

## 'Don't Wait to Anticoagulate'

### Outline Business Plan to Support Local Project Implementation

#### 1. Introduction

- a. 'Don't Wait to Anticoagulate' ('the project') is an initiative led by the West of England Academic Health Science Network ('the AHSN'). It is a joint working project with Bayer and has included a participation from Boehringer-Ingelheim, Pfizer and Daiichi-Sankyo (all of which has been in compliance with the ABPI Code of Conduct). The project has the following aims:

- i. To support primary care to reduce the burden of Atrial Fibrillation(AF)-related Stroke in our population through achieving the following clinical aims:
  1. To increase rates of appropriate anticoagulation use in AF patients identified as high risk of AF-related stroke.
  2. Optimise anticoagulation of AF patients unstable on Warfarin through transfer to Direct Oral Anticoagulants in accordance with NICE Guidance (CG 180)
- ii. To develop a quality improvement approach that will enable clinicians to re-evaluate how identification, diagnosis and treatment occurs and consider NOACs alongside traditional anticoagulants
- iii. To develop a strategic approach that will enable a CCG to sustainably drive implementation of the above (including appreciation of financial and other benefits and risks of implementation).

- b. The project does this by achieving the following objectives:

- i. Reduction in the number of high-risk patients currently receiving no treatment;
- ii. Reduction in the number of high-risk patients currently receiving anti-platelet therapy;
- iii. Improvement in the efficacy of anticoagulation in patients unstable on Warfarin through the offer of NOACs in line with local formularies.
- iv. Increase the number of GP practices with the knowledge of quality improvement approaches to support the embedding of best practice.
- v. Increase in clinician confidence in prescribing and managing all OACs

#### 2. Progress to Date

- a. The project approach was tested in eleven innovator practices between February and April 2015, and is being tested at scale in Gloucestershire Clinical Commissioning Group (CCG) between November 2015 and April 2016 with 59 practices.

- b. In the eleven innovator practices, 2,688 known patients with AF were identified. Of these, 335 patients were rated as being at 'high risk' (i.e. had a CHA2DS2Vasc score of greater than one). Over a three-month period, 131 patients high risk non-anticoagulated AF patients were reviewed, and subsequently anticoagulated. As a consequence, it has been estimated that between five and six strokes were prevented over this period. Investigations into the potential financial implications of a stroke have suggested an associated cost of £23,315 per stroke (National Audit Office, 2010). Applying this principle to the findings of the innovator phase could suggest costs between £116,575 and £139,890 may have been avoided.
- c. The UK sees 150,000 strokes per year of which 20% are attributable to AF (Ball 2013), giving a figure of 30,000 AF-related strokes. Extrapolating the results from phase one may result in approximately 15% fewer strokes in high risk patients across the UK.
- d. In Gloucestershire CCG, 59 of 82 practices have indicated their initial agreement to participate in the project (72% of all practices). Of these 59 practices, three have been unable to attend the required clinical update and quality improvement training and are will not be included in the overall project evaluation.
- e. The 56 remaining practices cover a combined population of 413,309, which is approximately 67% of Gloucestershire's 616, 000 population.
- f. A brief summary of Gloucestershire's public health profile with regard to AF and stroke is as follows:
  - i. The CCG has seen a fall in early deaths from CVD over the last decade at both county and district level (mirroring the national trend); and the rate of premature mortality from CVD remains significantly lower than the national average.
  - ii. Data indicates that 19.7% of the GP registered population in Gloucestershire is 65 and over, compared to an England average of 16.9%. Between 2011 and 2021 the county is projected to see 27.3% growth in those aged 65 plus; and 36% growth in those aged 85 and over.
  - iii. The prevalence of AF is 1.9%, significantly higher than the national average of 1.6%. The recorded prevalence of AF has been relatively stable over recent years with only slight increases, consistent with the national trend.

However, this is likely to be an under-estimation of true prevalence. CCG wide, modelled estimates suggest that 33% of AF cases are undetected.

- iv. Stroke prevalence is 1.9% compared to the national prevalence of 1.7%. Trend data shows that the prevalence of stroke has remained relatively stable in recent years. While recorded prevalence rates of stroke have been relatively stable since 2009/10, the county's ageing population is likely to mean increasing prevalence of CVD over time

### 3. Planning for Dissemination and Spread

- a. The AHSN has developed an outline set of suggested work packages and indicative budgets to support the implementation of the project in other CCGs (appendix one). An outline Gantt chart has also been developed to indicate a possible timeline for project implementation (see attached Excel document 'generic AF Gantt')
- b. In creating this outline plan, it has been assumed that:
  - i. The CCG has agreed to include the project as part of its business plan. If this is not the case, the CCG will need access to health economic modelling data to assist in coming to a decision as to whether to proceed. The AHSN can assist in sourcing this modelling data if required
  - ii. All practices implement the project simultaneously. The AHSN recommends that a small pilot be conducted initially with local early adopters; this would have the benefit of testing the local iteration of the project, whilst also providing a number of clinical champions to support a further phased roll-out. However, it is recognised that this may be precluded by external factors.
  - iii. That a level of industry involvement is agreed, necessitating a formal 'sign-off process' in accordance with ABPI requirements.
  - iv. That the required quality improvement capability is not already present locally. The project developed this capability in a cadre of local practice support pharmacists in line with the results of the pilot evaluation.
- c. Indicative Budgets
  - i. The indicative direct budgets allocated to the suggested work packages (appendix one) total £22,000
- d. Core Staffing Requirements
  - i. Modelled on the experience of implementing the project in Gloucestershire the core staffing suggested for the project team is shown in table 1.

- ii. The AHSN undertook to make a contribution of £40,000 to assist in covering the costs of local implementation in its CCGs. It is likely that many of the indicative budgets associated with the work packages (such as 'communications and engagement', 'project governance', 'data collection and analysis', et cetera) can be absorbed within existing CCG capacity and will therefore not be an additional cost pressure.
  - iii. Likewise, it is anticipated that project management and support capability will be allocated by the CCG as a precursor to inclusion of the project in its business plan.
  - iv. Therefore, the £40,000 contribution should be sufficient to address the costs of the lead roles (clinical, managerial and pharmacist) and the remainder of the exceptional work package costs.
  - v. The AHSN has undertaken to provide up to 15 hours per week of coaching and mentoring support to its phase three CCGs; this is not included in the budgets below.
  - vi. The largest financial risk lies with the development of quality improvement capability to support implementation. However, as this is a core license objective for the wider AHSN network, this may already be supported by the business plans of AHSNs that adopt this project for national roll-out.
  - vii. Furthermore, the costs do not take into account the potential for off-setting expenditure through the development of partnership working opportunities with industry.
  - viii. Core Staffing Costs overall amount to £94,700 (£120,700)
  - ix. **Grand Total projected costs (including 10% contingency): £128,500 (£154,500)**
- e. The suggested core competencies to support local implementation are as follows; these may be external to core project team.
- i. Communications
  - ii. Data Collection and Analysis
  - iii. Evaluation (quantitative and qualitative as required)
  - iv. Quality Improvement Training and Coaching
  - v. Event planning
  - vi. Coaching
  - vii. Patient and Public Involvement
  - viii. Information Governance

| Role                     | Requirement   | Projected costs (£k) | Assumptions   |
|--------------------------|---|----------------------|---|
| Project Manager (Band 7) | 22.5 hours/ week for project duration                                 | 29.7                 | Top of band 7; £33/hour inc. on-costs<br>40 weeks project duration  |
| Project support (Band 4) | 15 hours /week for project duration                                   | 9                    | Top of band 4; £15/hour inc. on-costs<br>40 weeks project duration  |
| Clinical Lead            | 26 days over project duration   | 17                   | Assumed to be an influential local GP<br>£85/hour inc. on-costs   |
| Managerial Lead          | 26 days over project duration   | 6.5                  | Top of band 7; £33/hour inc. on-costs   |
| Pharmacist Lead          | 26 days over project duration   | 6.5                  | Top of band 7; £33/hour inc. on-costs   |
| Quality Improvement Lead | (Dependent on size of CCG; this cost assumes 54 practices/ 780 hours) | 26<br><br>(52)       | if internal capability available) Top of band 7; £33/hour inc. on-costs<br><br><ul style="list-style-type: none"> <li>(for external resource) £66/hour</li> </ul> |

Table 1: Core project staffing requirements



NB: QI Lead requirement calculated as follows:

- 0.5wte during planning/ recruitment/ training phases (20 weeks x 18.75 hours)
  - 375 hours
- Coaching Phase
  - Assumes 70% sign up rate (Example CCG of 54 practices; 38 practices sign up)
  - 5% drop-out rate following sign-up (2 practices drop out, leaving 36 practices remaining)
  - Each practice will require 3.75 hours coaching contact (including travel time) during the initial, middle and final third of the implementation window.
  - Assuming a 12-week 'big bang' implementation in the example CCG, this would require 36 x 3.75 hours (135) during each four week segment. This equates to a capacity requirement of 33.75 hours per week over the 12 week period
    - 405 hours
- Total hours required: 780

#### 4. Strategic Management of Dissemination and Spread

- a. The West of England AHSN will undertake to provide 3.75 hours per week of coaching and mentoring support to AHSNs that include the project on its business plan for the coming year.
- b. It is recommended that a strategic steering group be established to support the following objectives:
  - i. Preservation of the quality and integrity of the 'Don't Wait to Anticoagulate' project
  - ii. Monitoring of reported long-term stroke prevalence and incidence data, comparing:
    1. CCGs implementing the project
    2. CCGs not implementing the project
  - iii. Centralised reporting and dissemination of 'lessons learned' between implementing AHSNs
  - iv. Promotion of constructive relationships with industry partners, through:
    1. Dissemination of good practice in partnership arrangements
    2. Promoting consistency of approach
    3. Ensuring transparency
  - v. Promoting effective public and patient involvement in the ongoing project
  - vi. Enabling evaluation of:
    1. The mechanism of dissemination and spread via the AHSN network.

2. The impact of the quality improvement approach on implementation
  3. The mechanism of transferability of the approach used to other disease areas within CCGs
- vii. Communication and engagement activities
- c. It is recognised that further planning (and development of an associated resource plan) to support the objectives above is required.

Appendix One: Suggested Work Package Outline

| Work Package (WP)             | Recommended Budget (£k; capacity/capability assumed to be available in-house unless specified) | Supports..... | Dependent on....   | Outcomes   | Outputs   | For Strategic Steering Group  | Notes   |
|-------------------------------|--|---------------|--|--|---|---|---|
| Project Governance            | 1  | All WPs       |  | A sufficiently robust set of structures and processes to enable ongoing management of delivery throughout the project lifetime               | *Project documents as required by implementing organisation | *Highlight Report (monthly)<br><br>*Exception Report (if appropriate) | *Recommend fortnightly Project Working Group meetings   |
| Communications and Engagement | 2  | *All WPs      | *Industry engagement<br><br>*All WPs for content<br><br>*Revision of Materials (for local use)<br><br>*Practice Sign-Up (plan) | All stakeholders are informed and engaged with the project in line with their potential to impact the overall aim (positively or negatively) | *Strategy and plan  |   | *Nature of industry relationship to be communicated clearly from outset<br><br>*Launch event a key component (possibly combined with clinical update training)<br><br>*Dissemination and spread of the project to other local organisations also to be considered; with regard to the QI element, this may include other unrelated disease areas. |



|                              |   |  |   |   |  |   |  |
|------------------------------|---|--|---|---|--|---|--|
| Clinical Update Training     | 3 | *Implementation                              | *Revision of Materials<br>*Implementation<br>* Data Collection and Analysis | Practice leads are sufficiently competent and confident to lead the required change at practice level             | *Skills audit<br>*Training Plan  |   | *Size. of events dependent on CCG; recommend three events to promote uptake<br><br>*May need to be staggered dependent on Implementation plan (staggered or 'big bang')<br><br>*Notice of dates should be out to practices 6 to 8 weeks ahead of event |
| Revision of Materials        | 3 | *Clinical Update Training<br>*Implementation | *Industry Engagement (due to possible requirement for sign-off)             | A set of materials that are acceptable at a local level and of an appropriate quality                             | *Training presentations<br>*Welcome Packs<br>*Bespoke web page content | * Bespoke web page content (for inclusion on master site) |  |
| Data Collection and Analysis | 1 | *Implementation                              | *Evaluation   | An evaluation report that provides local assurance as to the impact of the project as well as learning for future | *Data collection strategy and plan                                     |   | *Needs to be included in Clinical Update Training  |

|   |   |                                  |  |   |   |  |  |
|---|---|----------------------------------|--|---|---|--|--|
| Evaluation                                    | 5<br><br>(ten days @<br>£500/day if<br>qualitative<br>evaluation<br>required) | *Data Collection<br>and Analysis |  | A group of locally-<br>based staff who are<br>competent and<br>confident to support<br>the QI approach<br>taken by the project                          | *Evaluation<br>Framework and plan   | Copy of the<br>final<br>evaluation<br>report | *CLAHRC representatives should be<br>included as Subject Matter Experts<br><br>*May include qualitative as well as<br>quantitative elements (quantitative<br>considered as minimum requirement)<br><br>*Formative and summative evaluation<br>recommended  |
| Building Quality<br>Improvement<br>Capability | 1   | *Implementation                  |  | An effective action<br>plan to address the<br>needs of the<br>population with<br>protected<br>characteristics that<br>may be affected by<br>the project | *Recruitment and<br>resourcing plan<br><br>*QI training plan<br><br>*QI coaching plan |  | *Assumes internal capability not<br>currently present in CCG, and that<br>pharmacists will be primary change<br>agents in practices<br><br>*During delivery phase, suggested<br>that change agents should receive<br>appropriate training and then<br>complete a personal improvement<br>project (clinical or non-clinical) to<br>consolidate learning and build<br>confidence prior to Implementation<br><br>*During 'coaching' phase, assumes<br>three face to face sessions with<br>primary change agents (initial/<br>interim/ final), with ongoing remote<br>coaching and support as required |

|                                  |   |  |      |  |   |                             |  |
|----------------------------------|---|--|------|--|---|-----------------------------|--|
| Equality Impact Assessment (EIA) | 0 | *Revision of Materials   |      | Patient and public views are built in to and influence the project from inception                        | *EIA  |                             |  |
| Patient and Public Involvement   | 0 | *Communications and Engagement   | *EIA | Engagement with industry groups is conducted in a locally-innovative, transparent and appropriate manner | * Patient and Public Involvement strategy                                 |                             |  |
| Industry Engagement              | 0 | *Implementation<br>*Communication and Engagement<br>*(Resourcing Plan) Building Quality Improvement Capability |      | Data collection is managed in accordance with local IG requirements                                      | *Options paper<br>*(If appropriate) Industry Engagement Strategy and Plan | * Copy of the options paper |  |
| Information Governance           | 0 | *Data Collection and Analysis<br>*Evaluation   |      | 95% of all practices that sign up complete implementation (as defined locally)                           | *Level Two Information Governance Protocol (or equivalent)                |                             |  |

|   |                                   |   |                                  |  |   |  |  |
|---|-----------------------------------|---|----------------------------------|--|---|--|--|
| Implementation  | 5<br>(to cover contingency costs) |   | *All other WPs                   | A locally-decided percentage of practices agree to participate in the project                                    | *Strategy and Plan<br>*Tracking tool/<br>database                       |  | *Dependent on local requirements. However, would recommend a pilot in a small number of practices (as a first PDSA) and a phased roll-out (to reduce likely resource impact of 'big bang' needing all pharmacist resource to be deployed at one time across all practices) |
| Practice Sign-Up                                      | 0                                 | *Implementation<br>*Clinical Update<br>Training | *Communication<br>and Engagement | Increased local uptake of the New Medicines Service for patients with AF   | *Strategy and Plan<br>*Tracking tool/<br>database                       |  | *Suggested that 70% sign-up rate could be a suitable stretch goal  |
| OPTIONAL COMPONENT: New Medicines Service             | 1                                 |   |                                  | Increased number of practices conducting reviews of care of patients admitted to hospital with AF related Stroke | *Strategy and plan<br>*Locally-adapted process<br>*Method of evaluation |  |  |
| OPTIONAL COMPONENT: Out Patient Readmission Avoidance | 0                                 |   |                                  |  | *Strategy and plan<br>*Locally-adapted process<br>*Method of evaluation |  |  |

