

# Setting the Standards in Anticoagulation Service Delivery

## *A Step by Step Guide to Setting Up & Implementing an Anticoagulation Management Service in Primary Care*

### Why set up an anticoagulation service in primary care?

- Oral anticoagulation management in primary care, via near-patient testing (NPT), has been shown to result in effective therapy management, comparable to secondary care management.<sup>1</sup>
- Locally-based primary care services provide more choice and flexibility for patients in line with the government's 'Patient Choice' initiative.
- There are considerable financial rewards for practices choosing to offer a near-patient testing (NPT) anticoagulation service. Since the introduction of the GMS contract in April 2004, remuneration has been up-rated twice and practices are now entitled to receive up to £127.86 per international normalised ratio (INR)-managed patient for a level 4 service.<sup>2</sup> Further opportunities now also exist through practice-based commissioning.
- Shifting some of the burden of anticoagulation monitoring from hospitals into primary care will allow Haematology Departments to focus on new and problematic patients.
- An opportunity is provided to enhance the skill base of GPs and the wider primary care team.
- A more collaborative approach between the healthcare professional and the patient encourages patients to become more involved in their treatment and overall health, in line with government 'Self-Care' and 'Expert Patient' initiatives.

*Research shows that anticoagulation monitoring can be safely and effectively delivered in primary care using a point of care (POC) monitoring device and Computerised Decision Support Software (CDSS).<sup>3</sup>*

### Planning a service

- Set up a multi-disciplinary steering group to discuss how the service will work in practice and how the service can be transferred from secondary to primary care safely, effectively (both clinically and financially) and with minimal organisational disruption. Include the PCT lead responsible for service delivery, a secondary care representative, a GP, a Practice Manager, a nurse and a pharmacist if possible/appropriate. Consider also involving a patient representative. Hold regular meetings to share information and ensure everyone is involved and kept up to date.
- Identify eligible patients in your area – consider taking on patients from a neighbouring practice not providing the service. Most patients already taking warfarin will be identifiable from an existing manual system, from a computer search of anticoagulant drugs on repeat prescription or from the hospital anticoagulation clinic. Patients with atrial fibrillation not currently on warfarin should be considered for anticoagulation therapy and can be identified via morbidity registers or repeat prescription searches.

- Consider available local resources and select the most appropriate model/ level of service for your practice. There are four levels of service under the GMS contract:<sup>2</sup>

<b>Level 1</b>	Laboratory outreach sampling, test and dose
<b>Level 2</b>	Practice sample, laboratory test, practice dosing, externally funded phlebotomist or pharmacist
<b>Level 3</b>	Practice sample, laboratory test, practice dosing, practice funded phlebotomist or pharmacist
<b>Level 4</b>	Practice sample, test, dosing, practice funded phlebotomist or pharmacist

(Level 4 is the model profiled in this document)

- Estimate the impact on workload and staffing, including nursing and administrative staff
- Agree referral systems with secondary care
- Agree hours and location of service
- Develop a business case and present it to your relevant commissioning body

## Setting up a service

*Authored by Professor David Fitzmaurice, GP & Professor of Primary Care, Birmingham*

- Designate a clinical lead – this is usually a GP but could be a nurse or a pharmacist.
- Develop protocols and standard operating procedures – liaise with practices already running a service to provide you with a template and advice. Helpful templates may also be available from manufactures of POC devices or decision support software providers.
- Arrange for staff to attend training sessions to cover both the theory and the practice of anticoagulation monitoring and managing a clinic. Courses are available across the UK e.g. National Centre for Anticoagulation Training (NCAT) in Birmingham.
- Select and purchase a POC monitoring device - there are a number of devices available that can be used to measure INR levels from capillary blood. See Figure 1 for a list of criteria the device should fulfil.
- Select and purchase decision support software which will assist in translating INR results into a recommended dosage of warfarin and suggest a date for the next test. There are many systems on the market – try out and assess different software to see what best suits your practice. It is important that whichever system is used:
  - is capable of keeping track of all patients on oral anticoagulants so that patients are not 'lost'
  - ensures that medical information about the patient (e.g. new medications, change in diagnosis, adverse events) is transmitted to whoever is looking after the patient
  - has an alerting system for missed appointments/ discontinuation
  - is easily auditable with user-friendly record keeping systems.

### **Figure 1: Criteria for selecting a point of care monitoring device**

*Authored by Chris Gardiner, Chief Biomedical Scientist, Dept. of Haematology, UCL Hospitals*

When purchasing a POC anticoagulation monitoring device consider whether it:

- Has been evaluated by the Purchase and Supply Agency (PaSA) Centre for Evidence-Based Purchasing (CEP) and found to be safe and accurate for use in clinic or at home
- Has an International Sensitivity Index (ISI) of close to 1.0, in line with WHO recommendations, which specify that ISIs should be between 0.9 and 1.7 but that ISIs towards the lower end of the scale are preferable
- Has a means for providing both internal quality control and external quality assessment. Low coefficients of variation of 4-5% that closely match laboratory analysers are preferable
- Is easy to use
- Produces fast results
- Has data management capabilities that match your requirements
- Does the manufacturer offer any value-added support services?

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## Rolling out the service

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- Ensure that equipment meets the necessary quality control and assurance standards (See Figure 2).
- Hold regular meetings to evaluate the service offering and discuss possible ways in which it could be improved. Consider running a patient satisfaction survey.
- Assess staff competency at regular intervals and keep a training log.

### Figure 2: Quality control & assurance

*Authored by Steve Kitchen, Sheffield Haemophilia & Thrombosis Centre*

Quality assurance (QA) is the overall term used to describe all measures that are taken to ensure the reliability of INR testing and reporting. Internal quality control (IQC) and external quality assessment (EQA) are two distinct, yet complementary components of the quality assurance programme. Both are required. IQC is used to establish whether the INR results are consistent over time. EQA is used to identify the degree of agreement between INRs in different centres.

#### IQC

Some manufacturers of POC monitors produce test strips for INR determination in which there is in-built IQC. This is very useful because it checks each strip individually. In some cases however, liquid controls may also be recommended, depending on local protocols.

IQC is important to perform:

- When introducing a new batch/lot of test strips
- When commencing use of newly delivered strips (even if the same lot number as before)
- If there is doubt about the storage conditions of the test strips
- If an unexpectedly high or low INR result is obtained on a patient
- At the beginning of each clinic

If an out of limits IQC result is obtained patient testing must be suspended until the problem has been resolved.

Records should include:

- IQC result
- date of testing
- operator ID
- lot numbers of IQC and test strip

#### EQA

Some form of EQA is essential. The recommended option is to participate in an accredited EQA programme, such as the UK National External Quality Assessment Scheme (NEQAS). This involves regular distribution of samples which are then tested on the POC monitor and results returned for comparison with other centres using the same device.

POC and laboratory INRs on the same patient within 0.5 are considered acceptable for results in the therapeutic range. This is best performed using samples from stabilised patients. Initially one sample per clinic can be tested, but with evidence of good local agreement this can be safely reduced to 1 or 2 samples per month. Any INR result between 4.0 and 8.0 should be repeated using the POC monitor and the 2 results should be within 0.5 at INR 4 or 1.0 at INR 8.0. Greater discrepancy indicates a problem with at least one of the tests. If the INR is > 8.0 then a venous sample should be sent to the local hospital.

- Provide consistency for patients as far as possible, and provide them with sources of information that will engage them and empower them to take more control of their health (See Figure 3).

### Figure 3: Educating patients

*Authored by Eve Knight, Anticoagulation Europe*

- Providing patients with information is key to proper control and concordance
- Information needs to be available in as many formats as possible e.g. written, online, video
- Patients must be given time to ask questions and have an informed discussion with their healthcare professional (HCP)
- Patients must be invited to refer back to their HCP with any further queries
- Educating patients encourages them to be more involved in their own healthcare and can lead to self-testing in appropriate patients

## Planning a service

- Set up a steering group
- Identify eligible patients
- Select an appropriate model of service
- Assess the impact on workload & staffing
- Agree referral systems
- Agree hours and location of service
- Assess the financial implications and develop a business case
- Present your business case to the relevant commissioning body

## Setting up a service

- Designate a clinical lead
- Develop protocols/ SOPs
- Organise staff training
- Select and purchase POC monitoring device
- Select and purchase decision support software
- Inform patients of the service

## Rolling out the service

- Ongoing internal & external quality assurance
- Ongoing staff training and assessment
- Review the service at regular intervals
- Provide patients with a consistent quality of service



## Useful sources of further information

- Anticoagulation Europe [www.anticoagulationeurope.org](http://www.anticoagulationeurope.org)
- Anticoagulation Specialist Association [www.the-asa.org.uk](http://www.the-asa.org.uk)
- British Society of Haematology [www.b-s-h.org.uk](http://www.b-s-h.org.uk)
- British Society of Haemostasis and Thrombosis [www.bsht.bham.ac.uk](http://www.bsht.bham.ac.uk)
- Clinical Leaders in Thrombosis (CLOT) [www.clotuk.com](http://www.clotuk.com)
- Primary Care Cardiovascular Society [www.pccs.org.uk](http://www.pccs.org.uk)
- University of Birmingham [www.anticoagulation.org.uk/bam.htm](http://www.anticoagulation.org.uk/bam.htm)
- [www.coagucheck.co.uk](http://www.coagucheck.co.uk)
- International Self-Monitoring Association for Oral Anticoagulation (ISMAA) [www.ismaa-int.org](http://www.ismaa-int.org)
- UK National External Quality Assessment Service (NEQAS) [www.ukneqasbc.org](http://www.ukneqasbc.org)
- Medicines and Healthcare products Regulatory Agency [www.mhra.gov.uk](http://www.mhra.gov.uk)
- Self Care – A Real Choice. DH. 2005
- Supporting People with Long Term Conditions to Self Care. DH. 2005
- Expert Patient Programme [www.expertpatients.nhs.uk](http://www.expertpatients.nhs.uk)
- Self-Management Guidelines [www.bcsghguidelines.com/pdf/fitzmaurice\\_I00306.pdf](http://www.bcsghguidelines.com/pdf/fitzmaurice_I00306.pdf)

### REFERENCES

1. Hobbs FDR et al. A review of near patient testing in primary care. Health Technology Assessment. 1997; 1: 5.
2. Medeconomics, August 2006.
3. Fitzmaurice DA et al. Randomised controlled trial of oral anticoagulation using computerised decision support (CDSS) and near patient testing (NPT). Archives of Internal Medicine. 2000; 160: 2343-2348.