

Service Change Process

Gateway 1 – High-level Proposition

Innovation project name: **Patient Self-Monitoring/Management of Warfarin**

NHS Bury

Please describe the service change being proposed. Please describe what service(s) will change and how, how many patients are affected by the service. Summarise the evidence, rationale or drivers for the change, and the anticipated benefits for patients' and how these will be measured e.g.

- Reduces Health inequalities
- Promotes wider health
- Improves Access
- Improves Integration
- Other

Background

The availability of new oral anticoagulants has put increased focus on the management of patients with atrial fibrillation. Patients with AF are at 5-6 times greater risk of stroke compared to the general population, but anticoagulation remains suboptimal; according to the latest uploaded GRASP-AF data 35% of patients in Bury with a CHADS2 score >1 are not receiving anticoagulation. The reasons are multiple; variations in the quality of care, reluctance by GPs to recommend warfarin, available capacity of anticoagulation clinics and the reluctance of patients to take warfarin due to concerns with the drug and the inconvenience of regular monitoring.

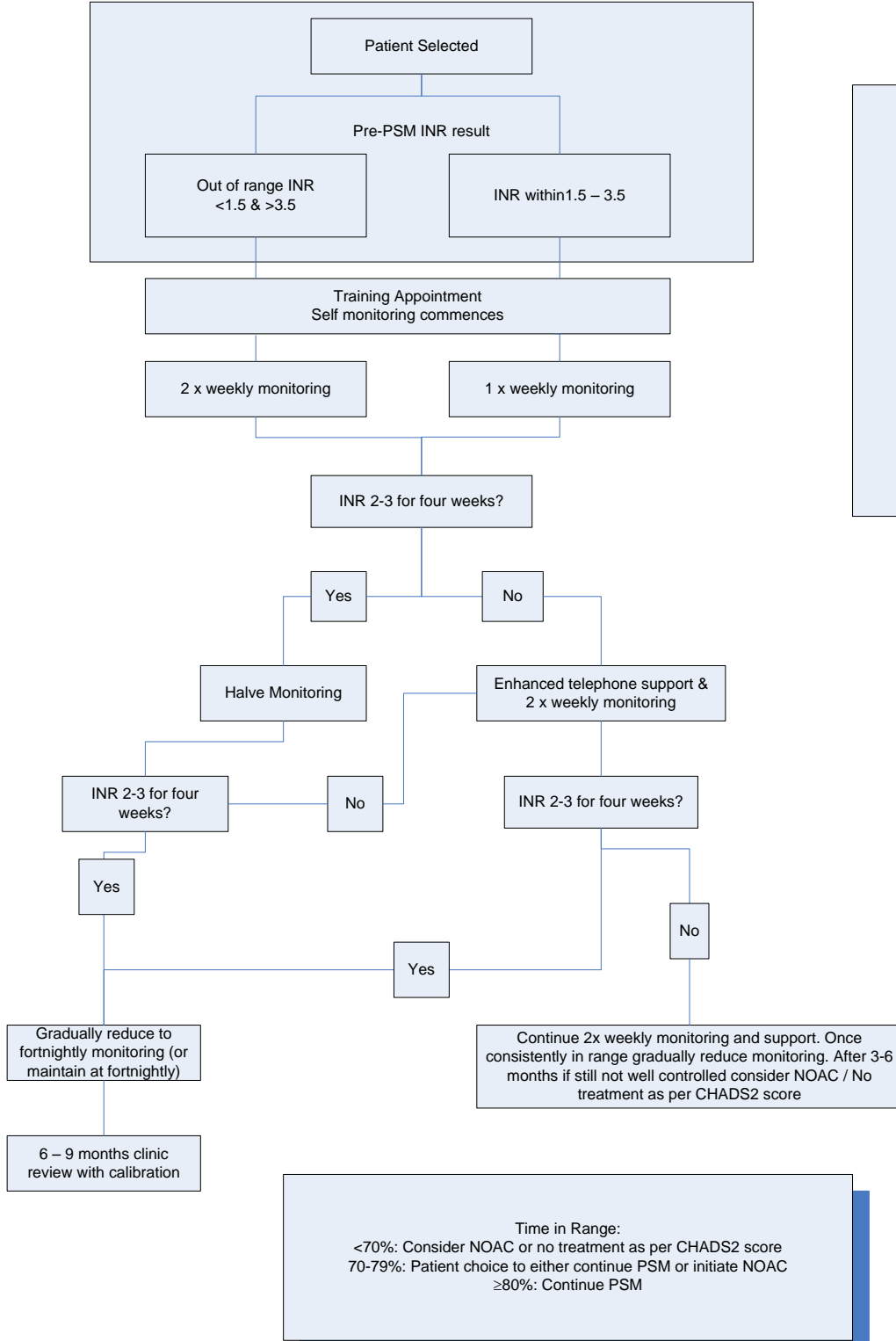
Now more than ever we need to offer patients greater choice and control of their care whilst also needing to identify cost savings and productivity opportunities . Following the publication of the NICE TA on Dabigatran and Rivaroxaban and the agreement of local guidance for anticoagulation of patients with AF it is expected that the number of patients prescribed a NOAC and the associated costs will rise slowly but steadily. Self-monitoring or self-management of warfarin provides an alternative to the existing anticoagulation service model, offering patients greater freedom and control and with demonstrable improvement in health outcomes.

Service Overview

Patient self-monitoring enables the patient to test their own INR and report to their anticoagulation clinician for dose adjustment. This gives the patient more freedom to travel and avoids the disruption to work and home life that potentially frequent visits to anticoagulant clinics creates. Patient self-management goes a step further, empowering the patient to determine the dose adjustment with the support of dosing charts and with access to advice if required. It is proposed that these options are offered to suitable patients who are either well controlled but would prefer to self-monitor due to the inconvenience of attending clinics, patients who are not well controlled who would appear to benefit from self-monitoring as an alternative to initiating an NOAC and patients who have requested a NOAC as an additional and more cost effective alternative.

Eligibility

- * Patients well controlled who would prefer to self-monitor
- * Patients out of range (any value) who would appear to benefit from PSM (Clinician/Patient Decision)



Guide sheet for dose adjustment and telephone support available

Time in Range:
 <70%: Consider NOAC or no treatment as per CHADS2 score
 70-79%: Patient choice to either continue PSM or initiate NOAC
 ≥80%: Continue PSM

Evidence

A Cochrane review was published in 2010 which included 18 clinical studies totalling 4,723 participants. The review concluded that both patient self-monitoring and self-management improves outcomes compared to standard models; thromboembolic events were halved (RR 0.50, 95% CI 0.36-0.69) and in the 16 trials that reported information on mortality, all-cause mortality was reduced by 36% (RR 0.64, 95% CI 0.46 to 0.89). Twelve trials reported improvement in the percentage of mean INR measurements within therapeutic range. The report concluded that “self-monitoring or self-management can improve the quality of oral anticoagulant therapy, leading to fewer thromboembolic events and lower mortality, without a reduction in the number of major bleeds.”

Health Inequalities

All cardiovascular diseases disproportionately affect people within lower socio-economic groups. An intervention which acts to improve cardiovascular outcomes therefore acts to reduce health inequalities. The prevalence of AF increases with age rising more sharply after age 65. Presently only patients who can afford to purchase monitors themselves have the opportunity to self-manage.

Number of people benefiting

The proposal seeks funding for 30 monitors thus benefiting 30 patients, with a view to expanding the pilot following evaluation. If fully implemented it has the potential to benefit at least 30% of patients receiving anticoagulation for AF.

Cost

- Each monitor costs £300 plus VAT.
- The Connect devices for transfer of data will be provided free of charge (up to 30, usual price £65 + VAT).
- Training and initial patient reviews up to three months will be provided free of charge
- Subsequent follow-up will be at a lesser frequency than patients receiving usual care.
- On an on-going basis a tariff will need to be agreed with the community anticoagulation service providers for provision of telephone dosing advice and 6-9 month review/equipment calibration.
- Test strips: £2.81 per test (approximately £112 per annum based on 40 tests)

If approved from when could this service be implemented? 4-6 weeks from the date of approval.

If this is a pilot how long will it run (max 6months) 6 months

Please summarise the potential impact of the service change in key areas

1. Measures of Success

Please identify how the service success will be measured in terms of Quality and safety, Innovation, Patient experience, Productivity, Performance, Savings Improved Clinical Outcomes

- Improved clinical outcomes will be measured by time in therapeutic range. This data will be collected and transferred by the XS Connect device.
- Patient experience will be assessed using the LTC6 questionnaire (pre-implementation and at 6 months)

Other measures to evaluate the pilot will include:

- Percentage of patients offered self-management and reasons for not offering self-management
- Take-up rate of self-management and reasons for declining
- Percentage of patients completing training
- Percentage of patients passing the assessment
- Percentage of patients continuing to self-manage at 3 and 6 months
- Testing frequency and associated costs
- Percentage of patients requiring additional advice on dosing and frequency of contact
- All related clinical events i.e. reported minor and major bleeds, thrombotic events

2. Workforce

Please bullet point key roles and responsibilities, skills mix and practitioners required.

- 1 GP Lead
- 1 Nurse Practitioner

3. Finance including capital

Demonstrate the: Set up costs; Sources of funding; Sustained funding;

- Each monitor costs £300 plus VAT.
- The Connect devices for transfer of data will be provided free of charge (up to 30, usual price £65 + VAT).
- Training and initial patient reviews up to three months will be provided free of charge
- Subsequent follow-up will be at a lesser frequency than patients receiving usual care.
- On an on-going basis a tariff will need to be agreed with the community anticoagulation service providers for provision of telephone dosing advice and 6-9 month review/equipment calibration. Proposed fixed cost of £100 per patient per annum
- Test strips: £2.81 per test (approximately £112 per annum based on 40 tests)
- Warfarin (average) = £31 per annum

Total Pilot costs (6 months)

	Unit Cost	Units	Total
Monitors	£360	30	£10,800
Connect devices	£0	30	£0
Test Strips	£2.81	600	£1,686
6-9month review/telephone support	£100	30	£3,000
Warfarin	£31	30	£930
Total			£16,416
Cost per patient			£547

Given that the total cost is heavily influenced by the monitors, it is more cost effective in the long term:

Cost Over Two Years:

	Unit Cost	Units	Total
Monitors	£360	30	£10,800
Connect devices	£0	30	£0
Test Strips	£2.81	2400	£6,744
6-9month review/telephone support	£100	60	£6,000
Warfarin	£31	60	£1,860
Total			£25,404
Cost per patient per year			£423

As a benchmark it would cost £612 per year for NOAC prescribing plus £50 for review, total £662 per patient per year.

4. Information Technology

The ConnectXS device will be provided free of charge. It is a USB which collates and graphs the INR data and testing frequency which is then emailed by the patient to the clinician.

5. Use of estates and facilities

The pilot is proposed to be operated at Tottington Health Centre. Given that the eligible patients would usually attend for INR monitoring, clinical space will be required less frequently than utilising this model however a room is required for the delivery of group training.

6. Impact on other services

E.g. Pathology, Radiology, primary or secondary care. How was this identified?

The pilot will only affect Tottington Health Centre. If it were to be expanded then it would affect all community anticoagulation services and would reduce the demand on clinic time. There would be no impact on pathology or other services.

7. Data recording requirements

- Improved clinical outcomes will be measured by time in therapeutic range. This data will be collected and transferred by the XS Connect device.
- Patient experience will be assessed using the LTC6 questionnaire (pre-implementation and at 6 months)

Other measures to evaluate the pilot will include:

- Percentage of patients offered self-management and reasons for not offering self-management
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- All related clinical events i.e. reported minor and major bleeds, thrombotic events

8. Contracts

Roll-out of the pilot would require changes within the community anticoagulation specification. This is presently being reviewed.

9. Other (please describe)

Please confirm membership of the bidder team

Nicola Harrison Public Health

Dr Rob Stokes GP and CCG Clinical Governance Lead