Eastern AHSN

Invitation to tender: Evaluating the impact of the Suffolk & North East Essex Atrial Fibrillation Remote Monitoring Pilot

Part of The AHSN Network

Office for Life Sciences

NHS

About the Eastern Academic Health Science Network

Our purpose is to turn great ideas into positive health impact.

We were established by the NHS to convene all partners in the health sector, to develop and deliver innovative solutions in health and care. Our focus is the East of England, but we are part of a national network which enables us to deliver at scale.

We believe citizens, academia, health services and industry will achieve more working together than they will in isolation. Our job is to make this happen. We do this by helping innovators to navigate complex systems, generate value propositions and connect stakeholders to overcome challenges together.

Introduction

This is an invitation to tender for research services to assess the feasibility and acceptability of a remote Atrial Fibrillation (AF) detection pilot within Suffolk & North East Essex (SNEE).

Following identification of populations at higher risk of AF, the pilot pathway will enable remote, self-monitoring of heart rhythms utilising innovative, evidence-based technology called FibriCheck and Zio Patch.

Eastern AHSN is seeking a suitably qualified supplier to provide evaluation services for this project.

The following table sets out the intended timetable for the submission of bids, their assessment and the conclusion of the contractual arrangements.

Date	**Milestone**
24th February 2022	ITT published and issued to known suppliers
10th March 2022	12:00 deadline for applications to be received
11th March 2022	Scoring of applications conclude, applicants notified by email, preferred supplier/s notified and due diligence begins
17th March 2022	Due diligence concludes, preferred supplier identified and Eastern AHSN sign MOU

This document sets out the lot available, the expected criteria suppliers should address in their bids, along with the timescale, methodology and process for submission, scoring and award.

A full timetable is available within this invitation to tender (ITT) but for clarity, this is a 6 month pilot and it is expected that the work of the independent evaluator should result in an interim output report presenting a findings summary in October 2022 followed by a final report in delivered at the end of December 2022.

Questions regarding this lot can be directed to Ben Jackson (ben.jackson@eahsn.org)

Background

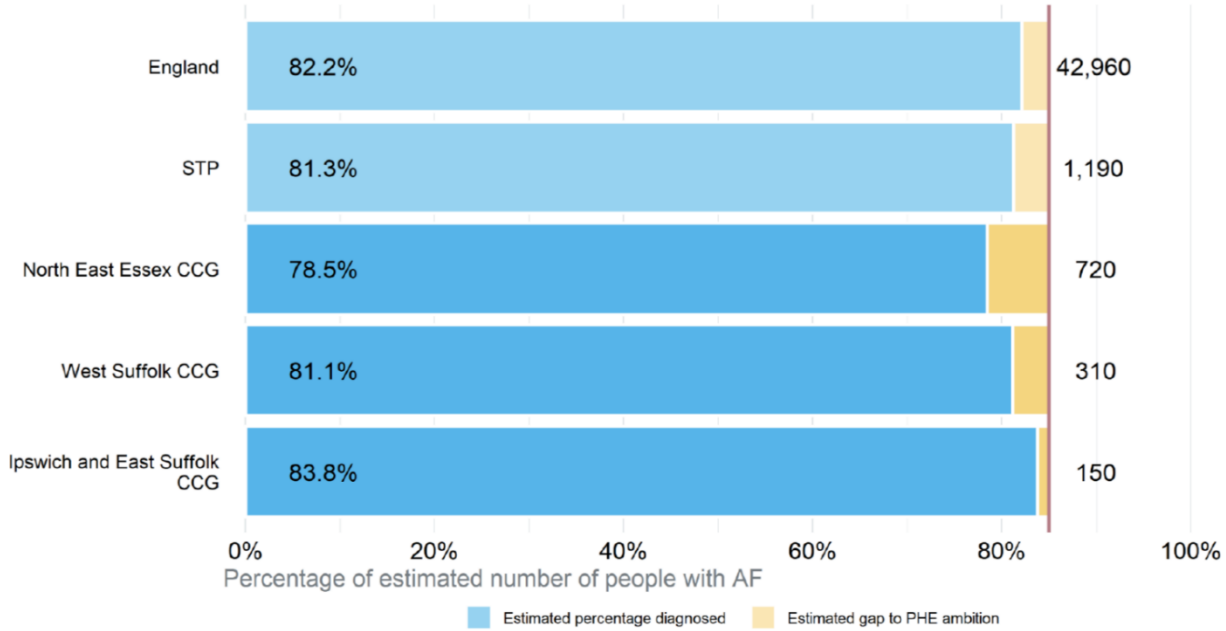
A collaborative partnership between Ipswich and East Suffolk CCG, East Suffolk and North Essex Foundation Trust (ESNEFT), West Suffolk CCG, West Suffolk Foundation Trust (WSFT) and Eastern AHSN (Academic Health Science Network) is undertaking a pilot project to identify patients at higher risk of Atrial Fibrillation (AF) and support them with a remote monitoring pathway in secondary care. The technology identifed has been used before in primary care settings (ref to 2019 report).

Cardiovascular Disease (CVD) is the single biggest condition where lives can be saved by the NHS over the next 10 years (NHS Long Term Plan,2019). Atrial Fibrillation (AF) is a chronic condition affecting around one million people in the UK and involves a significantly increased risk of stroke, with AF-related strokes more likely to be fatal or cause severe disability (AFA, 2016). Additionally, Ali et al (2015) suggested the cost of AF–related strokes was greater than for non-AF-related strokes.

Appropriate anticoagulant management of atrial fibrillation in all eligible patients could avert an estimated 4,551 strokes each year. This translates to £97 million savings in NHS and social care costs or £259 million savings in societal costs in the first year. (Stroke Association, Current, future & avoidable costs of stroke in the UK)

Atrial fibrillation diagnosis:

AF QOF recorded prevalence compared with estimated prevalence and estimated additional number of people with AF required to be diagnosed to meet the PHE ambition, CCG, STP and England, 2019/20



Source: QOF 2019/20 recorded figures. Estimated prevalence from the NCVIN, 2020. Numbers rounded to the nearest 10.

National strategy:

The NHS Long Term Plan identifies CVD as one of its priority disease areas, noting that it is the single biggest area where the NHS can save lives over the next 10 years. The national AF target ambitions are:

- Detection: 85% of the expected number of people with AF are diagnosed by 2029
- Treatment: 90% of patients with AF who are known to be at high risk of a stroke to be adequately anticoagulated by 2029

Local strategy:

The following have been identified as key local priorities for CVD in SNEE:

- People have the information and support they need to reduce the risk of developing CVD;
- People with CVD have the right treatment and support to manage their condition.

Innovations:

FibriCheck

FibriCheck is a smartphone and smartwatch application to monitor heart rate, heart rhythm and to track symptoms.

Following download and activation of the application, heart rhythm is measured by placing a finger over the camera on the smartphone for 1 min, which enables access to immediate and actionable results.

FibriCheck detects cardiac arrhythmias (including AF), thereby preventing debilitating strokes. With over 96% accuracy in the detection of AF, FibriCheck has proven clinical equivalence with single lead electrocardiogram (ECG) like AliveCor. Certified as a medical device in Europe, US and Australia, FibriCheck is used by over 350,000 people and is prescribed by more than 1,700 physicians.

Zio XT

Zio XT is recommended via NICE medical technologies guidance [MTG52] as an option for people with suspected cardiac arrhythmias who would benefit from ambulatory ECG monitoring for longer than 24 hours.

The biosensor patch is a small, lightweight, easy-to-wear ECG, that records and measures the heart's electrical activity. It is worn constantly for between 1-14 days and can be fitted by a patient at home, discreetly underneath their clothes.

As the patch can be worn for up to two weeks, the amount of analysable data is larger than the 24-hour Holter monitor, which is current NHS standard practice and, therefore, Zio XT is more likely to pick up arrhythmias.

After use, the patient removes the patch and sends it via freepost for analysis. The ECG recordings are then analysed using an AI-developed algorithm, overseen by the iRhythms cardiographic technicians. A full report is then supplied to the NHS clinician for final analysis and interpretation within two to four days.

Deliverables

The primary aim of the project is to assess if home monitoring for people at higher risk of AF is acceptable and feasible, whilst providing a suitable pathway for further home monitoring to support diagnosis and treatment without adding additional pressure on primary care services.

The project also aims to understand the demographic factors associated with the use of digital home-monitoring equipment and the relationship between demographic factors and populations at higher risk of AF (age, gender, ethnicity).

The pathway will identify higher risk patients, provide access to technologies to enable remote heart rhythm monitoring and provide effective therapy to manage those with detected AF.

The pathway will be piloted for 6 months within 2 NHS Trusts in SNEE, aiming to target 1000 patients at East Suffolk and North Essex NHS Foundation Trust (Ipswich) and 750 patients at West Suffolk Foundation Trust. The participants for this evaluation will be individuals who have been identified as at higher risk of AF, utilising a locally agreed risk stratification matrix, including factors such as age, blood pressure, underlying heart disease, as well as lifestyle factors and family history into account.

Evaluation

The key evaluation questions we are interested in are:

- What impact has the remote AF detection pathway had on the identification of AF and the estimated impact on AF related strokes?
- How acceptable is the remote AF detection pathway to a targeted, at higher risk cohort of patients?
- How acceptable is the remote AF detection pathway to healthcare professionals using the pathway, including identifying any time or process efficiencies? This would include administrative teams, Public Health teams, nurses, cardiologist and clinic leads. See Appendix 2 Remote AF detection pathway.

We would also like the appointed evaluation team to consider the impact of the project on patient understanding and awareness of AF as well as the strategic priorities of health inequalities, workforce and the green agenda where possible.

Proposed methodology

The research team should develop a methodology that they feel appropriate, but both qualitative and quantitative methodologies should be used. This could include for example:

- Analysis of AF detection rates; including subgroup analyses according to demographic characteristics – and comparison with pre-implementation rates, (keeping any other screening initiatives in mind)
- A patient survey – also informed by numbers around engagement with Fibricheck and Ziopatch
- Staff interviews / focus groups
- Analysis of data provided by the trusts to feed into analysis of acceptability

It will be the responsibility of the evaluation team to:

- Develop an evaluation methodology and framework
- Develop appropriate qualitative and quantitative measures to address the questions above
- Ensure required governance is in place to access pilot data (This will be supported by Eastern AHSN and system partners)
- Develop an approach for collecting required data that is not routinely available
- Provide regular updates (frequency to be mutually agreed) on progress and escalate any issues that may affect timelines or the quality of the evaluation to Eastern AHSN as soon as they arise

The following data is being collected by the project system partners and will be made available to the evaluation team, once a data sharing agreement is in place with appointed evaluator:

Indicator/metric	Data source
KPI 1 - Number of patients identified as at risk of AF (based on project inclusion / exclusion criteria)	WSFT AF dashboard Suffolk Primary Care / Prescribing Services Ltd
KPI 2 – Total number of participants invited to remote monitoring i.e. No. of patients who are eligible to be contacted	WSFT AF dashboard Suffolk Primary Care / Prescribing Services Ltd
KPI 3 - Number of participants consented to remote monitoring (FibriCheck)	WSFT AF dashboard Suffolk Primary Care / Prescribing Services Ltd
KPI 4 - Number of consenting participants that activate the FibriCheck licence code (either via text message or email)	WSFT AF dashboard Suffolk Primary Care / Prescribing Services Ltd
KPI 5 - Number of patients utilising FibriCheck as directed: • No. of days taken to activate FibriCheck following receiving activation link • No. of patients taking at least 1 heart rhythm check • No. of heart rhythm checks taken over seven days • Average activation time vs patient risk assessment	FibriCheck aggregated data report and pseudonymised clinician reports
KPI 6 - Number of participants identified as at risk of AF (Red report) and asked to complete further assessments (Zio XT)	FibriCheck aggregated data report and pseudonymised clinician reports
KPI 7 - Number of participants eligible and consent to use Zio XT (following clinical consultation)	WSFT - pseudonymised clinician data ESNEFT – Ipswich - pseudonymised clinician data
KPI 8 - Number of participants using Zio XT as intended / directed: • length of time to activate following posting • wearing the patch for 14 days • No. returned within 25 day threshold	WSFT - pseudonymised clinician data ESNEFT – Ipswich - pseudonymised clinician data
KPI 9 - Number of patients with confirmed AF	WSFT - pseudonymised clinician data ESNEFT – Ipswich - pseudonymised clinician data
KPI 10 - Number of participants prescribed anticoagulants	WSFT - pseudonymised clinician data ESNEFT – Ipswich - pseudonymised clinician data

Suffolk system partners will be available to work with the evaluator to support the collection of further data in line with local information governance policies.

The work of the independent evaluator should result in:

- An interim output presenting a findings summary in October 2022*.

- A final report delivered at the end of December 2022. This should be copy-edited and ready for publication.

* See full timetable below

Value

A budget of up to £20,000 (excluding VAT and expenses) is available for this evaluation.

Precise funding agreements will be determined based on evaluation of the initial bid, and agreement of outcomes and deliverables.

Timetable

Below is an approximate outline timetable for this programme. Exact timings will be agreed with the appointed evaluator based on their approach, a phased start of delivery at West Suffolk Hospital and Ipswich Hospital and an agreed timeline for data collection and analysis.

Date	**Milestone**
Project start (Delivery of new pathway)	WSFT - Testing in Oct-Dec, full launch March 2022 Ipswich – Testing March 2022, full launch April 2022
Evaluation framework completed	April 2022
Theory of change refined	April 2022
Interim output available	October 2022
Project end	October 2022
Final report delivered	December 2022

Reporting

During the project, the bidder will be required to report on the following areas:

- Monthly progress updates, as well as progress reporting against anticipated milestones and key deliverables.
- Early results as and when they arise (and an interim report in October 2022).
- Spend to date against projected spend.
- Risk and issue reporting – including the escalation of all risks and issues that could impact on timelines and the overall quality of the evaluation as soon as they arise.

Assessment Criteria

You are required to respond to all of the quality criteria below using the response to tender form. 70% of the marks will be assigned against the quality criteria with the remaining 30% allocated against the financial proposal.

Scoring Methodology

0	The Provider is unable to fulfil the requirement or no response is received
1	The Provider is only able to partly fulfil the requirement
2	The Provider is able to fulfil the requirement
3	The Provider exceeds fulfilment of the requirement

Quality – weighted at 70% of total score	
The Provider has demonstrated that:	
Review Deliverables	1. All the objectives and products contained within the specification will be delivered.
	2. Comprehensive and suitable methodologies are proposed for all aspects of the work, with the rationale for each.
Capability	3. Project challenges have been identified and suitable mitigations proposed.
	4. Experience of undertaking a similar piece of work, delivered to timescale
	5. The availability of suitably competent staff who have relevant experience, evidenced by CVs
	6. An understanding and application of, data confidentiality and information governance issues.
	7. Able to deliver the report within the project deadline with a realistic timetable.
Price – Weighted at 30% of total score	
Price	Price will be evaluated by the bid with the lowest score scoring 100 and all other bidder prices being expressed as an inverse proportion. *For example, where maximum value for an opportunity is £60 000* *Bid A – Price £30,000 = scores 100* *Bid B – Price £40,000 = scores 90* *Bid C - Price £50,000 = scores 80* *Bid D – Price £60,000 = scores 70*

Checklist for bidders

This check list may be helpful in developing your bid but may not be exhaustive:

- Each bid states 'Evaluating the impact of the Suffolk & North East Essex (SNEE) Atrial Fibrillation Remote Monitoring Pilot' as a foot note on each page
- Each bid is page numbered
- Price for the bid has been provided, is net of VAT and is not subject to any proposed discounting.
- Each bid excludes the cost of making a presentation to Eastern AHSN and SNEE on the findings.
- Each bid states the daily rate for the author and any associates and the number of days consumed in each element of the task.
- Each bid includes an overall timeline, broken down by task and milestone.
- Each bid includes CVs for the project team, outlining similar work previously undertaken.
- Each bid comes from the same organisation as the organisation which will submit the invoice for the report once complete, and the name of the invoicing organisation is clearly given
- Each bid states that the report will be delivered in Microsoft Word.

Responses

We invite interested bidders to submit their response describing how they would deliver the described requirements within the timeframe and cost envelope.

Completed responses should be sent by email to Ben Jackson (ben.jackson@eahsn.org) **by 12:00 on 10th March 2022.**

If you have any questions on the invitation document or the deliverables, please contact Ben Jackson by 12:00 **on 4th March 2022.**

We will circulate all questions raised (without disclosing the source of the enquiry) and all responses to those contacted about this opportunity unless they are considered commercially sensitive. Our view on whether a question is commercially sensitive or not shall be final.

We reserve the right to carry out clarifications if necessary; these may be carried out via email or by inviting bidders to attend a clarification meeting. In order to ensure that both the Eastern AHSN and bidders' resources are used appropriately, we will only invite up to three (the ultimate number will depend on the closeness of scores) highest scoring bidders to attend a clarification meeting, should a clarification meeting be required.

Scores will be moderated based on any clarifications provided during this meeting. You are responsible for all your expenses when attending such meetings. Eastern AHSN reserves the right to vary all dates in this Invitation to quote, to terminate this procurement process and/or decide not to award a contract.

Appendix 1 – Logic Model

SNEE AF Pilot Implementation Logic Model

Context	A collaborative partnership between Ipswich and East Suffolk CCG, East Suffolk and North Essex Foundation Trust (ESNEFT), West Suffolk CCG, West Suffolk Foundation Trust (WSFT) and Eastern Academic Health Science Network (EAHSN) is undertaking a pilot project to identify patients at higher risk of Atrial Fibrillation (AF) and support them with a remote monitoring pathway in secondary care.
Rationale	AF is a chronic condition affecting around one million people in the UK and involves a significantly increased risk of stroke, with AF-related strokes more likely to be fatal or cause severe disability. Increasing detection and perfecting management of AF in all eligible patients could avert an estimated 4,551 strokes each year.
Aim	Understand the acceptability and feasibility of identified at higher risk populations self-monitoring heart rhythms utilising innovative, evidence-based technology called FibriCheck and Zio XT Patch, to support diagnosis and treatment without adding additional pressure on primary care

Inputs	Activities	Outputs	Outcomes and Measures
SNEE / EAHSN - Project planning / management, funding and resource management, RAID, strategic alignment, clinical guidance, IG leads, PPI support, evaluation	**Project governance** - DPIA created at ICS, NHS trust and technology provider level. Account enrollment agreements and MOU's to enable transfer of funding. Working group established to review and have oversight of the project plan, including RAID assessments.	**Project guidance** - Signed DPIA. pathway implementation plan, IT/IG process plan	Increased understanding of the **feasibility and acceptability** of the care pathway from both clinicians and patients
ESNEFT - Workforce, Clinical guidance, IT/IG infrastructure, operational agreements, communication team,	**Communication plan** - Technical and patient resources developed and shared via NHS trust communication channels (web page, patient test messages). Primary Care stakeholders informed.	**Communication collateral** - Web page created at WSFT and ESNEFT, with patient information. Patient guidance, text messages and letters created	Reduction in **AF related stroke**
WSFT - Workforce, Clinical guidance, IT/IG infrastructure, operational agreements, communication team, Public Health team, DrDoctor AF matrix	**Patient identification** - WSFT, AF Dashboard, created via DrDoctor (population health management tool) used to identify and communicate directly with at higher risk patients. ESNEFT, AF matrix and questionnaire developed using the Health of the Nation data to identify at higher risk patients from across 6 practices within Suffolk Primary Care. Patients are asked to participate in the pilot.	**Pathway development** - Pathway mapped and iteratively developed following feedback from clinicians and patients.	**Increased detection** of at higher risk people with AF
Prescribing services - Health of the nation data, automated patient risk stratification, IG approved patient communication tools, project plan	**Workforce training** - Training sessions delivered for clinicians at both WSFT and ESNEFT in the use and assessment of FibriCheck and iRhythm web based dashboards and reports	**Workforce development** - 4 nurses, 4 consultants trained to access and view assessment reports and FibriCheck and iRhythm dashboards and reports.	
Suffolk Primary Care - 6 practices using Eclipse, Accurx / system one patient communication, IG approved patient communication tools	**Initial assessment** - Once approved, patients are sent a 7 day FribriCheck licence via a link in a text message or a QR code in an email. Patients are instructed to check their heart rhythms 2 times a day for 7 days. Patient reports presented to NHS Trust	**Heart rhythm checks** - Up to 1750 at higher risk patients activate a FibriCheck license and monitor heart rhythm for 7 days. ·No. of days taken to activate FibriCheck following receiving activation link ·No. of patients taking at least 1 heart rhythm check ·No. of heart rhythm checks taken over seven days · Average activation time vs patient risk assessment	Improved **patient experience** though at home monitoring
FibriCheck - Pathway guidance, approved technology / software, 7 day licenses, project management support, IG assurance, service level agreements, patient support	**Diagnostic assessment** - Patients recording a 'Red' report from FibriCheck are contacted by a clinician and offered a wearable Zio XT patch. Patients are instructed to wear the patch for 14 days and return directly to iRhythm. Patient report provided to Trust clinical team for further assessment.	**AF detection** - Up to 134 patients offered further diagnostic assessment via Zio XT. Activation rates to confirm AF detection. · length of time to activate following posting · wearing the patch for 14 days · No. returned within 25 day threshold	Increase in patients **awareness and understanding** of AF and impact on their own health
iRhtym - Pathway guidance, NICE approved Zio XT technology / software, project management support, IG assurance, service level agreements	**Clinical consultation** - Patients are invited for a virtual consultation with a cardiology consultant.	**Perfecting treatment** - 100% of invited patients attend consultation and treatment initiated if appropriate	**Reduction in patient travel** with increased use of remote monitoring technologies

Assumptions	• Delivery will be supported by a range of partners, including but not limited to Acute Providers; Clinical Commissioning Groups; Primary Care Networks, EAHSN, FibriCheck and iRhythm • Engagement is required from secondary care to sucessful deliver the pilot • Patients - It is assumed that enough at higher risk of AF patients will be identified via the risk stratification matrix to enable enough FibriCheck activation • Staff engagement is required to develop the pathway and deliver the pilot effectively • Technology - The technology has already been tested for clinical effectiveness, this pilot is to establish if the remote nature of the pathway and using the two identified technologies is acceptable and feasible
External factors	• The impact of Covid-19 on system capacity to engage and deliver the pilot • National and local strategic drivers focusing on CVD prevention programmes that don't focus on AF i.e. hypertension • National and local AF screening programmes that are already established or being established i.e. AF detection at vaccination clinics
Contributing strategies and policies	The Suffolk and North East Essex (SNEE) Integrated Care System (ICS) Strategic Plan and Stroke Strategy sets out the ambitions and priorities for AF in the local area.The ICS stroke charter sets out the delivery plan for 21/22 with a focus on the three key elements of the AF pathway: Detect, Protect, Perfect.

Appendix 2 – Remote AF detection pathway

The image below illustrates the remote AF detection pathway but can also be summarised in the following key check points (further information available on request):

1. A locally defined and agreed risk stratification matrix is used to identify patients at higher risk of AF
    a. West Suffolk: AF dashboard generated through the public health team and the DrDoctor system
    b. Ipswich: Prescribing Services Ltd generates the patient list via the Health of Nation Data
2. Identifed patients are contacted digitally and offered the opportunity to participate in the pilot. Once the patient has accepted, they are sent an electronic link to enable them to download and activate a 7 day free licence of the FibriCheck application
3. The results of the FibriCheck assessment are automatically sent to the NHS trust clinician. If a 'Red' report is returned, the patient is then contacted by a clinician and offered a Zio XT patch
4. The Zio XT patch is posted directly to the patient with an accompanying guide and letter to aid application. The patient is directed to wear the patch for 14 days. Once complete, the patient is requested to post the Zio XT back directly to iRhtyhm
5. The finalised Zio XT report is digitally transferred to the NHS trust clinician who then reviews, arranges a remote consultation and then initiates the appropriate treatment protocol.