active self-management of their condition;
- Encourages innovation.

### Weaknesses

- High entry costs associated with the hand held devices;
- Potentially only available to self funding patients creating a tow tier care system;
- Dependant on the establishment of a remote dosage adjustment support service;
- Variation in test strip availability via prescription.

## Point of Care Testing

- Immediate availability of diagnostic test results reducing the therapeutic turnaround time;
- Increased patient convenience and safety;
- Increased TTR for warfarin patients;
- Reduced pressure on acute AC clinic services;
- Significantly lower entry costs when compared to patient- self testing;
- Relative simplicity of establishing the service within existing community settings.

- Increased unit cost of PoCT compared to traditional laboratory based service.

# 8.0 Next Steps

Having completed the initial opportunity assessment for **Patient Home-Testing** and **Point of Care Testing** the Healthy Futures Programme Board and 10cc have to consider the potential next steps and decide how to proceed.

It should be noted that the Stroke programme has currently only been resourced to deliver against one of the opportunities during the next phase (until the end of August '15). The available options are summarised below:

## Do Nothing

- Having considered the information presented in this document, decide not to progress these particular service improvement opportunities any further;
- Consider exploring other opportunities from the original list of seven recommended for collaboration;

• **Timeframe: N/A**

The service opportunity assessment does not present a compelling enough case to warrant further investment.

## Feasibility Study

- Perform a time bound feasibility study for one or both of the opportunities;
- Hold a series of meetings and workshops with providers and commissioners to explore and test commitment;
- Develop a financial and economic model to quantify the impact;

• **Timeframe: 6wks**

Testing the commitment and desire of commissioners and providers within the local health economy to deliver the opportunities.

## Business Case

- Develop a detailed business case for one or both of the opportunities;
- Quantify the respective financial commitment required for each CCG to implement the opportunity;
- Develop a financial and economic model to quantify the impact;

• **Timeframe: 10wks**

Clarifying the financial commitment and delivery mechanism for each of the AC services to deliver the opportunity