Attachment 16

**Local Service Specification**

**ANTI-COAGULATION level 4 -NEAR PATIENT TESTING**

**1.1 Introduction**

Warfarin is being used in the management of increasing numbers of patients and conditions including post-myocardial infarction, atrial fibrillation, DVTs and other disorders. While it is a very effective drug in these conditions, it can also have serious side effects, eg severe haemorrhage. These side effects are related to the International Normalised Ratio (INR) level, which measures the delay in the clotting of the blood caused by the warfarin. While the “normal” INR is 1, the specific range of INR values depends on the disease and the clinical conditions. Warfarin monitoring aims to stabilise the INR within set limits to help prevent serious side-effects while maximising effective treatment.

The introduction of Near Patient Testing for measurement of INR has been instrumental in anti-coagulation monitoring and testing being delivered within the primary care setting for many patients. There are many significant benefits to the patient for delivering this service in the primary care setting, primarily eliminating the delay in waiting for the result to be processed by the hospital laboratory, and the subsequent delay in informing the patient of their dosing advice. However the service must be undertaken within the confines of safe practice involving quality control procedures.

**1.2 Definition**

Level 4 funded phlebotomist, nurse or pharmacist performing a practice sample and practice bases analysis and practice dosing.

‘Doser’ means any person who is suitably trained and qualified who, upon receipt of relevant information from laboratories or near-patient testing equipment or otherwise, with or without computer-assisted decision-making equipment, determines, the anti-coagulant dosage for patients of practitioners in a practice.

**1.3 Service Specification**

Warfarin is classified as a “critical medicine” as defined by the National Patient Safety Agency Rapid Response Report 18: Preventing fatalities from medication loading doses. The use of loading doses of medicines can be complex and error prone. Incorrect use of loading doses or subsequent maintenance regimens may lead to severe harm or death

Particular attention should be placed on assessing concordance and checking changes in medication, foods and lifestyles and the impact of these on the International Normalised Ration (INR)

**Accreditation Requirements**

Only accredited practitioners who meet the service specification and are contracted by the NEL CCG should provide this service. Practitioners managing oral anticoagulation must meet the required NPSA competencies. Every provider, providing this service must ensure that all staff involved in providing any aspect of care under this scheme have the necessary training and skills to do so.

Before a provider is accredited to provide the level 4 service, the provider will need to undergo an assessment visit which will cover all aspects of the current service to level 3 including:

Practice Register, Anticoagulation template, Call and Recall System, Education for newly diagnosed patients, Provision of current service, overall wellbeing of patient and significant / untoward events.

In addition, to satisfy the requirements of the level 4 service, there should be evidence of a policy / protocol, internal and external quality assurance e.g. NEQAS results, audit,  records of testing and calibration of equipment, details of computer assisted decision making equipment used and arrangements for internal and external quality assurance and a patient satisfaction survey / questionnaire.

* Coagulometers using capillary blood may not be accurate when the INR is elevated. For CoaguChek XS plus, when the INR is > 8 the capillary blood INR result should be confirmed with a second test and in addition a sample obtained by venepuncture and sent to the laboratory to determine the exact INR reading. The therapeutic decision around dosing and clinical management of the patient should not be delayed until the laboratory result is obtained. Clinical management will depend on whether there is bleeding or not which will also indicate need for vitamin K
* The use of 1mg strength Warfarin tablets is strongly recommended unless patients are on doses greater then 5mg and can manage different strengths
* Avoiding more then two different strengths is recommended
* Use of 0.5mg is not recommended to avoid confusion
* Strips for use with the near patient testing equipment should be provided by the practice as part of the Level 4 service and should not be prescribed individually to a patient.

This service is based on near patient testing and venous samples should only be used in exceptional circumstances.

The frequency of monitoring will vary but patients should have their INR checked at least every 10 -12 weeks. Every patient must be seen at least once every 12 weeks. Less stable and new patients will require more frequent tests

Recall dates will be suggested by the dosing support software; however, if the patient’s clinical condition is changing, or there have been alterations in other medication, then the INR should be checked more frequently and clinical judgement should override the Computerised Decision Support Software.

**1.4 Monitoring and Review**

All providers involved in the scheme must submit an annual review which includes:

1. information on the number of patients being monitored, the indications of anticoagulation, ie DVT etc, and the duration of treatment
2. brief details as to arrangements for each of the aspects highlighted above
3. details of any computer-assisted decision-making equipment and near patient testing equipment used
4. arrangements for internal and external quality assurance
5. details of training and education relevant to the anti-coagulation monitoring service received by practitioners and staff
6. details of the standards used for the control of anti-coagulation.

**1.5 Financial Implications**

Each provider contracted to provide Anti-Coagulation level 4 Near Patient Testing will receive

£40 per patient per year.

All claims must be submitted annually and entered onto Local Service Invoice System

**1.6 Governance**

This service should be delivered in accordance with the following policies and procedures:

* North East Lincolnshire CCG Infection Control Policy
* North East Lincolnshire Health & Safety Guidance
* Standing Operating Procedures – in-house guidance for all staff who are undertaking Near Patient Testing
* Management and Use of IVD Point of Care Test Devices, Medical Devices Agency; March 2002
* Royal College of Pathology Guidelines on Point of Care Testing; April 2004

1.6.1 Quality Assurance

* + The Lead for this service should be a Senior General Practitioner, although this responsibility can be delegated to another named clinical member.
  + All staff undertaking Near Patient Testing must have appropriate training. This should be updated if the equipment or the test arrangements are modified.

1.6.2 Training

Training should include:

* + Basic principles of the measurement
  + Demonstration of the proper use of the equipment in accordance with the manufacturer's specification
  + Demonstration of the consequences of improper use
  + Instruction in sample collection, including health and safety aspects
  + Instruction in the importance of complete documentation of all data produced
  + Appropriate calibration and quality control techniques
  + Practical experience of the procedures, including a series of analyses that satisfy the instructor\* that the trainee is competent.

\* Following initial training by the manufacturers of the Near Patient Testing equipment, it may be appropriate for a member of the clinical team to become the named instructor

1.6.3 Internal and External Quality Assurance

To ensure Accuracy of the Result, it is essential that the results generated by the equipment are reliable. To ensure and demonstrate this there are two elements of test result quality assurance:

**Internal Quality Assurance**

* Daily, or as directed by the manufacturers, calibration of the equipment
* In addition, the manufacturer will double check the accuracy of results by repeating the assessment on an agreed number of samples.
* It is recommended that this sampling is undertaken on a rotational basis through all of the sessions in which Near Patient Testing is undertaken and includes all of the members of staff providing the service

**External Quality Assurance**

* 10% of the INR assessments will have a duplicate sent to Diana, Princess of Wales Hospital Pathology Laboratory. As above, the external quality assurance to rotate through all sessions and all members of staff providing the service

1.6.4 Variance Remedial Action

Significant event analysis should be undertaken where a duplicate assessment sample shows a variation in the INR result that leads to a change in dosage. This review should involve the member of staff that took the results but should be led by the clinical lead of the service.

If more than 1 in 20 reviews from the internal or external quality assurance provides a variation result that leads to a dosage change this should prompt review of the machine and its accuracy and an immediate discussion with the manufacturer. The commissioner should be made aware of this action via the Datix incident reporting system. If this level of variation persists within the next review, the service should be suspended. In this circumstance, the commissioner should be contacted directly and payments to the practice would be suspended. It is anticipated that the period of review within the quality assurance arrangements would be no longer than two weeks. Therefore there would be an ongoing cycle of quality assurance every two weeks undertaken by the practice.

Where a computer assisted decision making tool is used, 10% of the management outcomes should have a blind review undertaken by a GP to demonstrate the quality assurance. Again, as before, the sampling should involve all those members of staff delivering the service. If there is a greater than 10% variation, this should be reported to the manufacturer of the computer assisted decision making tool. Whilst awaiting the outcome of feedback, it is recommended that the practice reverts to GP decision making. Where computer assisted decision making is being utilised the practice should evidence holistic management of the patient with appropriate GP input where necessary (for example supporting the ongoing management of patients where there has been a change in medication / new medication which may influence the INR. When the patient attends for their INR, the in-house practice care pathway must prompt consideration of change in medication or new medication and detail how clinical input will support the computer assisted decision making tool).