Service Specification

Level 4 Anticoagulation Management

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1 Introduction and Background:

Anticoagulation monitoring is one of the potential enhanced services under the new GP contract and lends itself to provision by other service providers such as pharmacists. This document summarises the proposed service specification developed by NHS Derbyshire County (NHSDC) and remuneration aspects of this. It includes initiation of warfarin therapy and anticoagulation management.

The Department of Health’s national specification has been modified on the basis of discussions with key partners within primary and secondary care and amended to reflect local service capacity and structures as well as population needs.

This specification requires anticoagulation management service providers in Primary Care to provide a Level 4 service as outlined in the national specification\(^1\). This means providers would be responsible for sampling, testing and dosing patients according to locally agreed protocols approved by NHSDC. Initiation of Warfarin will be regarded as a level 4B service which will require additional competencies.

This service will be agreed for a fixed term (1\(^{st}\) March 2011 – 31\(^{st}\) March 2012) with subsequent annual renewal dependent on future developments in anticoagulation treatment and technologies relating to monitoring.

Approximately 8700 patients are currently (August 2010) being monitored and managed in Primary Care. However NHSDC is anticipating the demand for this service will continue to rise based on national projections. It is envisaged that the Enhanced Service offered by Primary Care service providers be responsible for monitoring most of the NHSDC patients requiring this service and, in time, all patients who do not need to attend hospital and choose to be seen in Primary Care will be able to do so.

GPs may provide the service to all eligible patients from their own practice or refer to other service providers such as another local GP practice or community pharmacy. NHSDC will identify neighbouring service providers where required and all patients will be offered a choice where one exists.

Summary of Responsibilities

The role of the PCT is to ensure that services provided in Primary Care are in accordance with the service level agreement for the provision of Level 4 anticoagulation management. In particular, NHSDC will:

- Ensure that the service is only commissioned from appropriate providers who can demonstrate that they have achieved or are working towards Care Quality Commission (CQC) registration requirements.
- Ensure payments are made in a timely fashion when a claim is made;
- Approve Clinical Decision Support Software (CDSS) management programmes and Near Patient Testing (NPT) equipment prior to implementation;
- Publicise CPD training for service providers where we become aware of it;

\(^1\) See: [http://www.dh.gov.uk/assetRoot/04/03/49/26/04034926.pdf](http://www.dh.gov.uk/assetRoot/04/03/49/26/04034926.pdf)
- NHSDC will communicate any information that affects the delivery of the service to all providers;
- Ensure anticoagulation guidelines are available for the management of under/over-anticoagulation.

The anticoagulation provider will be responsible for ensuring that the service is provided according to the service specification. In particular, that:

- Dose recommendations and recall are made according to approved guidelines, in conjunction with approved CDSS;
- Patient education regarding anticoagulation therapy is provided and recorded and the patient hand-held record/yellow book is kept up-to-date;
- An annual patient review is performed;
- Patients are referred to A&E or Secondary Care or their own GP where required;
- Adverse events are reported to NHSDC Clinical Quality team;
- Contingency plans are in place to cover annual/sickness leave and staff turnover;
- Comprehensive policies and procedures are in place to ensure that all elements of the specification are met;
- Ensure that a system is in place for patients to receive urgent medical advice relating to anticoagulation through the Standard Operating Procedures (SOP);
- The provider is registered with and participates in the National External Quality Assessment Scheme (NEQAS) for Blood Coagulation;
- Maintain a regular system of clinical audit and annual reviews;
- Ensure that any staff involved in the delivery of the service have received appropriate training and maintain competences.

If a practice cannot meet the quality standards, then help will be provided by the PCT in terms of advice which will be implemented within the timescales identified. If this is not achieved, NHSDC may commission the service from an alternate provider.

A provider may not withdraw from the service without giving six months notice of intention, or by prior agreement with the PCT. It is the responsibility of the provider to communicate this to the patients.

The Clinical and PCT leads are as follows:

Clinical Lead: Dr Paul Cook, Medical Director
PCT Director Lead: Mr Andy Layzell, Director of Commissioning

2 Definition of service:

Overall Scope
The following are deemed to be within the scope of this Local Enhances Service (LES).

- NHSDC registered patients who require anticoagulation monitoring and who fit the criteria below will be eligible for the Primary Care anticoagulation service.
- In general, Secondary Care patients considered relatively ‘stable’ by the Consultant Haematologist will be referred to Primary Care.
• NHSDC recognises that some patients may wish to self monitor their INR but NHSDC does not specifically commission a self monitoring service within this specification. However, INR providers/practitioners can consider individual requests to self monitor on a patient by patient basis. Clinical risks should be assessed and provision of the service will be the responsibility of the provider.

NHSDC will pay for the management of self monitoring patients at the same level as other patients under this spec. NHSDC will not however bear the cost of the equipment/consumables required to provide this service, either directly or via a practice’s prescribing budget.

The provider should clearly define how self monitoring patients are managed and this should be included in its service SOP.

Out of Scope
The following are deemed to be out of scope of this LES:

• Unstable patients with complex needs.
• Patients with the following conditions/problems should be excluded from the primary care service:
  • A known hereditary or acquired bleeding disorder;
  • Children under 16;
  • Pregnant women;
  • Other conditions the Consultant Haematologist considers should exclude the patient from management in primary care.
  • Patients with Deep Vein Thrombosis (DVT) or Pulmonary Embolism who have not been stabilised in Secondary Care before being discharged from hospital.

Caution should be taken when monitoring patients with the following conditions/problems and where required advice from the Haematology department should be sought:

• A known hereditary or acquired thrombophilia;
• Have had a DVT/PE in previous month;
• Liver failure;
• Documented evidence of Central Nervous System haemorrhage in the previous 6 months;
• Gastric-intestinal bleeding in the previous 6 months;
• A known alcohol problem;
• IV drug users;
• Patients in care homes (because of other problems rather then being in a care home per se);
• Severe heart failure;
• On chemotherapy for malignant tumours;
• Some medications interact with warfarin and product information for any concurrent therapy should always be consulted for specific guidance on warfarin dose adjustment and therapeutic monitoring. If no specific information is provided the possibility of an interaction should always be considered. (Appendix 19 - section 4.5, MHRA Warfarin Public Assessment Report)
- There are a range of medications that are contraindicated for use in concurrence with warfarin therapy. Therefore, patients using these drugs, where a satisfactory non-contraindicated medication is not available, could potentially fall outside the scope of this service (Appendix 19 - section 4.5, MHRA Warfarin Public Assessment Report)
- Other conditions the Consultant Haematologist considers problematic for management in primary care.

Risks factors of bleeding should be considered. The following patient characteristics are:
- Indicative of a high risk for bleeding
- Age >70
- Hypertension
- Diabetes
- Renal Failure,
- Previous MI
- Previous CVA
- Previous GI Bleed
- Patients with Liver Disease.

3 Overall aims:

The overall aim is to provide an integrated anticoagulation service across Primary and Secondary Care. In particular, the Enhanced Service will:

- Ensure a safe, effective and consistent high quality service is delivered to patients by all anticoagulation service providers using appropriately trained staff;
- Ensure consistent procedures relating to testing, sampling and dosing across service providers and between Primary and Secondary Care services;
- Ensure that maintenance of patients is controlled and the need for continuation of therapy is reviewed regularly and therapy is discontinued where appropriate;
- Enhance the confidence and develop the skills of all service provider staff who have an interest in anticoagulation management;
- Improve the primary/secondary care interface resulting in a streamlined service that benefits patients;
- Provide increased capacity in the community to meet the rising demand for anticoagulation monitoring;
- To provide face to face consultation with an accredited practitioner for all mobile patients.
- Dosing done by an accredited practitioner.
- Provide more services that are near to patients and are easily accessible and flexible.

4 Key objectives:

The overall objective of the service is to provide near patient testing in Primary Care, thereby removing the need for venous samples being sent to laboratories unless in exceptional circumstances. In addition it will seek:
● To provide a safe, effective, quality service.
● To ensure that warfarin patients are maintained within their individual target International Normalized Ratio (INR) range;
● To provide a local service in Primary Care which is accessible and flexible, giving patients choice where possible;
● To improve the local arrangements for patients on warfarin and ensure that they are better educated about warfarin monitoring and their responsibilities.

5 Key outcomes:

The key outcome of the service is to ensure that all patients are managed effectively and anticipate risks thereby reducing the risk of complications.

● All patients are maintained within 0.5 and 0.75 of their target INR;
● A reduction in the number of critical incidents/untoward events over the review period that relate to the service;
● To clearly identify the number of patients being monitored in primary care, indications for treatment and the anticipated duration;
● A reduction in the number of bleeding episodes, during the review period, that required admission or referral to secondary care;
● All referrals back to secondary care are analysed and deemed clinically appropriate;
● Reduce the number of complaints received over the review period that relate to the service;
● Reduce the number of patient deaths over the review period;
● Increased levels of patient satisfaction.
● To reduce the times the patients are outside their INR range;
● To record the number of times patients have INR beyond 5;
● To improve convenience for patients;
● To improve the cost effectiveness of the service.

6 National context:

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

Locally-based primary care services provide more choice and flexibility for patients in line with the government’s ‘Patients Choice’ initiative.

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. As stated in the NHS

The NHS Constitution.DH:2009
Setting the Standards in Anticoagulation Service Delivery. National Centre for Anticoagulation Training.
Constitution, Patients and members of the public have legal rights, the patients rights for quality of care and the environment are to be treated by appropriately qualified and experienced staff in a properly approved organisation that meets required levels of safety and quality.

7 Local context, demographics, needs:

This Enhanced Service adheres to the NHSDC Primary Care Strategy.

Derbyshire County has a registered population of 750,000 people. 25% of the population are aged over 60 years and 5% over 80 years of age. The over 80 age group will increase by 23% by 2020 from approximately 38,000 people to 50,100 people.

The incidence of Atrial Fibrillation (AF) doubles with each advancing decade of age from 0.5% at age 50-59 to 9% at age 80-89 years. The prevalence in a general practice may range from 2- 4.7% A general practice with 10,000 registered population could be expected to have 200 -500 patients with AF.

A number of these people will be asymptomatic and not known to the practice. With an estimated average prevalence of 3.5% you would expect to have approximately 26,000 people with AF in Derbyshire County. The service currently knows of approximately 8,700 people.

AF is the most common sustained arrhythmia. AF is characterised by uncoordinated atrial contraction with a consequence of the deterioration of atrial mechanical function. The results of AF are the blood flow effects of a rapid and/or irregular heart rhythm and thromboembolic complications.

AF is associated with a pre-thrombotic state leading to a predisposition to thrombus (blood clot) formation. This predisposes to thromboembolism and stroke with a five-fold greater risk than that of people without AF.

AF accounts for about 15% of all strokes. It has been estimated that optimal treatment of AF in the population would reduce overall stroke risk by 10%. Anticoagulation can reduce an individual patient's risk by 70%. Hence it is important to identify people with AF, perform risk management and, when indicated, prescribe warfarin, ensure that it is monitored (INR tests) and levels are managed within the therapeutic range.

A stroke risk algorithm should be used in patients with AF to assess their risk of stroke and thromboembolism and appropriate thromboprophylaxis given. (See NICE guidance page 104 - http://www.nice.org.uk/nicemedia/live/10982/30055/30055.pdf)

8 Service outline:

NHSDC will fund the provision of community-based oral anticoagulation management clinics in primary care utilising Near Patient Testing (NPT) for INR monitoring and computerised decision support software (CDSS) for dosing advice.

All service providers must have a named a clinician as the clinical lead who will be responsible for ensuring that the service is delivered in accordance with the specification.
The dosing of Warfarin and the interval decision between test dates is the responsibility of an accredited health professional. All patients will be seen in person either in a clinic or at home by a health professional who has undergone appropriate training.

The service can be delivered by a GP or registered nurse within the practice or, alternatively, the Primary Care anticoagulation provider can be a pharmacist trained in anticoagulation management, a Practitioner with a Specialist Interest (PwSI) in anticoagulation management or a clinical nurse/pharmacist specialist working on an outreach basis to provide the service. Service providers must run anticoagulation clinics to meet the needs of their cohort of patients at least once a week or more often if clinically necessary. Providers must have robust mechanisms in place to manage any self monitoring patients safely and effectively, which must be communicated and agreed with the patient.

Providers can utilise Healthcare Assistants (HCA’s) and Pharmacy Technicians to carry out some aspects of the service on the condition that they have been appropriately trained.

The length of time between test dates will vary but every patient must be checked and dosed at least once every 12 weeks. Less stable and new patients will require more frequent tests. The management and monitoring procedures are included in the NHSDC guidelines.

The provider should ensure that a systematic call and recall system is in place and should be able to provide data to demonstrate the effectiveness of the system. Under normal circumstances, a patient who fails to attend a clinic at an agreed time should be contacted initially by telephone. The provider must implement appropriate and effective strategies for monitoring and targeting non-attendees. Where a patient fails to attend consideration should be given to stopping warfarin until the patient is seen. In the case of an alternative provider, should this occur, this must be clearly communicated to the patients’ home GP practice.

Service providers are clinically responsible for all patients under their care for anticoagulation management and must ensure that explicit contingency plans are in place to cover periods of absence for annual or sickness leave both for the running of clinics and for advice to patients who have queries or problems.

Where the service is not provided by the patients’ GP practice, the service provider and the patient’s own GP practice have shared responsibility in ensuring a robust communication system is in place.

This must be demonstrated in the form of a written communication protocol defining the communication between referring GP practice and the provider of the service and vice versa and which will include the communication of each INR test, recommended dosage, any significant events according to agreed protocols and any other change to patient information which may have an effect on their warfarin management.

9 Model for the service – pathways / interfaces:

For guidance on patient pathways see Appendices 12a and 12b. The referral process for new and existing patients is available in the NHSDC Guidelines.
Clinical Management
Clinical management of patients will respect and adhere to the Derbyshire Joint Area Prescribing Committee ‘Guideline on Oral Anticoagulation’\(^3\) (Appendix 1) and appropriate national guidelines issued by the British Haematology Society\(^4\) (BSH) (Appendix 2) and the National Patient Safety Agency (NPSA) (Appendix 3a – 3f). All providers should follow the recommendations of the NPSA Anticoagulation Patient safety alert 18\(^5\) (Appendix 4).

Warfarin Initiation
Only the GP or independent prescriber or appropriately qualified person in secondary care should determine diagnosis of condition requiring indication of warfarin. We expect all Primary Care anticoagulation providers to be able to initiate and stabilize their own patients. Warfarin initiation guidelines have been provided in the NHSDC ‘Guideline on Oral Anticoagulation’. Only practitioners who meet the necessary National Patient Safety Agency (NPSA) competencies and accreditation determined by NHSDC will be able to provide the warfarin initiation aspect of the service which will be referred to as Level 4B for clarity. This accreditation will involve successful completion of the BMJ E-learning module: Starting patients on anticoagulants: how to do it [http://learning.bmj.com/learning/main.html](http://learning.bmj.com/learning/main.html)

Patient education
Patients\(^6\) receiving their first Primary Care appointment for anticoagulation monitoring either at a clinic or through a home visit must receive information on the management and prevention of secondary complications of their condition. If the patient has a carer, they must be involved. This information will be reviewed with them and delivered by the accredited practitioner and educational counselling will be provided at the initial appointment, using an induction process (see NHSDC guidelines) and this will be reviewed regularly to ensure the patient is continually aware of and understands the following:

- Name of drug and current dose including tablet colours
- The contents of the yellow book and patient held information
- Target INR and range;
- Reason for and objectives of treatment;
- Anticipated length of treatment;
- What to do in the event of a missed or wrong dose;
- Symptoms of under dose (e.g. progressive worsening of thrombotic signs or new symptoms such as PE) and overdose and what to do if these occur;
- Complications of treatment including side effects and bleeding;
- Drug and food interactions;
- Changes in medication or new medication requiring early monitoring
- Which medications (e.g. antibiotics) including over the counter (OTC) medications require particular care;
- What to do if dental treatment or surgery is required\(^7\);
- Contact details for the provider in case of concerns.
- Carers leaflet. (See Appendix 13)

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\(^3\) Derbyshire Joint Area Prescribing Committee, Guideline on Oral Anticoagulation, Jan 2009.
\(^6\) And/or their carers when appropriate.
Hand-held records
Each patient must be issued with a ‘yellow book’ in which INR levels, dosing information, date of next test and contact numbers for advice are recorded, which they will take with them if they move from Secondary to Primary Care and which should be maintained by the Primary Care service. Patients should be encouraged to carry their yellow book with them at all times and to show it to any health professional whenever they seek treatment or advice. Each new patient will be issued with the new Oral Anticoagulation Treatment (OAT) pack and existing patients will be issued with replacement OAT/yellow book when required; these should be ordered direct from Lynn Judge, Logistics Administrator.

Record-keeping
Anticoagulation providers will keep a comprehensive record for each patient that will be updated at each INR appointment and will include:
- Patient’s INR;
- Dose of anticoagulant;
- Date of next appointment;
- Information from the patient about unusual bleeding or bruising, adherence to treatment, other medication, changes in diet, changes in alcohol or smoking, or planned surgery;
- Information from the prescriber (where appropriate) as above and below;
- Additional information from the patient’s medical notes (where appropriate);
- Prescribed medication, medication changes, OTC medication including homeopathic and herbal remedies.

If the provider is the GP, the patient’s medical records must be updated.

In addition, the provider must be able to provide the following for any patient under their care:
- Patient name and address;
- NHS number;
- Date of birth;
- Name of initiating Consultant or GP;
- Indication for treatment;
- Length of treatment;
- Target INR and range;
- Discontinuation date;
- Relevant notes supporting dose decision, counselling and self-management;
- Information relating to performance indicators and audit such as time spent within target range;
- Frequency of missed appointments;
- Medical conditions, hospital admissions likely to effect anticoagulation such as increased risk from haemorrhage;
- Bleeding episodes and adverse events including submission to the PCT of all patient safety incidents.
- Any actions taken other than dosing and retest dates.
- Any other significant information which may have an impact on their care (eg carer information, alternate contacts, hearing/reading difficulties, memory loss issues etc)

A CDSS solution must be used to record the necessary information.
Each patient will require an individual clinical record (for example, a GP medical record or pharmacy record) that contains all clinical information that cannot be stored on the CDSS.

**Medication**
The prescription of medication will remain the responsibility of the patient’s GP as at present on the advice of the anticoagulation monitoring provider whether in Primary or Secondary Care. Decisions on dosing will be the clinical responsibility of the provider.

Dosage of oral anticoagulants should be calculated in conjunction with using the CDSS. However, it is the responsibility of the clinician to make a clinical decision on dosing.

The anticipated duration of overall treatment will be documented at the point of the initial referral. Whether treatment should be discontinued should be reviewed regularly, before due date for end of treatment and at least annually. Responsibility for the decision to discontinue warfarin will reside with the patient’s GP, but the anticoagulation provider should raise the issue when appropriate. Oral anticoagulants will be discontinued on an agreed defined date and the patients and all people involved in the patient’s care informed.

**Individual annual review**
Service providers will be required to conduct a formal review of a patient’s health, relating to anticoagulation monitoring, at least annually, including continued need for anticoagulation, potential complications and, as necessary, a review of the patient’s own monitoring records and duration of treatment. Service providers must liaise with the referring practice to determine the patient’s continued need.

**Referrals out of Primary Care**
Patients with either of the symptoms below should be treated as a medical emergency and referred appropriately.

- Signs or symptoms of major bleeding or thromboembolism;
- A low INR and thromboembolism or stroke.

Administration of small doses of oral or IV vitamin k will readily reverse INR within 16 to 24 hours to therapeutic doses. Each service provider must have readily available vitamin k for oral use (Konakion MM paediatric may be administered by mouth). All service providers will need to sign up to the PGD for the Supply of Oral Administration of Vitamin K in over anticoagulated patients (Appendix 5). Expert advice must be sought immediately from the relevant Haematology Department when it is felt by the service provider that the management of a patient is outside their sphere of competence.

Recommendations for the management of bleeding and excessive anticoagulation are set out in the NHSDC ‘Guideline on Oral Anticoagulation’³.

**Adverse events**
It is a service requirement that any adverse event related to anticoagulation of any patient covered under this service, to notify the Clinical Quality Team as per significant event guidelines (e.g. 24 hours of death or 72 hours of SUI).
Serious untoward incident monitoring process – Significant Event Reporting and Investigation Involving Independent Contractors)

This is in addition to a practitioner’s statutory obligations.

An ‘adverse event’ is:

- Any untoward incident (such as equipment or serious communication failure or the issue of an incorrect prescription). This should be reported in the usual way using the PCT incident policy and the Clinical Lead should also be copied in.
- Any clinical event which is or may be due to usage of the drug(s) in question or attributable to the relevant underlying condition should also be notified to the Clinical and PCT Leads including:
  - Any patient who has a major bleed or thrombosis;
  - Death of a patient (in line with the PCT Significant Untoward Incident policy).
- Any other event involving the testing, prescribing or dosing of the patient which gives the patient’s GP or service provider cause for concern.

Near patient testing and quality control

Service providers will be expected to provide Near Patient Testing (NPT) to determine patients’ INR levels using accredited coagulometers. On behalf of the NHS Purchasing and Supply Agency (NHS PASA), the Centre for Evidence-based Purchasing provides independent and objective evaluations of medical devices available on the UK market. Results are available on the website (www.pasa.nhs.uk/cep). Service providers may only use coagulometers that have been evaluated as suitable, by the NHS PASA, for near-patient testing in the monitoring of oral anticoagulant therapy. This currently includes CoaguChek-S, CoaguChek XS plus, Haemosense INRatio and ProTime. NHSDC recommend CoaguChek XS plus monitors for consistency and ensuring adequate training and support is provided.

Service providers will pay for all NPT equipment and supplies including the test strips, finger prick equipment and internal quality control solution. The NPT equipment must be maintained and calibrated as per the manufacturer’s guidance and recorded. It is good practice also to be able to track the time of testing and lot number of test strip used for each patient should the need arise. Cleaning procedures recommended by the manufacturer should be adhered to and health and safety standards should be followed at all times.

The disposal of sharps should be in accordance with national guidance and the providers’ waste disposal and infection control policy.

Service providers will be expected to follow a prescribed Internal Quality Control (IQC) system that will include testing control samples with a known INR to ensure their coagulometer is calibrated correctly and working accurately. Quality control should be performed:
- At the beginning of each clinic,
- Each time a new box of strips is started or a new batch is used;
- Following an unexpected result.

Service providers must participate in the UK National External Quality Assessment Scheme (NEQAS) for Blood Coagulation (Appendix 6) that monitors the performance of
coagulometers. Service providers will be sent at least four surveys per year each comprising two samples for INR determination so that the quality of testing equipment can be assured and maintained. Comprehensive records of quality checks to include batch numbers of strips and control samples, time of test and operator must be kept.

Patient testing should be reviewed/stopped following any failure to produce an acceptable result as a result of the IQC system or if the instrument receives a result outside the consensus from NEQAS. Consideration should be given to stopping the service if judged unsafe by the responsible clinician for the premises. In such circumstances, advice from the PCT lead must be obtained to ensure that an alternative provider can be sourced.

### 10 Client group served / eligibility / access criteria:

- NHS Derbyshire County patients who require anticoagulation monitoring and who fit the criteria will be eligible for the Primary Care anticoagulation service.
- In general, Secondary Care patients considered relatively ‘stable’ by the Consultant Haematologist will be referred to Primary Care.

### 11 Quality targets:

The Primary Care provider must be compliant with the Standard for Better Healthcare 2005 (S4BH) and must be working towards the Care Quality Commission (CQC) registration in 2012/13.

National External Quality Assessment Service (NEQAS) registration is required within the specification and assures the Primary Care Provider that their equipment used in the delivery of the service meets the relevant standards.

Compliance with audit procedures as identified in the specification should allow the provider to identify and minimise risk where they occur in line with the NPSA and BCSH guidance. (Please see section 16 ‘Clinical and Corporate Governance’).

### 12 Output and outcome measure requirements:

- All patients are maintained within 0.5 and 0.75 of their target INR;
- A reduction in the number of critical incidents/untoward events over the review period that relate to the service;
- Number of complaints received over the review period that relate to the service;
- Number of patient deaths over the review period;
- Improved levels of patient experience;
- % of patients suffering a major bleed in first month of therapy and % of patients suffering major bleed with INR above therapeutic range (Incident data);
- % of patients transferred into Primary Care with incomplete discharge information from Secondary Care (Incident data);
- % of patients that were not issued with patient held information and written dosage instructions of therapy (Incident data);
- % of patients initiated on warfarin in the last 12 months who have not had a risk assessment undertaken.
• A patient satisfaction survey is completed annually.

13 Details of service monitoring, evaluation and review process / timescales:

Computerised decision support software (CDSS)
NHS Derbyshire County will fund new providers for the initial purchase or upgrade of Clever Clog INR Computerised Decision Support Software (CDSS). The software will provide guidance on dosing as well as record patient details and outcomes. The software will enable providers to develop and maintain an up-to-date register of patients that will include patient name, date of birth, the indication for anticoagulation and length of treatment, including the target INR.

Following the BSH Guidelines on Oral Anticoagulation, the CDSS solution should be set up as follows:

• Rapid retrieval of data to screen or printer;
• Data storage in chronological order;
• Dosage recommendations according to algorithm or guidelines approved by consultant in charge of the service - this should include evaluation of results over the full range of INR results;
• An alerting system for patient results which fall outside defined criteria;
• A facility to over-ride computer recommendations;
• Patient recall for testing according to agreed criteria based on previous stability with invalid date alerts;
• An alerting system for non-attendees;
• An alerting system for discontinuation of treatment;
• A prompt system to check for bleeding problems when high INR values are obtained;
• A system to record bleeding/thrombotic event or other rare side effects;
• A facility to audit results.

Any other CDSS systems should match the above criteria as minimum audit information.

Depending on the CDSS system used, some of the above information may be recorded in the patient’s own GP or pharmacy system lifelong record.

14 Finance:

Payments per patient
Primary Care anticoagulation providers will be paid from April 2010:

• £186.56 - per patient per year for a Level 4 service8 (including patients who are self-monitoring but are managed by the service provider).
• Plus £20.06 per home visit by an accredited practitioner – see conditions below
• £100.30 per patient initiated on Warfarin within the clinic setting, level 4B service, as per NHSDC 'Guideline on Oral Anticoagulation'4.

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8 Level 4 is defined as service provider funded practitioner accredited by NHSDC, service provider sample, service provider test and service provider dosing all done as a one-stop service.
The initiation fee will be paid for new patients who have never had Warfarin, for patients discharged by Secondary Care and taken on before three stable INRs are established and patients who are restarted after a planned stop say for surgery. The fee cannot be claimed for restarting after stopping treatment due to a high INR or other management issues. Initiation fees will not be paid for housebound patients since the greater number of tests required during initiation will be reimbursed by the fee per home visit.

Where the service requires a domiciliary visit to a housebound patient and is provided by an accredited practitioner, £20.06 will be paid for each patient visited at a separate address. For patients at the same address seen at the same time £20.06 will be paid for the second patient and £6 for each subsequent patient. This fee is in addition to the £186.56 per patient per year. This will be on the basis that a level 4 service, as specified by NHSDC is provided at the home by an accredited practitioner.

Where a provider can demonstrate that a member of staff is competent to carry out domiciliary visits (perform the finger prick test to gain a sample and use the coagurometer to determine the INR), the provider can claim via an ‘unaccredited’ rate. The fee is £6.02 for each patient visited at a separate address. For patients at the same address seen at the same time, £6.02 will be paid for the first two patients and then £1.80 for each subsequent patient.

It will be the service providers’ responsibility to ensure such staff are adequately trained. The dosing in all circumstances will have to be done by the accredited practitioner and all relevant information (date of test, INR and dosing information) must be recorded in the patient’s Yellow book at the visit. An accredited practitioner will need to see each permanently housebound patient every 6 months.

Providers will be required to keep detailed records of each home visit and initiation claims.

The payment per patient will be reviewed annually.

Payments will be made on a monthly basis, on the understanding that all relevant quality indicators have been achieved, via the Enhanced Service online claim system.

**15 Training and Accreditation:**

All practitioners providing the anticoagulation LES must meet the competencies stated in the specification and outlined in the accreditation pathway below and Appendix 7.

Practitioners who completed the accreditation pathway under the old Level 4 INR LES will not need to be re-accredited to provide this new LES. Practitioners who did not finish the accreditation pathway previously are still required to undertake the elements they missed.

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9 A housebound patient is one who is "unable to leave their home environment through a physical and/or psychological illness" (Oxford English Dictionary). A patient is **NOT** housebound if they are able to leave their home environment with assistance.
Anticoagulation Accreditation Pathway

Practitioner to complete suitable background reading.

Practitioner to successfully complete practice identified training to meet competencies identified in the Level 4 INR specification*.

Practitioner to successfully complete BMJ or CPPE modules** (and observations if deemed appropriate). Observation record sheet also available for practices to use.

Practice INR Clinical Lead 'signs off' practitioner as competent to take capillary blood samples, use coagulometer and CDSS.

Practitioner submits completed accreditation checklist to PCT with commitment to undertake External Peer review at 6 months; able to commence delivery of the service without supervision.

Practitioner completes external peer review within 6 months.

Practitioner accredited. All relevant training records to be maintained on site to demonstrate compliance with this accreditation pathway.

*The theoretical elements of the course should ensure that the practitioner of each Primary Care service has:
- The ability to safely manage a Primary Care based anticoagulation clinic using near patient testing for INR estimating, interpreting INR results and assessing the dose of oral anticoagulation in order to maintain results within their appropriate therapeutic ranges;
- A comprehensive understanding of the conditions requiring oral anticoagulation therapy and the target ranges for Warfarin therapy;
- The ability to evaluate which target INR is required when treating different conditions;
- An understanding of the pharmacology of Warfarin and determine the relevant medication, side effects, antidotes, interaction and dosing;
- The ability to critically analyse all aspects of anticoagulation management and therefore evaluation aspects for safe practice.

**Maintaining patients on anticoagulants: how to do it' (http://learning.bmj.com/learning/main.html)
Anticoagulation; managing patients, prescribing and problems. CPPE 2007 (http://cppe.manchester.ac.uk)
'Starting patients on anticoagulants: how to do it' (http://learning.bmj.com/learning/main.html)
This pathway puts the responsibility on the provider INR Clinical Lead to assess the practitioner’s scope of knowledge and competencies relating to anticoagulation management and decide which path of accreditation best meets their learning needs to provide safe quality services to patients.

Practitioners have a duty to ensure they do not work outside their scope. Practitioners will need to self declare they meet the relevant NPSA competencies and clinical leads within each provider will be requested to support the declaration. External peer reviews within 6-months of starting the service will provide added reassurance. Copies of all relevant training documents must be retained by the provider to show compliance with the accreditation pathway. Commissioners may check that all the requirements are met as part of the quality assurance and monitoring process.

Providers may access any relevant training they determine appropriate to meet the requirements specified. The PCT may support the process by providing half day briefing sessions to cover operational and commissioning aspects of the service. However, the PCT cannot sustain provision of clinical training courses to prepare providers to meet competency requirements.

As part of business continuity plans, providers need to maintain accredited practitioners and resources required to continue to provide the service.

Providers can use unaccredited staff (Health Care Assistant/Pharmacy Technician) to carry out domiciliary visits where they can demonstrate that they are competent to do so. The staff member must have:

- Worked with an accredited practitioner to understand the scope of the service;
- Been trained in how to obtain a sample;
- Been observed and deemed competent by an accredited practitioner in taking samples;
- Been trained in the use of the relevant coagulometer and the method of determining the INR;
- Been observed and deemed competent by an accredited practitioner in the use of the relevant coagulometer;
- Understands the use of the Yellow Book and the information that must be recorded in it.

The provider must record that any unaccredited practitioner utilised in delivery of this service has received the above training and has understood it and had the chance to ask questions.

**Practitioners with a Special Interest (PwSI)**

**Draft definition for Derbyshire County PCT**

A PwSI is any independent contractor or member of their staff that provides a clinical service beyond the scope of their core professional role not normally undertaken by their peers to patients that are not registered with them and to which referrals can be made by other professionals.

They will have demonstrated appropriate skills and competencies to deliver those services without direct supervision.
For GP practices, services that are delivered to only their own registered patients are excluded from this process at this point in time.

Anybody acting as a clinical assistant to another provider e.g. acute trust is excluded as the provider will be expected to assure competence through their own process. This process only applies where the PCT commissions direct from the primary care provider.

If there is any doubt on whether a service requires accreditation under the PwSI scheme, the accreditation panel will be asked to decide.
The panel will consist of the following people as a minimum:

- NHSDC Medical Director;
- Assistant Director of Commissioning – Primary Care;
- Head of Clinical Quality – independent contractors;
- Lay representative;
- Clinical specialist from the area of work for which accreditation is sought;
- Local Representative Committee representative as appropriate.

16 Clinical and corporate governance:

One of the important advantages of CDSS is that it provides a facility for audit of performance on a regular basis. The audit parameters will include measures on therapeutic control as well as clinical outcomes measures. The time patients spend within therapeutic range can be calculated using the software package provided. Patients should expect to be within their own therapeutic range (i.e. +/- 0.5 of target INR) for at least 60% of the time and within +/- 0.75 of their target INR 80% of the time.

Providers must complete a quarterly audit indicating the achievement of quality criteria both in terms of systems management and clinical outcomes.

Quarterly audits will be performed to assess:
- Whether INR results are within the recommended target range;
- The number of critical incidents/adverse events

If the audit results fall out of the scope it must be reported through the significant event process and the PCT Clinical Lead informed. The provider must deliver, implement and review an action plan within the specified timescales.

All service providers involved should perform an annual summary audit report by 31st October which should be forwarded to the PCT Clinical Lead that should include information on:

- The number of patients being monitored, indications for treatment and the anticipated duration;
- Details of the Near Patient machine used (make, model and serial number);
- Age and performance of machine against quality checks;
- Details of IQC and EQC;
- Details of trained staff, qualifications, and skill review dates;
- Number of complaints received over the review period that relate to the service;
Summary of patient satisfaction questionnaires (Appendix 8);
Number of critical incidents/untoward events over the review period that relate to the service;
Number and percentage of patients within, above and below target INR range over the review period (within 0.5 and 0.75 of target INR);
Number of bleeding episodes, during the review period, that required admission or referral to secondary care;
Number of patients referred back to Secondary Care and the clinical reason for the referral.

Most of this information should be derived from the CDSS or electronic patient record.

The provider is required to have clear policies, practices and procedures for clinical governance, including:

- Clinical Governance Lead
- Incident Reporting – including the notification of all incidents to the PCT and other bodies are required
- Infection control
- Significant event analysis
- Complaints
- Record Keeping
- Managing alerts (equipment etc)
- Quality Assurance
- Home Visiting

17 Policies / protocols / legal requirements:

The Service Provider must comply with their Standard Operating Procedures (SOPs) which will include the following policies:

- Communication Protocol (Appendix 9)
  - Patient Information leaflet and Carers leaflet
  - Record Keeping (Patient ➔ Clinic Dosing information ➔ GP)
  - Telephone Advise and Communication
  - Referrals
  - Special consideration to vulnerable people
  - Secondary Care Communication
  - Information Sharing Policy with partners
  - Transfer information
  - Timescales of information transfer regarding change in condition or medication
  - Joint Visits
  - All information communicated must be recorded

- Training and Education Policy
  - Patient education

- Statement of targeted population
• Provision of Care Policy
  ▪ Adverse events
  ▪ Recall appointments
  ▪ Health & Safety
  ▪ Record Keeping
  ▪ Patient annual review
  ▪ Vitamin K PGD
  ▪ Cover policy for sickness and leave
  ▪ Self Monitoring policy (if relevant)

• Equipment, Maintenance and Ordering Policy

• National External Quality Assurances Services (NEQAS)

• Information Governance Policy

• Patient Compliance Policy

18 Appendices:

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