Section A.

The Academic Health Science Networks (AHSNs) and Pfizer Independent grants for learning and chancg (IGLC) on behalf of the Bristol-Myers Squibb – Pfizer Alliance.

Health system wide approach to improving and innovating in the management of people with Atrial Fibrillation (AF) through medication optimisation.

Blackburn with Darwen CCG

Blackpool CCG

Fylde and Wyre Clinical Commissioning Group (CCG)

Chorley & South Ribble CCG

East Lancashire CCG

Greater Preston CCG

West Lancashire CCG

North West Coast Innovation Agency

InHealthcare

Midlands and Lancashire Commissioning Support Unit (CSU)

Stroke Association

University of Central Lancashire (UCLAN)

Section B

2. Abstract*:*

Please include an abstract summary of your proposal including the overall goal, target population, methods and assessment. Please limit this to 250 words.

People who have a stroke caused by Atrial Fibrillation (AF) are often not anti-coagulated effectively. We know that Lancashire (population 1.5 million) has a poor rate of anti-coagulation, with time in therapeutic range often outside NICE guidelines. We have some good practice, but need a system-wide approach to ensure that we achieve results and efficiencies at scale. Our overall goal is to reduce AF related strokes, by optimising medication through introducing innovative combinatorial technologies in the care pathway. Our target population is newly diagnosed AF patients referred for anti-coagulation. We will introduce innovative technologies which will help us offer patients the anti-coagulation approach (genotype-guided dosing) and manage their medication if they are using warfarin (self-monitoring Coaguchek). We will support these systems through a system integrator provided by in-health care, to ensure a joined up approach to informatics. This will save time and clinic visits, and empower patients and ensure successful anti-coagulation. This provides us with efficiencies to manage future demand and complex patients. Our approach to introducing technology will be delivered in three phases. CCGs will continue with the technology after the programme ends if it is effective and cost neutral. The programme will be assessed in terms of numbers of people effectively anti-coagulated as per NICE guidelines (1). We expect that 85% of people are effectively anti-coagulated after 2 years, saving at least 250 strokes (a conservative estimate) in a two year period. This is a potential saving of over £5million (if each stroke costs the NHS £24K per year).

Contents Table

C. Main Section of the proposal:

1. Overall Goal & Objectives:

The overall goal for the project is to reduce and prevent strokes caused by Atrial Fibrillation (AF) across Lancashire by engaging key service providers in:

- Delivery of the service integration - removing any barriers to implementing a refined AF pathway across primary and secondary care
- Optimising medication - matching the right anti-coagulation therapy with the right patient to achieve optimal results
- Realising the health economy wide benefits from a focused approach to the identification and treatment of AF.

The key objectives of the programme will be measured against our five key outcomes:

1. We will reduce the number of AF related strokes across our target population by 5% by December 2019.
2. We will reduce the number of AF related strokes caused by uncontrolled anti-coagulation or AF that is not known in each CCG by 10%.
3. We will increase the number of well managed patients (managed within NICE guidelines – 65% Time in Therapeutic Range - TTR) in each CCG by at least 15%
4. We will explore the factors that influence the implementation of programmes including context and patient and clinical experiences. The exploration will be modelled on a theoretical framework designed for clinical practice.

This is in line with shared targets and indicators discussed with Lancashire clinical leads. To date there has been a significant effort in the region to increase the number of AF patients identified, with a range of initiatives including:

a) cohesive training offered to all CCGs, including clinical and quality improvements
b) an AF collaborative, led by the Innovation Agency, aimed at reducing practice variation
c) numerous local projects which look at better identification of AF using technology in primary care settings
d) the use of practice-based pharmacy
e) development of an AF commissioning tool-kit, clinical pathway and service development for people being identified and managed in hospitals.

However, there are still improvements that can be made across the pathway in engaging both primary and secondary care in developing a streamlined, evidence-based approach using the latest available technology. Key innovations which have been implemented in Cheshire and Merseyside can be replicated in Lancashire include:

- The use of genotype-guided dosing equipment in conjunction with an algorithm developed at the University of Liverpool, to personalise anti–coagulation therapy. The genotype test will identify people who are sensitive to Warfarin (and therefore unlikely to achieve therapeutic stability), allowing them to be immediately prescribed alternative therapy (DOAC) or identify the correct initiation dose

- Introducing a process for self-monitoring – for those patients who require regular international normalised ration (INR) monitoring, self- testing has been shown to support the achievement of a (TTR) of >65%
- Using integrated technology to enable the transfer of results between systems to optimise use of staff time. Through the use of cloud based technology, this enables clinical information to be shared amongst all providers along the AF pathway (in line with the Lancashire Digital Health Strategy).

Key Objectives:

- Establish a programme leads group to oversee the programme (and its workstreams)
- Refine/redesign the AF pathway with key service providers in Lancashire to ensure medicines are optimised and a focussed approach put in place for patients who have INRs outside the therapeutic range.
- Introduce genotype-guided dosing in hospital clinics for patients at the anti-coagulation initiation point – identifying those suitable for warfarin and those who would benefit from immediate DOAC therapy.
- Develop AF Community Champions (in partnership with the Stroke Association) who will develop relationships in their community and work with groups to raise awareness of AF and include the patient voice in the development of the service.
- Implement a digital pathway that allows patients to self-test their INR within a system that moves data around the health economy, integrating the data with key service providers / clinical systems
- Explore the factors that influence implementation.

2. Current Assessment of need in target area

a) We currently have excellent pockets of best practice in Lancashire, but are still experiencing a high number of strokes compared to other regions. Lancashire has the 4th worst rate of AF related strokes in the country, with approximately 404 strokes per annum compared to a national average of 1,000 (SSNAP 2015/16). There are 27,058 AF patients on our QoF registers and we spend approximately £3.1 million per year on NHS costs of AF stroke amounting to 17,360 bed days.

Currently 247 AF related strokes in our region per year result in death and between 35% and 85% (depending on the area) of those that are identified with AF are poorly managed, which leads them more vulnerable to experiencing a stroke.

b) Table 1. AF related strokes in Lancashire compared with national average and effective anti-coagulation

Number (%) of stroke patients who have AF related strokes in Lancashire		**National average (%)**	**Number (%) of patients who have AF who are not effectively coagulated**	**National average (%)**
Fylde & Wyre CCG	17.8	12%	18.5	25%
Blackpool CCG	16		22.2	
Chorley & South	17.6		46.2	

Ribble CCG				
Greater Preston CCG	17.8		25	
West Lancashire CCG	30.4		58.3	
East Lancashire CCG	16.6		45.2	
Blackburn with Darwen CCG	14.4		53.6	

Data from Sentinel Stroke National Audit Programme (SSNAP) Annual Team Results Portfolio Apr.15 – Mar16

Having looked at our AF related strokes compared with the national averages, it is clear that we can do better on supporting our stroke patients. Our work in this area will need to focus on the effective anti-coagulation of existing stroke patients who have been identified and are undergoing management in our local services. Currently there is a disconnect in the systems which allow people being initiated on warfarin in hospitals and then receiving ongoing management in the community. Currently the "yellow book" is something that all AF patients have to carry which details patients INR levels. Our region has identified a number of issues which are essential to ensuring patients are well managed: timely information sharing (currently services share paper information) and supporting patients who wish to take warfarin to become better self-managed and relieve pressure on services.

Table 2. AF patients using warfarin who self-monitor and patients who are anti-coagulated

Number of AF patients who are self-monitoring		**% patients with AF, CHADS2>1, and on Anti-Coagulation Therapy**
Fylde & Wyre CCG	70	72.29
Blackpool CCG	60	74.88
Chorley & South Ribble CCG	5	69.19
Greater Preston CCG	11	70.60
West Lancashire	12	68.50
East Lancashire	15	70.08
Blackburn with Darwen	12	70.62
Total	***185 (0.06% of patients using warfarin)***	

QoF AFOO4 data 2014/15

Currently we can see that a tiny percentage of people with AF are self-monitoring. Currently people can self-monitor if they purchase their own equipment and monitoring strips.

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 25-33% of patients in Lancashire with a CHADS2 score >1 are not receiving anticoagulation (table 2). 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 guidance on direct oral anti-coagulants (DOAC)s[2] and the agreement of local guidance for anticoagulation of patients with AF it is expected that the number of patients prescribed a DOAC and the associated costs will rise slowly but steadily. In order to optimise medicines for the Lancashire population there needs to be a systematic approach to anti-coagulation to ensure the right patients get treatment at the right time. Deaths of AF related stroke in Lancashire (currently 247), will be reduced by optimising medication.

A **genotype-guided dosing** programme will ensure that patients receive the correct dose of warfarin and stabilised more efficiently - those who may be unstable will be managed more appropriately. Genotype-guided dosing will ensure that patients who present with the genotype variants – indicating poor Warfarin uptake will be placed on a DOAC (if appropriate). Patients not displaying the genotype variants will, if prescribed Warfarin be offered 'self-testing' to monitor their INR. Patients will receive the correct dose of warfarin and stabilise more efficiently, and those who may be unstable will be managed more appropriately. Recent evidence demonstrates that a genotype test with a suitable algorithm which allows the clinician to fine tune the dose was more effective than standard clinical care[3-5] . Effective genotyping on 3 alleles related to clotting and metabolising have been shown to be effective *in partnership with an algorithm* in establishing warfarin dosing.[5]. Patients who have an irregular INR are at more risk of bleeds and frequent clinic appointments. A 10% improvement of TTR leads to a 20% improvement in clinical outcomes. 10% increase in time out of range leads to 20% increased risk of mortality.[5] LGC are a company which produce genotype testing for forensic and other environments and have successfully supported the introduction of this technology into three hospitals in Cheshire and Merseyside to support the dosing of AF patients using warfarin and deep vein thrombosis (DVT) patients**.** The odds ratio for individuals with a low warfarin dose requirement having one or more CYP2C9 variant alleles compared with the normal population was 6.21 (95% CI 2.48-15.6). Patients in the low-dose group were more likely to have difficulties at the time of induction of warfarin therapy (5.97 [2.26-15.82]) and have increased risk of major bleeding complications (rate ratio 3.68 [1.43-9.50]) when compared with randomly selected clinic controls.[3]

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 DOAC and patients who have requested a DOAC as an additional and more cost effective alternative. A Cochrane review was published in 2010 which included 18 clinical studies totalling 4,723 participants[6]. 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." If fully implemented it has the potential to benefit at least 30-50% of patients receiving warfarin as anticoagulation for AF. A 7% increase in TTR →1 less major haemorrhage/100 patient years; a 12% increase in TTR →1 less thromboembolic event/100 patient years; a 5% improvement in time in therapeutic range across UK anticoagulation clinics would prevent 400-500 strokes per year[6]; in international studies, a marked benefit was found against stroke and total vascular events for patients who had mean TTRs ≥65%[6]

Our current use of direct oral anti-coagulants (DOACs) DOAC Items prescribed per QoF AF Registered Patients (average) Fylde & Wyre CCG - 1.04 Blackpool CCG - 0.7 Chorley & South Ribble CCG - 1.45 Greater Preston CCG - 1.71, East Lancs CCG - 1.15 West Lancs CCG - 1.29, Blackburn with Darwen 1.96

3. Target Audience: Describe the primary audience(s) targeted for this project.

a) We are going to focus on newly diagnosed patients who are sent to clinic with warfarin. In Lancashire most patients are sent for dosing in the hospital (**Cardiology, stroke physicians, haematology, anti-coagulation nurses and team**). It is here that they can undertake the genotype guided dosing test. We have spoken with two of our key providers (**Blackpool Hospital Foundation NHS Trust and the Royal Preston Hospital Trust**) and they are both knowledgeable about the genotype-guided dosing programme and willing to work with the team to implement it. We have positive feedback from patients who have undergone the test in Cheshire and Merseyside clinics, who enjoy feeling that they are being cared for in the best way as well as the teams looking after them. In addition we have consulted with **expert patients** who are self-monitoring and have purchased their own equipment about how it is difficult to integrate their system and the hospital trust and monitoring through **primary care**. We will recruit patients from the hospital trusts (the genotype testing will be integrated first in Blackpool and then at Lancashire Teaching). The systems will be run sequentially (mainly due to the cost of the device), allowing the **CCGs** to examine how the service adds value to the clinic visits and the ongoing management of the patients and their anti-coagulation within NICE guidelines. This will play a role in their continued commissioning of the genotype-guided testing device. Suitable patients who are new to the service will be offered self-monitoring. This phase of the work can start immediately. Existing self-monitoring patients can also be linked into the IT system provided by inhealthcare which will link to DAWN, INR Star and also other GP systems eg EMIS or Vision One. Again, we will have a phased approach to this, working in the Fylde Coast region, then Central Lancashire, finally integrating West Lancashire. We will recruit patient champions who are using self-monitoring in each of the regions, supported by the Stroke Association. These patients will support service redesign. **GPs and other service providers** will also be involved. A number of **CVD GP leads** are supporting this bid

Table 3. Our plan for recruitment of patients is as follows:

1	Patients will be referred to their usual service provider for anti-coagulation.
2	All new patients on the warfarin pathway will receive a genotype guided test in clinic. Results will be available within 50 minutes at first appointment. Clinic consent models for genotype testing will be followed.
3	Results will be applied to the algorithm developed by the University of Liverpool and the dose established.
4	We expect that we will be able to examine 100 patients per site, who will take approximately 6 months to recruit. This is based on our experience of recruitment in clinics in Cheshire and Merseyside and allows the service to make a decision about efficacy of the device. Not all patients will wish to have or be suitable for a genotype test. Patients from an ethnic group outside Europe will not be suitable as research with these patient groups is still ongoing.
5	Patients medication will be managed according to their genotype and options discussed with them at the initial appointment.
6	Patients will also be assessed for their suitability for self-monitoring in accordance with NICE guidelines[1] and local clinical governance guidelines – SOPs will be developed to ensure that staff are able to assess patients. We expect that 40-50% will be suitable[7] and desire to self-monitor. We offer it to new patients over the period of a year and expect 400 new people to commence self-monitoring. This will allow us to examine the effects on clinic visits, patient and staff experience and outcomes for anti-coagulation and INR within therapeutic range.
7	Ongoing monitoring (either self-monitoring or face-to-face) will be carried out by the relevant service provider. This will be facilitated digitally to ensure that the patient has taken their reading at the correct time, the reading is within range and the GP or service looking after the patient knows the patient is up to date. Patients will be reviewed as per guidelines.
8	Patients provided with DOACs will be reviewed yearly as per NICE guidelines.[1]
9	Awareness will be raised in the community through community champions who will be service users who are self-monitoring who can advise the programme and provide information in the community from a service user perspective. One service user has already been identified. These champions will be key in the delivery of the programme and will have roles to advise the steering group and also provide feedback to the services and CCGs about service design. They will be a point of contact for new patients self-monitoring if they need one and will play a role in championing the programme.

b) Our key focus is to see an improvement in people with AF being effectively anti-coagulated as well as staff and services effectively engaging with new technology. We expect to see an increase in the number of people who have their INRs within therapeutic

range in accordance with NICE guidelines and by the end of year 2 we expect to see a reduction in the number of AF related strokes. The project offers the opportunity to make a major change in developing the services in our region and optimise medicines with AF patients as well as offering patient's choice and empowerment. We expect to see a much higher number of patients self-monitoring and using technology effectively in the home. Our previous work indicates that the majority of patients are happy to engage with technology. This work is in line with the implementation of the Clinical Commissioning Toolkit developed by the Strategic Clinical Network in 2015

c) Patients will benefit from the programme in terms of being offered more choice and opportunities to self-manage and being offered the most appropriate medication. Staff will benefit through a cohesive electronic system which enables them to better manage patients from presentation at the clinic, review 'hard to manage' patients on warfarin and those self-testing, as well as optimise their time with complex patients. We expect that this model could be replicated elsewhere or adapted to local circumstances, including, when technology allows, the use of genotype testing at GP surgeries (currently the equipment does not lend itself to this). Direct beneficiaries will be frontline staff and the patients themselves. Staff will develop confidence to help patients better manage their condition through greater awareness and choice. The Innovation Agency supports the development of the genotype-guided dosing model through a series of tool-kits that are in development.

Project Design and Methods: Describe your project design and methods.

a) Overall strategy: To ensure that the care pathway for patients with AF maximises the opportunities that up-to-date technology enables. This will allow us to realise the benefits with more informed choice, integrated information across the system and optimal medication. This will deliver the key outcomes of improved TTR of >65% and a reduced number of strokes in the AF population. We intend to achieve the goal of reducing AF related strokes from 1200 to 1000 in the first instance, which is the national average and to continue improving year on year in the future. Cost savings may be in excess of £5million.

Phase 0. 0-3 months. This will be preliminary work to take place in all sites.

Governance**:* We intend to deliver a programme of activity to help improve the identification and management of AF patients, both in the clinical setting and outside. We will use existing governance systems and a project operational group. We will operate a structured project management approach to the programme to oversee the individual projects and ensure delivery over the project timescales. External monitoring and assurance will be provided through the Stroke Prevention Board. We also need to ensure that devices have the necessary governance from the hospital trusts ready for the "go live" date. In addition the evaluation may need to seek ethical approval to carry out interviews and surveys with NHS staff. ***Partnerships**:* Our plan is to work with a range of partners to deliver a comprehensive programme which covers innovation, training, quality improvement (establishing and embedding processes and procedures in practices to ensure the ongoing management of patients is clear). ***Engagement: We will use a series of low cost mechanisms to ensure that we highlight the project and engage with relevant stakeholders. We will hold a series of social media events and webinars to give more information for stakeholders in Lancashire. All partners will support this work.

Phase 1. Fylde Coast. 3-9 months

Implementation. The implementation plan will be locality based over three sites. We propose to start with Fylde Coast, move on to Central and West Lancashire and end with East Lancashire and Blackburn with Darwen CCG.

Table 4. Target numbers of each phase

Area	Population	Expected prevalence	Number of patients
Phase 1. *Fylde Coast*	*386,774*	*4.54%*	*7,282*
Phase 2.*Greater Preston, Chorley & South Ribble, West Lancashire*	*518,998*	*5.22%*	*8,539*
Phase 3. *Blackburn with Darwen and East Lancashire*	*580,379*	*3.5%*	*9,008*

Population data source: NHS England Weighted Populations for Core CCH Allocations Oct 15 Registrations. Prevalence and Patient Numbers data source: HSCIC CCG Level Data (AF) 2014-2015

Pathway redesign: The CSU Stroke Prevention team are experts at redesign and will support any redesign in services that is needed in partnership with front-line staff. Our initial phase will look at services provided by Blackpool Hospital Foundation Trust and incorporate lessons from Warrington and Wigan where they have incorporated these services. ***Training****:* staff in the clinics will be trained on use of the genotype guided dosing tool (LGC will provide this) and also the use of self-monitoring equipment (Roche will provide this). All patients who sign up for self-monitoring will also be trained on how to use the equipment by a nurse (Roche). Four clinical champions will be recruited and trained as part of the programme set up (Stroke Association). ***Engagement****:* Further engagement will be carried out with key personnel including all GPs in the region informing them of the project. This will be done by the CSU Stroke Prevention team and also the Innovation Agency. Engagement will be with local clinicians and patient groups through focus groups. The technology – both equipment, data platforms and tests will be demonstrated through a 'show and tell' type event. Clinicians will also be invited to look at how the clinics run in our existing sites (for genotype guided dosing) and Wigan (self-monitoring)

Phase 2. 9-15 months. Phase 3 15-21 months

Key reports. The project will be reviewed and reported on to the Stroke Prevention Board at key gateway points, to ensure that it is delivering effectively and to give CCGs important information about the investments that are being made. One review point will be at month 3, where the effectiveness of set-up will be monitored. Reviews will also take place at month 9, when phase 1 is complete and also month 15 and month 21, when phases 2 and 3 are complete. Reviews at phase ends will include a collation of information from staff, service information and an assessment of costs.

b) The management of patients with AF is already a significant pressure on our health services. Decisions on treatment regimes, monitoring and optimising care are being

compromised by the capacity available within the system. Additionally we estimate that the Lancashire AF population will increase by at least 10% in the next 10 years and is set to double by 2050[8] placing an even greater burden on our health economy. To meet both todays demand and the expected increase in presentations the system has to respond with innovative ways to manage this population effectively. There are issues in our region that have meant that stroke prevention has made slow progress across the region. These will be addressed by this project as follows:

Table 4. Needs, actions and results.

Need / challenge	**Project Action**	**Expected result**
To do things differently using the latest technology	To allow the introduction of a a proven system to look at how it integrates into services in Lancashire	To demonstrate how innovative services can improve AF related stroke outcomes
A piecemeal approach to service improvement	A region-wide approach	A system-wide evaluation which can demonstrate improvements and efficiencies
Poor information flows across shared care pathway	Developing an integrated IT system can give professions the confidence that they are receiving timely information	Improved management of patients who are anti-coagulated
Patients who find it hard to attend clinic visits for warfarin	Self-testing will provide greater convenience and lower cost for patients	More empowered patients who have more TTR
Confusion for staff over different options for anti-coagulation	A system which gives staff the opportunity to ensure that the options given are the best for patients	More effectively anti-coagulated patients
Slow anti-coagulation can leave patients at risk of stroke	Genotype guided dosing can speed up the processes for establishing the correct warfarin dose and identify patients best suited for warfarin	Reduced risk of stroke while the dosing is established
Lack of patient choice for medication and management	Choices will be offered to patients	More empowerment and opportunity for self-testing
Poor information collateral to support patient led decision making	Introducing a system such as genotype guided dosing can give health care professionals more confidence in discussing options with patients	Improved number of people anti-coagulated
Poor compliance	Options to make it easier to comply with medication	Improved number in therapeutic range

c) Our key indicator of our target audience (patients with AF) being engaged will be in two ways: a) their willingness to consent to a genetic test; b) their willingness to take-up self-monitoring. We will monitor this closely with the services and unblock any blocks that we can in supporting staff and patients if they need it. Our experience suggests that very few patients turn down the test.

d)The Innovation Agency (North West Coast AHSN) is part of the national AHSN AF community and regularly shares information of its approach to AF. Whilst other AHSN's are looking to bring in updated information on technology and evidence based practice, the North West Coast is the only AHSN that is focusing on the immediate uptake and deployment of new technology and information flows across the pathway. Our plan is to engage, train, equip, recruit and deliver a revised AF pathway. As well as sharing learning we will also take best practice from other areas, e.g. training materials which we consider to be high quality and supportive of the project, and developing the work done with AliveCor, MyDiagnostick and the Self-Monitoring and Genotype-guided dosing. We have been early adopters of genotype guided dosing in the North West Coast, with three clinics in hospitals up and running since March 2016. This project compliments our roll-out plan of this technology across our region.

e) The Innovation Agency is currently supporting a number of AF related projects:

- We have supported genotype guided dosing in the North West Coast since 2016 . It is currently limited to 3 clinics and has so far seen 45 patients tested. This programme will allow us to build on this work. Our evaluation of this work is in progress and we expect to have preliminary results by the end of the year.
- Since 2015 we have supported a self-monitoring pilot in East Lancashire for patients in care homes. Nurses support care homes staff and patients by helping identify patients with AF (using the MyDiagnostick) and when identified, support them using Coaguchek. The service is monitored by the GP practice.
- We have assisted the roll-out of MyDiagnostick and AliveCor devices across the region helping in the initial diagnosis of AF. We have also used these devices in a number of forward looking campaigns.
- The Innovation Agency is developing a support package for a number of GP practices in Lancashire as part of the AF Collaborative in the North West Coast and part of the *Don't wait to anti-coagulate* initiative roll-out. This will raise awareness of the latest evidence base and available technologies in use to support the pathway.

CCGs in our region have also developed initiatives:

- Using practice pharmacists to identify and manage patients with AF. The programme indicated 19 strokes saved in Fylde and Wyre
- Programme of identification using a locally enhanced scheme for pulse checking in Blackpool which led to an increase in AF prevalence from 1.6% to 2.24%. and an overall stable number of strokes where it was expected to increase.
- Quality improvement for stroke prevention – a programme delivered by the North West Advancing Quality Association.

f) We are not proposing to develop new tools, however we expect to develop protocols, SOPs and information required to ensure technology is used safely and any patient data generated is linked to the GP record and integrated into systems such as DAWN, RAIDR and INR Star. Lessons learnt will be shared regionally and locally as well as with the national AHSN AF group and the Stroke Prevention group. Reports will be shared locally and nationally and will be disseminated through our stakeholders. Academics will generate peer reviewed papers and conference material.

5. Evaluation Design

a. In terms of the metrics used to assess the need for this project, describe how you will determine if the practice gap was addressed for the target group .

The overall aim of the improvement project is to reduce the number of avoidable strokes due to AF in patients at risk within the region. Using the established clinical dashboards (via Aristotle and the IA dashboard) this will be monitored throughout the course of the project to monitor changes on a regular basis. The evaluation will play a key role in the gateway reviews. The principles of Cane et al (2012) will be used to underpin qualitative work.

Clinical information that is can be collated at CCG level and across the region. This will include clinic visits, and data collated from the Aristotle system including GRASP-AF, SSNAP and other local data from clinics electronic systems including visits and TTR. Data on incidence will be collected. We will analyse data in accordance with demographic change including increasing prevalence. This will allow determination of change and whether the target reduction intended has been required. This information will be available for review on a regular basis to allow modification of interventions as required within the timeframe of the project. Our analysis will follow the phase approach of the programme. In addition a range of both quantitative and qualitative methods[9] (surveys, interviews and focus groups) will be used to capture the experience of those involved in the programme, to provide information on the context and identify the key factors that influence change. This will allow demonstration of not only of what has been achieved but also allow exploration of the how change has been achieved and the influences on this. This is an important consideration for further roll out across other health care systems.

b) We will be able to ensure that results are attributable to the programme by explicit tracking of patients being offered technologies. We can make comparisons with comparable patients who are not offered technologies. We are able to adopt a cross-over design that will allow us to review sites with and without the technologies. From baseline we will be looking for a number of key items: number of clinic visits to establishing dosing (expecting a 10-15% reduction); number of visits with post dosing (expecting a reduction of over 50%). We will look at the overall rate of change in strokes (expecting 5% or more) and the TTR of patients on our programme (expecting that all CCG areas should reach a minimum of NICE guidance of 65% - or a 10% increase per CCG.

c) A comprehensive dissemination plan for ensuring that the project outcomes will be delivered by the Steering or oversight Group. The plan will not only ensure that there is effective communication of the outcomes of the project but will ensure that there is appropriate communication about the project throughout its lifespan. The members of the group and the partnership is ideally placed to ensure that the outcomes of the project are

made available at multiple levels. Intended routes of dissemination include: submission for peer review publication; presentation at local, regional, national meetings; dissemination of information across clinical networks, AHSN networks and other clinical groups; input into guidance and reviews; provision of information to patient organisations and the third sector; use of social media; co-ordinated media campaign; reports to our funders and the Innovation Agency; publications in targeted "trade" journal such as HSJ or similar; launch and Close of project events

6. Detailed Work Plan and Deliverables Schedule:

October 2016 – January 2017. Pre-implementation phase. Scoping care pathway across Lancashire, identifying training dates, ensuring key strategic drivers are in place such as commissioning intentions for 2017/18. Making links with Healthier Lancashire workstream leads to ensure plans are aligned. Recruiting clinical champions.

January 2017-January 2018.

- Service redesign to include genotype guided dosing and use of self-monitoring for patients who are using warfarin. Genotype-guided dosing has demonstrated effectiveness at establishing warfarin dosing and also identifying patients who will never be stable on warfarin and require other medication. Self-monitoring has been shown to be effective in improving TTR, is popular with patients and cost effective.[6]
- We will work with all service providers and two companies – LGC and Inhealthcare to introduce the necessary protocols and service specifications to introduce these changes. In addition we will work with IT teams to ensure that AF patients are well supported through the pathway and clinical teams have the ability to monitor patients effectively. Training will form a part of this for clinical teams where the services will be deployed. Roll-out will take a staged approach.
- Develop AF Community Champions (led by the Stroke Association and in partnership with organisations such as the Rotary Club and University of the third age) who will develop relationships in their community and work with groups to raise awareness of AF. A programme of these will be timetabled and a link will be given to the local practice or participating service provider

March 2017-June 2018. Training will be developed and delivered in Fylde Coast, to a wide range of professionals. Training will be monitored and supported by a project manager dedicated to the programme. Phase 1 work to start.

Table 6. Activities and deliverables.

Activities	What will be delivered?	When?	Responsible	Cost
Establishment of Programme management team	Team with key roles and responsibilities; Commissioning intentions	January 2017	Stroke Prevention Board	N/A
Engagement of staff in the region	Communications plan for GPs and hospital staff and plans implemented including FAQs and Q&A	January -March 2017	Leads @ Blackpool and Fylde & Wyre CCGs	N/A – use of existing channels

Plan for PPI and engaging patients	PPI plan, recruitment of AF champions, training programme designed and delivered	January -April 2017	Stroke Association	N/A
Phase 1 – Fylde Coast				
Service scoping and pathway redevelopment	An outline of the existing pathway for patients	January -March 2017	Hospital and CCG leads	Nurse costs
Development of service SOPs	SOPs for genotype guided dosing and self-management in line with NICE	January – March 2017	Hospital	Nurse costs
Training for staff on using the genotype guided dosing equipment	Trained staff who are confident to implement	March 2017	Hospital/CCG /Project manager	Companies to provide
Implementation of informatics support	Digital support provided for hospital systems to link with DAWN and other relevant systems to provide a fully integrated IT system	January 2017	InHealthcare	Companies to provide
Audit and measurement system in place	Systematic data collection	March 2017	Hospital/inhealthcare/UCLAN	UCLAN evaluation
Evaluation designed and systems set up	Plan for evaluation and ethics approval	March 2017	UCLAN	UCLAN
Service going live	Go Live	April 2017	Hospital/ALL	
Monitoring and review	Reports to the Stroke Programme Board quarterly	From September 2017	Hospital/UCLAN	UCLAN
Phase 2. **Central Lancashire (Greater Preston, Chorley and South Ribble) and West Lancs**				
Service scoping and pathway redevelopment	An outline of the existing pathway for patients	March 2017- June 2017	Hospital, Primary Care and CCG leads	CSU/CCG/IA
Development of service SOPs including hospital where anti-coagulation is initiated and with other primary care providers	SOPs for genotype guided dosing and self-management in line with NICE guidance	March- June 2017	Hospital	IA

Training for staff on using the genotype guided dosing equipment	Trained staff who are confident to implement in the hospital	June 2017	Hospital/CCG /Project manager	Companies to provide
Implementation of informatics support	Digital support provided for hospital systems to link with RAIDr/INR Star and other relevant systems to provide a fully integrated IT system	January 2017	InHealthcare	Companies to link to existing systems
Audit and measurement system in place	Systematic data collection	June 2017	Hospital/inhealthcare	UCLAN
Evaluation designed and systems set up	Plan for evaluation	June 2017	UCLAN	UCLAN
Service going live	Go Live	September 2017	Hospitals	
Monitoring and review	Reports to the Stroke Programme Board	From January 2018	Hospital/UCLAN/Inhealthcare	UCLAN
Phase 3. **Blackburn with Darwen & East Lancs**				
Service scoping and pathway redevelopment	An outline of the existing pathway for patients	March 2017-June 2017	Hospital, Primary Care and CCG leads	CSU/CCG/IA
Development of service SOPs including hospital where anti-coagulation is initiated and with other primary care providers	SOPs for genotype guided dosing and self-management in line with NICE guidance	June 2017-September 2017	Hospital	IA
Training for staff on using the genotype guided dosing equipment	Trained staff who are confident to implement in the hospital	July 2017	Hospital/CCG /Project manager	Companies to provide
Implementation of informatics support	Digital support provided for hospital systems to link with DAWN/INR Star and other relevant systems to provide a fully integrated IT system	January 2017	InHealthcare	Companies to link to existing systems
Audit and	Systematic data collection	June	Hospital/inhe	UCLAN

measurement system in place		2017	althcare	
Evaluation designed and systems set up	Plan for evaluation	June 2017	UCLAN	UCLAN
Service going live	Go Live	Novem ber, 2017	Hospitals	
Monitoring and review	Reports to the Stroke Programme Board	From March 2018	Hospital/UCL AN/Inhealthc are	UCLAN
Review and monitor.				
Reviews and monitoring will be implemented by all the sites	Quarterly reviews will be received by the Stroke prevention Board. Gateway reviews will be provided as previously outlined	Quarter ly from Septem ber 2017	Leads at each site	UCLAN

D. References (no page limit)

1. NICE Guidance CG 180, June 2014. **https://www.nice.org.uk/guidance/cg180/chapter/1-Recommendations**
2. NICE. Support for commissioning: Anticoagulation therapy; May 2013.
3. Aithal GP[1], Day CP, Kesteven PJ, Daly AK .Association of polymorphisms in the cytochrome P450 CYP2C9 with warfarin dose requirement and risk of bleeding complications. Lancet. 1999 Feb 27;353(9154):717-9
4. Bourgeois, S., Jorgensen, A., Zhang, E. J., Hanson, A., Gillman, M. S., Bumpstead, S., Pirmohamed, M. (2016). *A multi-factorial analysis of response to warfarin in a UK prospective cohort.* Genome Medicine, 8(1), 315-21
5. Belley-Cote, E. P., Hanif, H., D Aragon, F., Eikelboom, J. W., Anderson, J. L., Borgman, M.,Whitlock, R. P. (2015). Genotype-guided versus standard vitamin K antagonist dosing algorithms in patients initiating anticoagulation: A systematic review and meta-analysis. Thrombosis and Haemostasis, 114(4), 768-777.
6. Garcia-Alamino JM[1], Ward AM, Alonso-Coello P, Perera R, Bankhead C, Fitzmaurice D, Heneghan CJ.Self-monitoring and self-management of oral anticoagulation. Cochrane Database Syst Rev. 2010 Apr 14;(4):
7. Self-monitoring of oral anticoagulation: a systematic review and meta-analysis C Heneghan, P Alonso-Coello, J M Garcia-Alamino, R Perera, E Meats, P Glasziou. Lancet 2006:367, 404-11
8. Miyaska Y, Barnes MF, Gersh BJ,et al.Secular trends in incidence of AF and implications on the projection for future prevalence. Circulation 2006:114, 119-25
9. Cane J, O'Connor D, Michie S (2012)**,** Validation of the theoretical domains framework for use in behaviour change and implementation research. Implementation Science 7:37