Setting up an Anticoagulation Clinic in Primary Care

This paper aims to outline the decisions and practical steps needed to set up and run a successful anticoagulation clinic in a primary care setting.

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Introduction

The monitoring of anticoagulation for patients taking oral anticoagulants has traditionally been performed in hospital anticoagulation clinics. There has been a trend over the last few years for this activity to be transferred into primary care and many practices are setting up practice based anticoagulation clinics. This trend has accelerated since the introduction of Primary Care Groups and Trusts, many of which are actively encouraging and supporting practices to set-up and run anticoagulation clinics.

Benefits of an in-practice anticoagulation clinic

- Improved anticoagulation control
- Reduced number of INR tests required to maintain good control
- Improved patient safety
- Reduced potential for errors in dosing
- Improved patient convenience
- Improved efficiency in the use of doctor/nurse/staff time
- Improved efficiency in the use of resources
- Contribution to practice financial income

It has been shown that anticoagulation control achieved by practice-based anticoagulation clinics is at least as good as that in hospital clinics and that patient convenience is much improved. The use of near patient testing (NPT) techniques and computerised decision support systems (CDSS) improve the efficiency and quality of anticoagulation control attained.

The likelihood of dosing errors or mistakes in transmitting results of INR tests to patients is greatly reduced by running an in-practice clinic where patients are given printed dosing instructions at the time of their INR test.
Most PCG/PCTs are now recognising the benefits to patients of practice-based clinics and many PCG/PCTs pay practices for providing this service. A properly run anticoagulation clinic can thus provide an improved service for patients whilst at the same time making a significant contribution to practice income.

**Issues to be considered before setting up a clinic**

**Identification of suitable patients**

Most patients already taking oral anticoagulants will be identifiable to the practice either from an existing manual system, from a computer search of anticoagulant drugs on repeat prescription or from the hospital anticoagulation clinic. This is a good time to review the original indication for anticoagulation for each patient and decide a suitable INR target and length of treatment as appropriate. It is a common experience to find several patients for whom the original indication for anticoagulation has been lost in the midst of time and for whom it might be appropriate to discontinue treatment. Likewise many patients may have an inappropriate INR target (usually too low).

In most practices there are reasonably large numbers of patients with atrial fibrillation, currently not taking anticoagulants, who should be considered for long term anticoagulation. These patients should be identified from morbidity registers or via repeat prescription searches. Most practices should expect the prevalence for patients on oral anticoagulation to be around 1-1.5%.

**Estimation of workload and staffing implications**

Setting up and running an anticoagulation clinic has major staffing and workload implications for the practice. The following chart gives an estimate of the likely clinic workload based on total number of patients on warfarin and the average review period between INR tests.

This chart assumes 10 minute appointments and clinics running on 46 weeks/year.

It can be seen from the chart that the major factor in predicting workload for a clinic is the average review period between INR tests.

Computerised Decision Support Software can reliably increase the average review period without reducing the quality of anticoagulation control.
The experience of most practices is that there is an initial increase in workload as the numbers of patients seen in the clinic expands and as the staff members gain familiarity with the INR testing equipment, dosing software and clinic protocols. INR tests tend to be done more frequently during the early stages until staff confidence builds up and it can take several months before the workload settles down to a lower “steady state”.

**Training**

When a practice performs INR estimations using NPT equipment it is, in effect, running as a pathology laboratory and it is therefore important that practice is aware of the relevant regulations and protocols associated with running a laboratory.

Several major hospital laboratory services run schemes in which practices doing NPT are accredited by the hospital laboratory. The accreditation process varies locally but usually involves visits to the practice by hospital laboratory staff to oversee practice staff training, quality control and health and safety issues.

Training needs to cover several areas:

- Basic theory of anticoagulation.
- Clinic aspects of warfarin: side effects, contraindications, interactions, dosing schemes.
- Detailed training on the use of the coagulometer apparatus in use at the practice.
- Detailed training on the use of any CDSS in use.
- Practice-based protocol for the clinic (e.g. who to ask if there is a problem with the equipment, who to ask if an INR is out of range etc).
- Health and Safety procedures.
- Quality control procedures.
- Record keeping and audit.

Training should be coordinated by the lead clinician for the clinic and may involve input from hospital coagulation departments, equipment manufacturers, and software suppliers as well as from the practice team itself.

Use of the coagulometer equipment and CDSS should be restricted to those staff that have completed the training.

It is a good idea to keep a training record log for all staff members involved in the clinic.

**Health and Safety at work considerations**

The taking and testing of blood samples and the use of chemical reagents are activities with Health and Safety at Work implications and these need to be evaluated and documented. Many of these may already be in place and documented in the case of practice nurses.

The main implications include written protocols for:

- Safe venesection / finger-prick blood tests
- Glove/eye protection policy
- Pipetting / transfer of samples from specimen bottles to test cards (if applicable to your testing machine)
- Sharps disposal
- Needle re-sheathing
- Spillages
- Needle-stick injury procedure
- Hepatitis vaccination and antibody testing
- Safe use of any reagents (manufacturer will advise)
Quality Control and assurance

Hospital laboratories are required to undergo rigorous internal and external quality control to guarantee the accuracy and reliability of their results. It is important that practices undertaking NPT activities also apply similar standards of quality assurance.

There are three main methods of ensuring reliability and accuracy of results in the practice setting.

1. **Internal controls**

   This involves testing control reagents with known INRs in the practice coagulometer. If the result is within the expected range then this gives a degree of confidence that the equipment is calibrated correctly and is working accurately. The equipment manufacturer will usually supply suitable control reagents.

2. **External controls**

   This involves the sending of a number of samples from each clinic to a coagulation laboratory (usually the local hospital) having tested them in-house and then comparing the practice’s INR result with that from the hospital. Generally speaking, the results should be within about 10% of each other. Regular feedback from the hospital enables trends to be identified, which might indicate a problem with testing procedures or reagents. Several hospital laboratories offer this service to practices for an annual fee with regular documented feedback on performance.

3. **National Quality Control Scheme**

   A National scheme for the monitoring of NPT anticoagulation testing exists, based in Sheffield. This subscription service involves the practice testing a control sample, which is sent to the practice on a 2 - 4 monthly basis. The practice’s performance can then be assessed against practices across the whole country.

Audit

Clinical audit has become an increasingly necessary part of all clinical activity and anticoagulation monitoring is no exception. Luckily it is very easy to audit.

Outcome events such as thrombosis/embolism or bleeding can be audited as can the actual INR result over time.

The currently preferred method of auditing INR results is that described by Rosendaal et al. in which the total amount of time that each patient has an INR within the therapeutic range is estimated. This is then calculated for the practice population as a whole and presented in terms of number of patient-days (or patient-years) within defined variations from the target INR.

The other recognised method (called point prevalence) is to measure the proportion of patients with INR results that are within, above or below the therapeutic range at any given time.

INRstar software produces these audits automatically, as well as other functions such as identifying patients who are overdue for an INR test.

Finance
There are several financial aspects to consider before setting up an in-house anticoagulation clinic.

**Set-up costs.**

These include the costs of purchasing a coagulometer system (along with an initial supply of reagents/test cards/control reagents etc.), CDSS software costs, training costs and administration time.

The cost of coagulometers suitable for primary care use varies from a few hundred pounds to two or three thousand pounds. CDSS systems likewise vary from around £100 to £1000 or so. The manufacturers may provide initial training as part of the purchase price of the equipment.

More recently some equipment manufacturers and software developers are offering complete packages in which the coagulometer and CDSS are provided on an annual “leased” basis with no initial capital cost involved. Many PCG/Ts are purchasing or leasing systems on behalf of their practices, as practice-based clinics can offer significant cost benefits to PCTs when compared to hospital out-patient anticoagulation clinics.

**On-going costs**

These mainly comprise the cost of staff time, reagent costs and the cost of the clinic accommodation. Quality control costs vary depending on how many control samples are sent to the local laboratory and on whether the National Quality Control Scheme is utilised. A typical Hospital laboratory offering accreditation and on-going support would charge the practice in the region of £150/year.

These figures can be used to calculate an approximate “cost per test” (making educated guesses as to the likely number of tests/year). The following example gives an outline of typical costs.

<table>
<thead>
<tr>
<th>Item</th>
<th>Typical cost</th>
<th>Your costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent costs/test (CoaguCheck)</td>
<td>£3.00/test</td>
<td></td>
</tr>
<tr>
<td>Nursing staff time (@ 4 tests/hour)</td>
<td>£12.00/hr</td>
<td></td>
</tr>
<tr>
<td>Administration staff time</td>
<td>£5.00/hr</td>
<td></td>
</tr>
<tr>
<td>Clinic accommodation (heating/light/cleaning etc) estimated</td>
<td>£10/clinic</td>
<td></td>
</tr>
<tr>
<td>Hospital accreditation/support</td>
<td>£150/year</td>
<td></td>
</tr>
<tr>
<td>NQCS</td>
<td>£150/year</td>
<td></td>
</tr>
<tr>
<td>Software - INRstar maintenance &amp; support (UK cost)</td>
<td>£147/year</td>
<td></td>
</tr>
<tr>
<td>Stationary/postage</td>
<td>£2.00/clinic</td>
<td></td>
</tr>
</tbody>
</table>
Estimated cost/test for 100 patients (1200 tests/year) = approx £10.50

Developing a protocol for the clinic

All aspects of the running of the clinic should be documented and collated into a Practice Anticoagulation Protocol. Many PCG/Ts require a detailed protocol when agreeing to fund a practice for anticoagulation services. Areas to cover in the protocol would include:

- Aims of the clinic
- Areas of responsibility
  - “Lead clinician” taking overall responsibility
- Training requirements
- Training log
- Detailed instructions about the use of the NPT instrument
  - General care of instrument
  - Calibration
  - Running a control test
  - Running a patient test
  - Recording results
  - What to do in case of a problem
- Detailed protocol for dealing with patients in the clinic
  - Asking about side effects
  - Confirming current warfarin dose
  - Checking on compliance
  - Asking about other medication
  - Procedure for “in-range” results
  - Procedure for “out-of-range” results
  - Procedure for making follow-up appointments
  - Procedure for non-attenders
- Handling and storing of reagents
- Detailed instructions about use of CDS software
  - Adding a new patient
  - Producing dosing instructions
  - Overriding computer suggestions
  - Recording results
  - Identifying non-attenders / overdue tests
  - What to do in case of a problem
- Health and Safety policy
  - Venesection/finger-prick blood taking
  - Handling of blood samples
  - Dealing with spillages
  - Needle-stick injury
  - Hepatitis immunisation/testing
- Administration
  - Making appointments for clinic
  - Claiming payment from PCG/T
  - Clinical audit
  - Policy for patients unable to attend surgery

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