



# Adoption support resource – insights from the NHS

Implementation support

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# Contents

1 Introduction .....	3
2 Current practice .....	5
3 Summary of NICE recommendations .....	6
4 Tips for adopting point-of-care coagulometers for self-monitoring coagulation status ..	7
5 Insights from the NHS.....	8
Tottenham and Greenmount Medical Practices, Bury.....	8
County Durham and Darlington NHS Foundation Trust.....	12
6 How to implement NICE's guidance on point-of care coagulometers for self-monitoring .....	19
Project management.....	19
Overcoming implementation challenges.....	20
Business case development.....	21
Development of local documentation .....	22
7 Acknowledgements.....	23
8 About this resource.....	24
Update information .....	25

# 1 Introduction

**Published date:** February 2015 **Last updated:** June 2018. See [update information](#) for a summary of the changes.

This resource has been developed to provide practical information and advice on self-monitoring coagulation status using a point-of-care coagulometer (the CoaguChek XS system) for people having treatment for atrial fibrillation and heart valve disease with a vitamin K antagonist, as recommended in the [NICE diagnostics guidance on atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers](#).

It is intended for use by both clinical and non-clinical staff who are planning to implement this NICE guidance and start using this technology.

NICE's Adoption team worked with NHS organisations to share their learning and experiences of using CoaguChek XS for self-monitoring of coagulation status. The information presented in this resource is intended for the sole purpose of supporting the NHS in adopting or further researching use of CoaguChek XS for self-monitoring.

The information presented here has not been assessed by the independent External Assessment Group and was not considered by the Diagnostic Assessment Committee when making its decision on the use of point-of-care coagulometers for self-monitoring coagulation status in the NHS.

The benefits of using CoaguChek XS for self-monitoring coagulation status reported by the NHS staff involved in the production of this resource include:

- Increasing the time that the person's international normalised ratio is within therapeutic range, which is associated with a reduction in adverse events such as stroke and major haemorrhage.
- Releasing time in clinic for people who have more complex problems.
- Reducing workload on pathology services.
- Empowering people to take control and ownership of their own healthcare.

- Reducing visits to anticoagulation services, leading to less work and home life disruption.
- Allowing people to travel more easily, both within the UK and abroad.

The learning gained from existing users is presented as a series of examples of how NHS sites have adopted and used this technology in current practice rather than suggested best practice. The examples extend beyond the positive guidance recommendations and are presented to assist organisations and clinicians in considering the use of CoaguChek XS for self-monitoring coagulation status in the NHS.

NICE technology appraisal guidance recommends the use of 3 non-vitamin K antagonist oral anticoagulants (NOACs), apixaban, rivaroxaban and dabigatran etexilate, for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation. These do not need therapeutic monitoring but may be unsuitable for some people.

## 2 Current practice

Many conditions can result in people having an increased risk of thrombosis, and consequently having long-term oral anticoagulant therapy. These include atrial fibrillation and heart valve disease.

[NICE's guideline on atrial fibrillation](#) recommends offering anticoagulation therapy (apixaban, dabigatran etexilate, rivaroxaban or a vitamin K antagonist) to men with a [CHA2DS2-VASc score of 1](#) and to people with a [CHA2DS2-VASc score of 2 or above](#), taking bleeding risk into account, as an intervention to prevent stroke. [NICE has produced a patient decision aid](#) to help people with atrial fibrillation make informed decisions about their treatment and care with their healthcare team.

Those people having vitamin K antagonists are at risk of under-coagulation, which may lead to thrombosis, and over-coagulation, which can result in haemorrhage. Both of these conditions can cause serious illness or death. People taking these drugs need regular monitoring of their international normalised ratio (INR). INR is a measure of the time it takes for blood to clot, and the prescribed dose of vitamin K antagonists can then be adjusted depending on the test result. CoaguChek XS is designed to measure INR and can support 2 different methods of care: self-testing and self-management. The person performing the test can either feed their result back to the relevant healthcare professionals, who may alter their dose of vitamin K antagonist (self-testing) or adjust the dosage themselves (self-management).

Measuring the person's time spent in therapeutic range (TTR) as a method of assessing INR control is an indicator of the standard of anticoagulation therapy. Results from the [SPORTIF III and V trials](#) showed that people with a TTR less than 60% have higher rates of annual mortality and major bleeding compared to patients with good INR control (TTR >75%).

It is estimated that there are currently 305,000 people<sup>[1]</sup> in the UK on long-term anticoagulation warfarin therapy (the most common vitamin K antagonist used in the UK) for the management of atrial fibrillation.

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<sup>[1]</sup> IMS Disease Analyzer 2012/13 and GRASP-AF database download, April 2014.

### 3 Summary of NICE recommendations

NICE's diagnostics guidance on atrial fibrillation and heart valve disease assessed 2 point-of-care coagulometers (CoaguChek XS and InRatio2 PT/INR) to help the NHS decide whether to use these products for people to self-test or self-manage their coagulation status.

The recommendations originally included the InRatio2 PT/INR, but this was withdrawn from the market in October 2016 and is no longer available

CoaguChek XS is recommended for self-monitoring coagulation status in adults and children on long-term vitamin K antagonist therapy who have atrial fibrillation or heart valve disease, if they prefer this form of monitoring and they (or their carer) are both physically and cognitively able to self-monitor effectively.

People (and their carers) who will be using 1 of these devices should be trained in their effective use and clinicians involved in their care should regularly review their ability to self-monitor.

## 4 Tips for adopting point-of-care coagulometers for self-monitoring coagulation status

- Assess current results for time in therapeutic range for people currently on vitamin K antagonist therapy to make a case for change. See [measuring success](#) for further details.
- Identify the potential demand for self-monitoring among people with atrial fibrillation or heart valve disease who are taking vitamin K antagonists. See [insights from the NHS](#) for further details.
- Identify how the service will be measured in terms of quality and safety, patient experience, productivity and improved clinical outcomes. See [measuring success](#) for further details.
- Develop clear selection and training criteria for the service. See [education](#) for an example.
- Develop local protocols for supporting people to self-monitor. See [development of local documentation](#) for examples.
- Ensure that all supporting staff have training on the use and quality assurance of coagulometers. See [insights from the NHS](#) for further details.
- Commissioners and providers need to work together to assess the whole system cost benefit to the widespread adoption of self-monitoring. See [business case development](#) for further information.

## 5 Insights from the NHS

During the development of this resource, NICE worked with the manufacturer to identify NHS organisations using CoaguChek XS for self-monitoring. These organisations agreed to provide structured feedback on their experiences of using the technology as detailed in this section.

### Tottington and Greenmount Medical Practices, Bury

Tottington Medical Practice is the largest GP practice in the Bury clinical commissioning group (CCG) area with a practice population of 12,323 and 8 GPs. Greenmount Medical Centre has a practice population of 9309 and 6 GPs. Nurse-led anticoagulation clinic services have been provided by both practices for a number of years.

Since August 2010, both practices have provided a 'stable patient' anticoagulation service through a local enhanced service agreement with Bury CCG. The service involves near-patient testing using finger-prick blood testing.

The lead GP for the anticoagulation service in the Tottington practice wanted to make it more efficient, with quicker results and less disruption for users. Even though practice-based clinic appointments tended to be quicker than hospital-based ones, people still had to make the appointments, take time to attend and wait for their international normalised ratio (INR) results. Two patients in the practice had self-funded CoaguChek XS meters as they had found it difficult to attend the practice for INR testing due to the nature of their jobs. They were supported by the practice nurse and GP in this decision. Both patients had gone on to improve the INR time in therapeutic range following self-testing. This prompted the lead GP to explore the development of a self-monitoring anticoagulation service.

A Programme Manager in the CCG Public Health Team worked with the lead GP from the Tottington practice to develop an application for funding from the CCG Innovation Fund for a pilot period of 6 months. In order to meet the timescales required to implement the pilot and recruit 30 service users, Greenmount Medical Centre was also invited to participate. Following a successful bid, 30 CoaguChek XS meters were purchased in December 2013. Tottington practice was allocated 22 devices and 8 of these were allocated to



Greenmount. A service algorithm was designed for the managing clinicians as a guide for frequency of monitoring and level of telephone support needed depending on individual INR results.

Both practices recruited 30 patients, aged 24–75 years, on the basis that their GP was confident:

- in their motivation and ability to participate
- that they wanted to self-monitor
- that they were visually and physically able to perform the test.

The practices ran 3 education evenings in January 2014 to enable all people to attend one session. A nurse practitioner from the company provided training, delivered in a 2.5 hour-long session with support from the lead GP and practice nurse for the pilot. The focus of the training session was to assess peoples' dexterity, and their ability to perform the test and understand and comply with the proposed regimes. Everyone started self-testing in the first instance to gain self-confidence in doing the test and to give them and the practice staff confidence in the self-monitoring service. Everyone was given a named contact in their practice for queries or concerns. At the end of the session, each person was provided with a meter and test strips and an agreed action plan based on their individual needs and level of confidence.

People were asked to practise self-testing at home to gain confidence. They were given a specific date when the practice nurse would ring them to discuss their progress and any health-related issues, who would then enter their INR result into anticoagulation software for dosing and review period suggestions. Another telephone appointment was then made, dependent on the result, for the next test. People were encouraged to monitor their INR between these appointments if they had any concerns or changes to other medication, and to phone the practice if their INR results were not within their target range.

Within 3 months, 27 people were successfully self-monitoring and continued to do so. During the course of the pilot, 3 people moved away. Of those continuing to self-monitor, 8 have a diagnosis of atrial fibrillation; 7 have recurrent deep vein thrombosis; 5 have antiphospholipid syndrome; 4 have pulmonary embolism; and 3 have heart valve disease.

Telephone contacts from people requiring support and advice reduced after this period. In line with quality assurance measures, everyone was asked to visit their practice after

3 months, to perform a CoaguChek test at the same time as the practice undertook a venous test. All readings from the self-testing devices in the previous period were recorded on the practices' anticoagulation data record. This quality assurance is intended to continue on a twice-yearly basis.

The pilot has been evaluated positively by all the service users involved and was considered to be a success by the clinicians supporting the service. The average time in therapeutic range for people self-monitoring in the Tottington practice improved from 64% to 71%, and in the Greenmount practice from 55% to 63%. There have been no emergency department attendances related to anticoagulation and no serious adverse events reported.

One person was supported to move to self-management to support their personal choice. They had additional training from the practice nurse on understanding the dosage algorithm. Initially, they followed the same procedure as for self-testing and rang their practice nurse with their INR result. The practice nurse would then enter this into the anticoagulation software and ask them, based on their result, what they would do in terms of dosing and next test based on their dosage sheet. This gave both the individual and the practice staff confidence in progressing to self-management. The practices are now planning to offer other people who are self-testing the opportunity to progress to self-management, for whom this would be a preferred option.

The CCG local enhanced service agreement for practices providing a 'stable patient' anticoagulation dosage and monitoring service, allows for up to 10 visits to the practice per year, up to a maximum cost of £200 per patient. While both practices would like to extend the opportunity to self-monitor to other people, at this time there is no financial model to support this due to the high initial investment which was supported by innovation funding for the pilot. Any future agreement, whether local enhanced service or any qualified provider, for people supported to self-monitor would need to take these up-front costs into account.

## Mrs A case study

Mrs A is a 73-year-old retired health care professional who has been treated with warfarin since 1979 for heart valve disease caused by rheumatic fever. She had 2 prosthetic heart valves (aortic and mitral) fitted in 1992 to treat this and continued her anticoagulation orally with warfarin. Initially she was under the care of the hospital, but for the past 20 years has been attending the anticoagulation clinic at her GP practice. She has been self-testing her INR for 7 months. "I was going to the practice about once a month for my INR testing but sometimes my level would go off if I had been taking antibiotics or had been unwell and then I had to go every week. I didn't know you could do the testing yourself until the nurse contacted me. I think they asked me because they know me really well and thought I could probably do it. I said yes straight away because I thought it would be a lot easier and more convenient than going up to the surgery, I live about 4 miles away and there isn't a direct bus route so I have to go by car. I went to the training session with 5 or 6 other people. The nurse gave us all a machine and went through everything we had to do then she went individually round the table watching us do it ourselves and get the readings. I found it quite hard at first and had to have a few goes at getting the blood directly on to the strip in the right area. I practiced at home for the next week and once I'd done it 3 or 4 times I could do it easily and now it's no problem. I rang the nurse once a week for the first 3 weeks to tell her my results and now she rings me about once a month on a day and time we have already arranged. I generally know when I'm OK from the reading on the machine and would consider self-managing as long as I still had the back up from the surgery to make sure I was doing it right. I'm really pleased they put me on to self-testing and am very happy with this arrangement because going to the surgery used to take up a whole morning, now they ring me at a set time and it's much easier for me."

## Mr B case Study

Mr B is a 56-year-old self-employed man who has been having warfarin therapy since he was diagnosed with antiphospholipid syndrome in 2012, following a stroke. "My INR was initially monitored at the hospital but in January 2014 I transferred to the practice anticoagulation clinic. Whilst this was much more convenient as I live only a mile and a half from the practice and 5 miles from the hospital, it still meant at least an hour out of work for a 2-minute procedure every couple of months. When the nurse rang to ask if I would like to try self-monitoring I really wanted to give it a go. I found the training pretty easy as I was already used to finger-prick testing for blood sugars from my time in the Mountain Rescue Service. My INR was already pretty stable and it has stayed this way since I have been self-testing for the past 7 months now and I aim for a reading of 2.5 but know that I'm safe between 2 and 3. I probably wouldn't want to manage my own dosing as I have become quite forgetful since the stroke, but the self-testing really suits me. Where it has been a real advantage is when I've had to go into hospital and come off my warfarin. I had an angiogram a couple of months ago and had to stop warfarin 5 days before the procedure. As soon as it was done I went straight back on warfarin and was injecting myself with Clexane®\* every day until my INR levels got back to normal. I needed to test my INR for 4 days in the week after the angiogram, if I'd not been doing this myself I would have had to go back to the practice for this with a lot of time out of work and real inconvenience. Once my INR level was OK, I could stop the Clexane injections and know I was safe. I'm having a triple heart bypass in a month's time and have already discussed doing more INR tests once I get home with my doctors. If I wasn't self-testing they would need to send the district nurse out which seems like a real cost to the NHS. It's made me feel much more confident about having such a major operation, knowing I can have some control. I'm really happy being able to test myself, it works for me and life is just easier."

\*Clexane®: enoxaparin sodium administered by subcutaneous injection until adequate oral anticoagulation is established.

## County Durham and Darlington NHS Foundation Trust

County Durham and Darlington NHS Foundation Trust is one of the largest integrated acute and community services providers in England. 8000 staff serve a population of around 600,000 across County Durham, Darlington, North Yorkshire, the Tees Valley and

South Tyneside. Acute hospital services are provided from 3 main sites.

The NHS trust is commissioned by local CCGs to provide anticoagulation services under an 'any qualified provider' tariff. There are 2648 people who take warfarin, who are supported by the trust in a number of locations including hospital outpatient clinics, community satellite clinics and in people's homes.

In 2012, the Clinical Director for Adult Nursing led a successful bid for regional innovation funding for a number of telehealth projects to address capacity issues across the trust. The trust wanted to provide services which could use an automated phone system to help deliver care and ensure an audit trail. Working in partnership with Inhealthcare Ltd, the 'Health Call' digital healthcare service was developed.

The first clinical pathways to be automated and digitised included international normalised ratio (INR) self-testing. Project management within the trust was provided by the Care Closer to Home Programme Manager for Telehealth, working with the Business Development Manager.

A draft care pathway for the INR self-testing service, including the protocol for patient selection and training and the specification for the Health Call INR service, was developed together with the clinicians working in the anticoagulation clinic and the chief pharmacist. This ensured engagement with key stakeholders from the beginning of the project.

For the implementation pilot phase, 100 CoaguChek XS meters were bought. The initial plan had been to focus the self-testing INR service on people who were house-bound, as home testing is the most costly element of the overall service. District nurses identified people who they thought could manage and offered them training and the opportunity to self-test. Very few people wanted to take this up, generally because they valued the contact from their district nursing team.

Anticoagulation clinic team members were then asked to identify people attending clinic-based services who they thought would be interested and fulfilled the criteria for inclusion:

- Stable INR.
- Over the age of 18 years who are deemed suitable to use the service by their GP or anticoagulation nurse.
- Able to give consent and willing to participate.

- Able to understand the concept of oral anticoagulation treatment and the potential risks associated with the treatment.
- Dexterity and acuity of vision to enable them (or their carer) to use the device and telephone.
- On long-term anticoagulation therapy and requiring regular check of INR.

Within 3 months 100 people had been recruited to participate in the pilot. During this recruitment phase the anticoagulation lead nurse and Care Closer to Home Manager worked with Roche to develop a [training package](#) for patients. The training was delivered on a phased basis over a 3-month period from April 2013.

The first session, delivered to up to 10 people, was designed to cover correct use of the meter and to make sure people could get an adequate ('ladybird' size) drop of blood. Everyone was then issued with a meter and asked to practice self-testing once a day at home for 1 week.

In a second one-to-one (15 minute) training session a week later, the readings on the device were checked and the person was asked to give feedback on how they had managed and if they wanted to continue with the service. If they did, their mobile phone was checked for compatibility and they were then given training on answering the automated telephone calls and understanding the process. This session included test calls to ensure people could follow the instructions.

Once an individual had successfully completed training they filled in a [registration form](#). On this form they indicated their preferred time for getting the 2 automated phone calls. To ensure that people who didn't respond to the automated service were followed-up, calls were only made Monday to Thursday, which enabled clinic staff to chase up people on Friday, if needed. All people were given a [record pad](#) for their INR results and dose adjustments.

#### Call 1:

- On the agreed day of the INR test the individual measures their INR using the CoaguChek XS meter.
- At their preferred time they receive [automated call 1](#) on their nominated UK mobile or landline number and are asked to enter their INR reading, current warfarin dose, and have to answer 3 questions around bleeding and medication.

- The INR results, and any clinical alerts generated by their responses, are sent to the warfarin clinic through the automated portal.
- Using anticoagulation software and clinical judgement, their warfarin dose and date of next INR test is determined.
- The dosing regime and date of next INR test is then entered into the portal by the member of staff.

#### Call 2:

- The person then receives automated call 2 which instructs them on their warfarin dose and the date of their next INR test.

During this pilot phase, feedback was gathered from all participants to understand their issues and find out what was needed to design the service to meet their needs. Some changes were made to the instructions they were given during the calls and the initial sessions were reduced to 5 people to ensure more one-to-one support. A third session was also offered to people who needed extra reassurance.

Service user feedback was extremely positive with comments typically being around:

- Reduced time attending clinics
- Less impact on work disruption and money lost from taking holiday or no pay to attend clinic
- Money saved from travel costs and parking
- Ability to test whilst working away from home or on holiday
- Flexibility

Staff confidence in the system grew as it became evident that time in therapeutic range results for people in the pilot were at least as good, and in most cases improved, compared with those measured prior to self-testing, with an average 20% improvement for 70% of those involved.

It was decided to expand the service to another 100 people and a Trust procedure document was approved by the Clinical Standards & Therapeutic Committee in February 2014.

People in the second cohort were not selected by clinic staff. Posters and [leaflets](#) were displayed in out-patient and community anticoagulation clinics inviting people to apply to become self-testing. People who applied were often working and trying to fit clinic appointments around work, therefore training sessions were organised flexibly in the evenings in order to accommodate their needs. The same training package and support was provided and after 6 months the time in therapeutic range for both cohorts was reviewed. The age range in both groups was similar at 30–80 years, with most people being in their sixties or seventies. Table 1 demonstrates that the results from a self-selected group of people were as good as those from people hand-picked by staff.

**Table 1: TTR results pre- and post-implementation of self-testing**

	Cohort 1	Cohort 2
Number of people in cohort	100	100
Recruitment selection criteria	Narrow Most were hand-picked by staff	Broad Most were recruited from advertisements
TTR 6 months before (%)	60.4	59.0
TTR 3 months before (%)	58.9	59.0
TTR 3 months after (%)	72.8	71.0
TTR 6 months after (%)	74.4	75.0
Abbreviation: TTR, time in therapeutic range		

The drop-out rate was relatively low (17 people: 2 moved area, 4 died (due to non-related reasons), 5 had difficulty due to frailty, 5 stopped warfarin treatment, 1 returned to clinic).

Of the people remaining under the care of the trust and continuing to self-monitor: 38% have atrial fibrillation; 38% have pulmonary embolism or recurring deep vein thrombosis; 12% have mitral valve disease and 12% have other diagnoses.

People who are self-monitoring are now asked to return to the clinic every 6 months for a



quality control check of their meter and observation of technique. Once they are proficient, it is intended to move this to a yearly check if their INR remains stable. The average anticoagulation clinic attendance in the Trust is 18 times per year, saving 16 out-patient appointments per year, per patient. People can still contact the clinic Monday to Friday during working hours for additional support and advice if they need to.

The business manager responsible for the service presented a cost report to the NHS trust board in May 2014 examining the financial implications of introducing an INR telehealth service in Durham and Darlington with a view to expanding the service on a sustainable basis. The key findings were:

1. The INR telehealth service can be cost neutral from the perspective of variable NHS costs per person compared to the INR outpatient clinic when the savings from the reduction of strokes and other thromboembolic events for self-monitoring is taken into account.
2. For the existing service models, estimated variable INR monitoring costs per person are lowest for the INR outpatient clinic at £152 per year compared to satellite clinics (£190) or home care (£333).
3. Costs for the INR telehealth service are estimated at £146 per person per year for the current cohort of 200 people where the meters are already funded separately.
4. Costs for fully funded INR telehealth services are estimated at £210 per person, per year. Expanding the service beyond an additional 200 people would require additional CCG funding above the any qualified provider contract of £170 for stable patients. One option is to cover the £40 prescription charge for test consumables on the CCG formulary budget.

A paper has now been submitted to the Trust Board outlining the case for INR self-monitoring. This is summarised below:

1. Operational: it increases capacity of existing clinics
  - i) Include the anticipated costs of extra clinics needed to address growing need
  - ii) Proposed integration with dosing software to reduce clinician time needed per telehealth patient and reduce transcribing error risk
2. Clinical: it improves clinical outcomes

Self-testing has improved time in therapeutic range by 20% for 70% of patients

3. Financial: it is cost neutral when all CCG costs are included

i) Include savings from the known reduction in adverse events

ii) Avoid large capital spend by using a rental scheme for meters

iii) Focus on the 20% of warfarin patients whose monitoring is the most expensive (that is, people who are house-bound and those who attend satellite clinics)

4. Strategic: it supports Department of Health and NHS England objectives

i) Improves quality of life for people with long-term conditions

ii) Patient satisfaction for INR self-testing is close to 100%

## 6 How to implement NICE's guidance on point-of care coagulometers for self-monitoring

The experiences of NHS organisations have been used to develop practical suggestions for how to implement NICE guidance on point-of-care coagulometers for self-monitoring coagulation status.

### Project management

It is the experience of the Health Technologies Adoption Programme that in order to gain maximum benefit, this technology should be adopted using a project management approach.

[NICE has produced the into practice guide](#) which includes a section on what organisations need to have in place to support the implementation of NICE guidance.

### Measuring success

In order to demonstrate the benefits of adopting CoaguChek XS for self-monitoring coagulation status, it is important to take measurements before, during and after implementation. This will enable the benefits and impact achieved at a local level to be measured and built on. Some of these measures will not be routinely collected and consideration will need to be given to data collection methodology appropriate to the service. Suggested measures from the sites involved in developing this resource are:

- Time in therapeutic range: 3 and 6 months before and 3 and 6 months after people begin to self-monitor.
- Patient experience (pre-implementation and post-implementation).
- Number of people offered self-monitoring and reasons for not offering it.
- Take-up rate of self-monitoring and reasons for people declining.
- Number and percentage of people completing training.

- Number and percentage of people passing the assessment.
- Number and percentage of people continuing to self-monitor at 3 and 6 months.
- Testing frequency and associated costs.
- Number and percentage of people requiring additional advice on dosing and frequency of contact.
- All related clinical events, for example reported minor and major bleeds and thrombotic events.

## Overcoming implementation challenges

A number of implementation challenges were reported by NHS sites using CoaguChek for self-monitoring coagulation status as set out in table 2.

**Table 2: Reported implementation challenges when using point-of-care coagulometers for self-monitoring coagulation status**

Implementation challenge	Solution
Capital and ongoing revenue costs	Prepare a <u>business case</u> including full cost considerations for INR self-monitoring compared with current service models across a complete service budget. Consider leasing arrangements.
Clinical confidence	Select appropriate <u>metrics</u> to demonstrate clinical benefit, safety and demand.
Patient confidence	Develop <u>training packages</u> and <u>information</u> for service users. Initially introduce self-testing. As confidence grows consider introducing self-management for appropriate people.

# Business case development

## Cost savings

NICE has published a [costing statement](#) that can be used by NHS trusts to assess the local impact of implementing NICE guidance on point-of-care coagulometers for self-monitoring coagulation status, based on the local population. The statement highlights that avoiding a small number of high-cost adverse events has the potential to make the initial investment cost saving if a whole system view is taken.

## Service commissioning

Local enhanced service or any qualified provider agreements for anticoagulation services should take into account the:

- initial investment in supporting self-monitoring including cost of equipment and training and support
- reduction in ongoing support required once self-monitoring has been established
- potential savings resulting from decreased adverse events.

A fully commissioned anticoagulation service within a whole system budget may be the only sustainable model in which to include a self-monitoring service. This would allow for savings made in improved outcomes (reduced cardiovascular events from improved time in therapeutic range) to be redirected towards anticoagulation management services.

## Business case

The implementation team should treat the development of a robust business case as an early priority in the life of the implementation project.

Local arrangements for developing and approving business plans will vary and each organisation is likely to have its own template and process in place.

The following are examples of documents developed by sites using point-of-care coagulometers for self-monitoring which can be used to inform the development of local business plans.

[Bury CCG Innovation Funding application](#)

[County Durham and Darlington NHS Foundation trust cost report](#)

## Education

County Durham and Darlington NHS Foundation Trust have developed a [training pack](#) for people, which details the criteria they must meet to be issued with a meter.

The manufacturer of CoaguChek XS provides online and telephone support for people. For further information please see [training and support for CoaguChek XS system users](#).

## Development of local documentation

The following are examples developed by NHS sites using point-of-care coagulometers for self-monitoring coagulation status which can be used to inform the development of local documentation.

[International normalised ratio \(INR\) self-monitoring service algorithm](#) (Bury clinical commissioning group [CCG])

[INR dosage algorithm for self-management](#) (Bury CCG)

[INR monitoring service procedure document](#) (County Durham and Darlington NHS Foundation Trust)

[INR monitoring patient information leaflet](#) (County Durham and Darlington NHS Foundation Trust)

[INR monitoring registration form](#) (County Durham and Darlington NHS Foundation Trust)

[INR record sheet for patient use](#) (County Durham and Darlington NHS Foundation Trust)

## 7 Acknowledgements

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**Mr Ian Dove**

Business Development Manager, County Durham and Darlington NHS Foundation Trust

**Mrs Jeannie Hardy**

Care Closer to Home, Programme Manager Telehealth, County Durham and Darlington NHS Foundation Trust

**Dr Rob Stokes**

General Practitioner, Tottington Medical Practice, Bury

**Dr Tal Wasty**

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## 8 About this resource

The NICE Health Technologies Adoption Programme produces practical advice on adopting health technologies in the NHS in England.

NICE's Health Technologies Adoption Programme worked with NHS organisations to collect and share their experiences of using CoaguChek XS for self-monitoring coagulation status with other organisations that may want to start using this technology in the future. The information gained from these NHS organisations and included in this resource is intended for the sole purpose of supporting the NHS in adopting or further researching point-of-care coagulometers for self-monitoring coagulation status. The information has not been assessed by the independent External Assessment Group or considered by the Diagnostic Assessment Committee when making its decision on the use of point-of-care coagulometers for self-monitoring coagulation status in the NHS.

This resource accompanies [NICE's diagnostics guidance on atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers](#). It was developed using the NICE Health Technologies Adoption Programme process. It is an implementation tool and discusses and summarises the experiences reported by NHS sites who have previously adopted this technology and shares the learning that took place.

Implementation of the guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this document should be interpreted in a way that would be inconsistent with compliance with those duties.

[More information about the Health Technology Adoption Programme.](#)



## Update information

**June 2018:** The CoaguChek XS system has been updated since the original publication of this adoption resource. A [technical supplement](#) published in May 2018 provides information on the version of the technology included in the guidance and highlights the major features of the updated version. This adoption resource refers to the original version (CoaguCheck XS). There are no new adoption issues relating to CoaguChek INRange which has the same functionality with some additional new features.

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