

REPORT TO THE PBC GOVERNANCE TO BE HELD ON

Enclosure:						
Subject:	Anticoagulation – East Locality					
Lead Director:	Sue Price					
Lead Officer:	Rachael Bolton and Debbie Floyd on behalf of the East Locality PBC leads					
Recommendation:	For Approval	x	For Discussion		For Information	

PURPOSE OF THE REPORT:

<ul style="list-style-type: none"> • Business case outlining the option for practices in the East Locality to provide patients with a local, in-practice testing and dosing service for anticoagulation, with the aim of increasing the accessibility of testing for Warfarin patients. The service is offered to practices as a LES, based on the highest level of the Anticoagulation NES. • Service specification detailing the expectations of this service at practice level.
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IMPLICATIONS:

Legal and/or Risk	Warfarin dosing											
Standards for Better Health	<p><u>Fifth domain; Accessible and responsive care</u> C17; We have taken into account the views of patients that took part in the Hill Street phlebotomy survey where the majority of patients were pleased at not having to attend the hospital for routine blood tests.</p> <p><u>Sixth Domain: Care Environment and amenities</u> C20; Near patient testing will provide an environment which promotes effective care by allowing patients and professionals to carry out a dialogue on the dosing, reducing irregularities and encouraging patient to become more involved in their treatment and overall health.</p>											
Financial	The business case highlights that a cost saving can be made if surgeries sign up.											
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Good Hope Hospital Clinics	£14.99				
Postal Dosing	£13.53				
Training	Training will be provided for the machines, software and oral anticoagulation management as outlined in the service specification and business case.				
PBC	The business case has been requested by the PBC leads on behalf of the GP Consortia in East and South East Staffordshire.				
Other					

RECOMMENDATIONS / ACTION REQUIRED:

PBC Governance to approve business case to allow the project to move to implementation.

Anticoagulation Near Patient Testing

Introduction

The monitoring of anticoagulation for patients taking anticoagulants has traditionally been performed in hospital clinics. Through the development of software and computerised decision support software(CDSS), effective and efficient testing can be performed in house.

Benefits

As well as providing a safe and convenient location for accessing anti coagulation testing, it also means that patients are in a familiar environment. There is evidence that immediate dosing of patients also results in fewer clinic attendances, as patients and professionals can carry out a dialogue on the dosing and irregularities are reduced.

What does it involve?

Near patient testing requires:

- A receptionist to meet and greet patients
- An appointment booking system
- A trained Healthcare professional
- A treatment room with
 - 2 power points
 - Sink
 - Work surface
 - Waiting area
 - Wheelchair space in the room
- A computer with approved CDSS
- A coagulometer
- Test strips
- Quality control solution
- Lancets

The coagulometer is switched on and the user ensures that the correct code chip is inserted, the test strip is then inserted into the coagulometer. The user takes a pinprick of blood and places it on a testing strip, this generates an INR reading and results are displayed on the screen of the coagulometer. The results from the coagulometer are then inputted manually into the computer software to calculate the dosing. Results are then written up in the patient's hand held notes (yellow book).

Quality Control

A standard anticoagulation near patient testing protocol will be developed centrally.

Internal Quality Control:

The Coagulometer has several quality control functions including: a check on the different electronic components and instrument functions upon switching on the monitor; test-strip temperature monitoring during testing; checks on test strip expiry date. Every test strip has an incorporated quality control function which assesses integrity in the measuring channel after sample application. Liquid control solutions are also recommended for the following:

- When introducing a new batch/lot of test strips
- If there is doubt about the storage conditions of the test strips
- If an unexpectedly high or low INR result has been obtained on a patient
- At the beginning of each clinic.

External Quality Control

Some form of external quality control is essential, the recommended option is to participate in an accredited external quality assessment (EQA) programme this comprises of four surveys per year, each containing two samples for INR determination. This will be available through UK NEQAS and surgeries will be sent a registration form to complete.

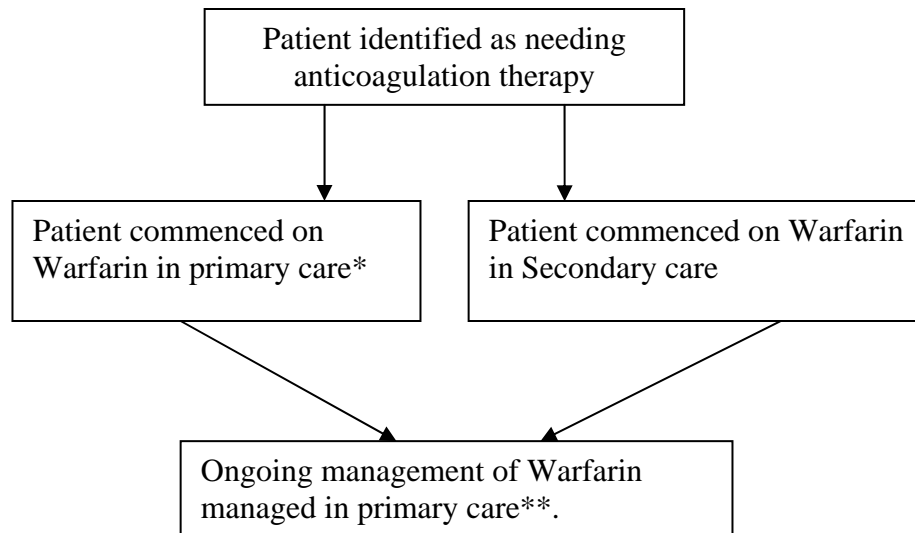
Training

Training will be mandatory for the following:

- **Coagulometer:** Half day course, the person who will be using the machine in clinic would benefit from attending this course.
- **CDSS:** Half day course, the person who will be using the software in clinic would benefit from attending this course.
- **Oral anticoagulation management:** This is a three day course at Birmingham University with the following learning outcomes, it is anticipated that either a nurse or GP will need to attend this course:
 - An understanding of the theory underpinning anticoagulation management
 - An understanding of the pharmacology of vitamin K antagonists and the relevant medication, side effects, antidotes, interactions and dosing
 - A knowledge of the management of anticoagulation and prevention of complications on the basis of current guidelines and existing research evidence
 - An understanding of the roles of the multi professional disciplinary team in managing anticoagulation safely
 - An understanding of the requirements of clinical governance for anticoagulation management developing / adapting and applying audit tools with performance indicators

The PCT will pay for 1 person per practice per course no backfill will be provided, dates of the courses will be sent out to those surgeries that have signed up to the top level of the LES along a register requesting names of who will be attending each course.

Referral Pathway



* Not all patients are suitable for in practice testing (e.g. bleeding disorder, liver failure, pregnancy)

** Patient supplied with enough Warfarin to dose adjust as instructed by the GP or Consultant.

Clinic appointments

Currently patients access the current Warfarin monitoring services anything between 9 and 15 times a year. It is likely this face-to-face, instant dosing will be at the lower end of the scale as patients and professionals have the opportunity to discuss the dose.

Cost

LES payment £127 per patient per year will include the following:

- Strips
- Quality Control Solution
- Lancets
- NEQAS

The PCT will send out an excel spreadsheet which allows practices to input their annual overheads for running the clinics and their Warfarin population. It will then calculate the costs and estimated profit for the surgery.

The PCT will provide the following:

- Purchasing of the machines (including branch surgeries if needed) – Damage due to excessive force, dropping the machine, incorrectly cleaned and therefore not covered by the company’s warranty will need to be replaced by the surgery.
- Purchasing of the software and ongoing annual licenses
- Initial Oral Anticoagulation Management Training
- Initial Software Training

Service Provision Business Case Template

This template has been designed to assist in submitting an outline business case proposal for local service provision. This template should be used for proposals to be submitted under contracting schemes such as a Local Enhanced Service (LES), PMS, SPMS and APMS etc.

The PCT can provide assistance in completing this template. Please provide as much information as possible to enable the PCT to make a provisional informed decision in principle. The PCT will be looking for the proposal to meet local needs as well as falling within the scope of the PCT strategic commissioning framework and priority areas as listed in Section 1 of this template. The PCT will also be looking for evidence that this proposal has been developed in line with local public and front-line staff opinion and that local public health issues have been addressed.

TITLE OF PROPOSAL	Anticoagulation Clinics in Practices
ORGANISATION/ COMMISSIONING BODY	South Staffordshire PCT (East Locality)
LEAD NAME FOR PROPOSAL	Rachael Bolton and Debbie Floyd on behalf of the PBC leads
TELEPHONE	01283507148 or 01283507164
EMAIL	rachael.bolton@southstaffspct.nhs.uk debbie.floyd@southstaffspct.nhs.uk

Document Control

Document Version	Date of Revision	Summary of Revision
Version 1	27/5/09	Business plan already written but put into the formal template

Document Version	Committee submitted to	Date Submitted	Approved
Version 1	PBC Exec/PBC steering committee		

Section 1: Compliance with the PCT Commissioning Framework

This business case complies with the following priority areas as outlined in the PCT Commissioning Framework:

PCT Commissioning Framework Priority Areas: <i>PCT to complete PCT Commissioning Framework priorities as outlined in the PCT LDP and ISIP.</i> <i>Full details of each of these areas are available from your PCT</i>	This business case relates to the following <i>(Proposer to tick as appropriate):</i>
<i>PCTS have specific targets on all of the following areas in line with national directives regarding achievement thereof, and practice are expected to work within these priorities as practice based commissioners. With regard to your specific service proposal, please tick all appropriate boxes served by your scheme.</i>	
1. National priorities	
1.1 Improving health of the population	
1.2 Supporting people with long term conditions	X
1.3 Access to services	X
1.4 Patient/user experience	X
1.5 Achieving financial balance	X
1.6 Implementing reform	
1.7 6 key service priorities:	
- health inequalities	
- cancer 31 and 62 day waits	
- 18 week wait	
- MRSA	
- Patient Choose & Book	
- Sexual health & access to GU medicine	
1.8 Links with Integrated Service Improvement Plan (ISIP) & Benefits Realisation Plan (BRP)?	
2. Local priorities	
Care Closer to Home	X

Section 2: Outline of the Proposed Service Provision

<p>Introduction <i>Give a brief out line of the background (i.e. current service provision and demonstration of need for improvement. Include Health Needs Assessment)</i></p>	<p>The monitoring of anticoagulation for patients taking anticoagulants has traditionally been performed in hospital clinics. Through the development of software and computerised decision support software(CDSS), effective and efficient testing can be performed in house.</p> <p>As well as providing a safe and convenient location for accessing anti coagulation testing, it also means that patients are in a familiar environment. There is evidence that immediate dosing of patients also results in fewer clinic attendances, as patients and professionals can carry out a dialogue on the dosing and therefore reducing irregularities.</p>
<p>Outline of Proposal <i>How does this link to PCT & Local priorities?</i></p>	<p>To offer surgeries in the East Locality the opportunity to work at the highest level of the anticoagulation NES whereby the practice funded phlebotomist/nurse takes the blood sample, tests and doses the patient accordingly using the software provided and a GP is responsible for the overall delivery of the service. The payment will be £127 per patient per year and out of this the practice will need to purchase the strips, lancets and quality control in the form of a liquid solution and a nationally run programme called NEQAS (National External Quality Assessment Scheme).</p> <p>To support and encourage surgeries to sign up to the scheme the PCT will provide the following:</p> <ul style="list-style-type: none"> • Purchasing of the machines (including provision for large branch surgeries if needed) • Purchasing of the software and ongoing annual licenses • Initial Oral Anticoagulation Management Training • Initial Software Training <p>This will mean that patients will not need to go to the hospital to have their INR tests and the clinic will be in a familiar setting.</p>
<p>Aims & Objectives <i>(Please expand on the brief outline that you gave in the Commissioning Proposal)</i></p>	<ul style="list-style-type: none"> • To offer surgeries the opportunity to work at the highest level of the NES • Care Closer to Home; Encourage surgeries to take part and therefore more patients being managed by their practice rather than the hospital • Reduce the PCT overall costs of monitoring/tests • Break the link between condition management and acute care
<p>Management of the Service <i>(Explain how the service will be managed i.e.</i></p>	<p><u>Referral Pathway</u></p>

<p><i>receiving referrals, appointments, outcomes and waiting list requirements)</i></p>	<div style="text-align: center;"> <pre> graph TD A[Patient identified as needing anticoagulation therapy] --> B[Patient commenced on Warfarin in primary care*] A --> C[Patient commenced on Warfarin in Secondary care] B --> D[Ongoing management of Warfarin managed in primary care**] C --> D </pre> </div> <p>* Not all patients are suitable for in practice testing (e.g. bleeding disorder, liver failure, pregnancy) ** Patient is supplied with enough Warfarin by their pharmacist to dose adjust as instructed by the GP or Consultant.</p> <ul style="list-style-type: none"> • It is anticipated that the average number of Warfarin tests per patient per year will be 12 • Appointments will be arranged by the surgery at the necessary frequency to which the patient needs to be monitored (details of this are outline in the Anticoagulation LES)
<p>Scope of the Proposed Service <i>(i.e. which patients will be using the service, Target Localities/patient profile)</i></p>	<ul style="list-style-type: none"> • Patients who are at risk of DVT • Patients with pulmonary embolisation and those who have atrial fibrillations who are at risk of embolisation
<p>Clinical Effectiveness <i>(What evidence is there of the clinical effectiveness of the proposed service?)</i></p>	<ul style="list-style-type: none"> • Oral anticoagulation in primary care has been shown to result in effective therapy management, comparable to secondary care management¹
<p>What will be the benefits to Patients? <i>(e.g. How will this link in to Choice/Choose & Book?)</i></p>	<ul style="list-style-type: none"> • More flexibility for patients • More collaborative approach between healthcare professional and patient encourages patient to become more involved in their treatment • Care Closer to Home • Free parking

¹ Hobbs FDR et al. A review of near patient testing in primary care. Health Technology Assessment. 1997; 1:5.

	<ul style="list-style-type: none"> Instant results and the chance to discuss them face to face 														
<p>What will be the benefits for Clinicians/Staff?</p>	<p><u>Primary Care</u></p> <ul style="list-style-type: none"> Opportunity for surgeries to enhance their skill base Financial reward for those surgeries choosing to offer this service <p><u>Secondary Care</u></p> <ul style="list-style-type: none"> Moving some of the monitoring from the hospital to primary care will allow pathology, haematology and biochemistry departments to focus on new and problematic patients 														
<p>What will be the anticipated benefit area for the PCT <i>(i.e Number of Reduced Admissions / Avoided Out Patient attendances)</i></p>	<ul style="list-style-type: none"> Average cost per test decreases Acute capacity is released Below is a table demonstrating that costs savings can be realised based on a cost per test for ease of comparison <table border="1" data-bbox="581 886 1432 1178"> <thead> <tr> <th>Name of Service</th> <th>Cost to PCT per test</th> </tr> </thead> <tbody> <tr> <td>LES</td> <td>£15.09*/£11.13**</td> </tr> <tr> <td>Burton Hospital (BHFT), test and dose</td> <td>£14.75</td> </tr> <tr> <td>BHFT including phlebotomy</td> <td>£17.57</td> </tr> <tr> <td>Provider Arm</td> <td>£20.81</td> </tr> <tr> <td>Good Hope Hospital Clinics</td> <td>£14.99</td> </tr> <tr> <td>Postal Dosing</td> <td>£13.53</td> </tr> </tbody> </table> <p>*Year 1 costs including training and machinery costs. **Subsequent year costs * and ** based on INRStar practice edition and Roche Coagucheck and training provision, 12 tests per year</p> <ul style="list-style-type: none"> Currently East Staffordshire pays for more than just the cost per test as the majority of surgeries are also signed up to the anticoagulation LES. E.g. a surgery with 100 warfarin patients working at level 3 of the LES will get paid £26.84 per patient per year and so an additional costs of £2684 per annum on top of the cost per test. 	Name of Service	Cost to PCT per test	LES	£15.09*/£11.13**	Burton Hospital (BHFT), test and dose	£14.75	BHFT including phlebotomy	£17.57	Provider Arm	£20.81	Good Hope Hospital Clinics	£14.99	Postal Dosing	£13.53
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Milestones & Timescales	Milestone	Timescale
	Sign off of LES and service specification by LMC, PEC	WC 1 st June
	Sign off of LES and service specification and business case by PBC Governance	10 th June

	Launch LES at consortia meetings	WC 15 th June
	Send LES out along with spreadsheet requesting surgeries to identify who will be attending training	22 nd June
	Deadline to receive signed LES from surgeries	8 th July
	Names of people from the surgeries attending the anticoagulation training	WC 13 th July
	Software and machines purchased	WC 13 th July
	Inform secondary care re the numbers of surgeries signing up	As of the 8 th July
	Organise training dates	As of the 8 th July
	Training dates fed back to surgeries	WC 13 th July
	Machines, consumables and software delivered	WC 3 rd August
	Software and machine training	August (holiday period)
	Oral Anticoagulation training	WC 7 th Sept
	Practices to commence service	From 14 th September

Initial Risks Associated with the Service Provision Proposal and Strategy for managing those risks (Countermeasure)	Risk	Countermeasure
	Disagreement with contents of the service specification	Final draft of service specification and LES sent out to GP practices, LMC, PEC and PBC Governance.
	Practices unhappy with level of payment	Details regarding who is paying for what outlined in the service specification to make it clear and an excel spreadsheet sent out that calculates for the practice their profit after purchasing consumables etc.
	Delay in some practices signing up to the LES therefore numbers for training etc are unclear	Deadline will be attached to the LES. PCT to ring and email surgeries before the deadline if the LES has not be received.
	Delay in the delivery of the machines and software	Project managers to contact the companies to get specific timelines based on the companies past experiences
	Software not compatible with some practice systems	Project managers working with IT department to find out which surgeries have which programmes and whether this will be compatible with the software. Actions will depend on the findings.

	Numbers of patients that attend the hospital clinics do not go down	Performance analyst to monitor hospital activity. Details regarding which surgeries fed back to relevant people to action
	Training dates not attended	Should be made mandatory before clinics are commenced. PCT to try and accommodate staff unable to attend
	Birmingham University unable to provide training in the desired time lines	Contact Birmingham university to find their availability and booking process so that the when numbers have been agreed dates can be arranged quickly
	Surgeries signing up to the LES after the initial launch will not have access to organised training days	This can not be avoided and any surgeries signing up after the initial launch will need to arrange their own training. This will need to be made clear to practices at the beginning

Section 3: Financial Implications

- Costs are based on 18 practices with a total of 1450 warfarin patients being tested 12 times a year.
- Year 1 pro rata from 1st September 2009

Annual Expenses (Cost of New Service) <i>List a breakdown of all expenses, remembering to add on-costs to staff costs</i>	Year 1 pro rata from 1st September 2009 – 31st March 2010	Year 2	Year 3
Capital Costs	0	0	
Staffing Costs, including backfill for clinicians running new service provision	0	0	
Training and Supervision Costs	<ul style="list-style-type: none"> • £690 for software training • £24300 for oral anticoagulation monitoring training for 18 people 	0	
Equipment & Materials	<ul style="list-style-type: none"> • £15,000 for machines (20 machines to be purchased) • £5800 Software license per annum (base on 18 practices with 1450 Warfarin patients) 	<ul style="list-style-type: none"> • £5800 Software license per annum (base on 18 practices with 1450 Warfarin patients) 	
Other Expenses	<ul style="list-style-type: none"> • £107420 LES 	<ul style="list-style-type: none"> • £187,833 LES payment 	

	payment pro rata 7 months (LES payment of £127 per patient per year)	of £129.54 per patient per year (based on 2% uplift)	
Total Cost of New Service	£153,210 Based on 18 practices in the East Locality signing up with 1450 patients	£193633 Based on 18 practices in the East Locality signing up with 1450 patients	£
Anticipated Revenue <i>please explain source of revenue</i>	£	£	£
Profit Element for Service Provider	£48,339 for 1450 patients. Based on 45% of LES payment being profit & presuming overheads are midpoint band 6 nurse	£84,524 for 1450 patients. Based on 45% of LES payment being profit & presuming overheads are midpoint band 6 nurse	£

Anticipated Financial Benefit to PBC Budgets	Year 1	Year 2	Year 3
Anticipated freed up resources achieved through avoided secondary care activity. <i>Please specify:</i>	East Staffs £102666: <ul style="list-style-type: none"> Costs removed BHFT pro rata £91,000 Costs removed from previous LES payment pro rata 	East Staffs £176,000: <ul style="list-style-type: none"> Costs removed BHFT from £156,000 Costs removed from previous LES payment £20,000 	

	<p>£11,666</p> <p>Average cost per test based on 12 tests a year for LES is £15.09 year 1 compared to:</p> <ul style="list-style-type: none"> • BHFT £14.75 • Provider arm £20.81 • Good Hope Clinics £14.99 • Postal dosing £13.53 	<p>Average cost per test based on 12 tests a year for LES is £11.13 compared to:</p> <ul style="list-style-type: none"> • BHFT £14.75 • Provider arm £20.81 • Good Hope Clinics £14.99 • Postal dosing £13.53 	
Less Cost of new Service Provision to users of the service	<p>East Staffs Total £70,844:</p> <ul style="list-style-type: none"> • £2783 software costs • £380 training costs • £13,500 oral anticoagulation management training • £8250 for 11 machines • £45931 LES payment for 620 patients pro rata 	<p>East Staffs Total £83097:</p> <ul style="list-style-type: none"> • £2783 software costs • £80314 LES payment for 620 patients 	
Surplus to PBC Budgets	<p>East Staffs £31,822</p> <p>South East: Same</p>	<p>East Staffs £92,903</p> <p>South East: Cost per test</p>	

	<p>methodology will apply to South East once the activity data has been confirmed with providers.</p>	<p>does highlight a saving, however savings will be calculated once all activity data has been confirmed with the various providers in South East.</p>	
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<p>How much funding is being requested & identification of purpose</p>	<p>Year 1:</p> <ul style="list-style-type: none"> • £15000 for 20 machines • £107,420 for LES payment for 1450 warfarin patients • £24,300 for 18 people to attend oral anticoagulation training • £5800 for software (based on INR Star Practice Edition) • £690 for Software training <p>Total: £153,210</p> <p>Year 2:</p> <ul style="list-style-type: none"> • £187,833 for LES payment for 1450 warfarin patients • £5800 for software <p>Total: £193,633</p> <p>Grand Total £346,843 for the East Locality</p>
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Section 4: Corporate Governance

Please note that some contracting methods will entail certain liabilities, for example a Limited Company option under APMS. It is therefore essential specialist advice is taken to understand clinical/personal liability, medical indemnity etc.

<p>On which contracting basis do you intend this service provision to be based? <i>e.g. LES, PMS, SPMS, APMS, PCT GPSI Commissioned Service, please explain.</i></p>	<p>LES that is already in place in East Staffordshire.</p>
<p>Which National, NSF and PCT Targets will this service provision deliver against?</p>	<p>Care Closer to home Support patients with long term conditions Financial stability</p>
<p>Demonstrate links to Standards for better Health <i>(Please identify standards and describe how this plan will support achievement of the standards)</i></p>	<p><u>Fifth domain; Accessible and responsive care</u> C17; We have taken into account the views of patients that took part in the Hill Street phlebotomy survey where the majority of patients were pleased at not having to attend the hospital for routine blood tests.</p> <p><u>Sixth Domain: Care Environment and amenities</u> C20; Near patient testing will provide an environment which promotes effective care by allowing patients and professionals to carry out a dialogue on the dosing, reducing irregularities and encouraging patient to become more involved in their treatment and overall health.</p>
<p>Patient, Public & Front-line Staff Involvement. <i>Please describe how you have involved Patient, Public and front-line staff in this proposed development.</i></p>	<ul style="list-style-type: none"> • We have worked with local GPs when developing the service specification • Service specification sent to East and South Practices, LMC and PEC members for comment. • A patient satisfaction survey for the phlebotomy service at Hill Street (that has Warfarin patients and patients with other long term conditions that require monitoring) was completed by 321 patients and 98% of those were happy with the overall service. Feedback from some of there were; <p>'much more simple than waiting at the hospital' 'its near to home for me' 'handy to get to and no parking costs'</p> <p>One of the areas the feedback highlighted was that whilst patients</p>

	<p>felt Hill Street was more convenient than the hospital their surgery would be even more convenient. Surgeries encouraged to work at the top level of the LES would therefore meet the patients expectations.</p>
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Section 5: Quality & Corporate Assurance

Please note there is value in discussing your proposals early on with your PCT Clinical Governance Lead

Clinical Governance Assurances	
Please provide details of how the intended provider location meets Health & Safety and other Clinical Governance Assurance standards	Provided by GP practices currently assessed under the GP contract
Please Specify Audit arrangements ie, patient satisfaction surveys, reduction of hospital referrals & admissions	Performance analyst to monitor secondary care activity for Warfarin testing The software will enable practices to send the PCT the numbers of Warfarin patients and testing being done if required for review and audit
What Quality Checks will be in place?	Surgeries as part of the LES will be expected to purchase an external quality assurance programme from NEQAS (National External Quality Assurance Scheme). This service provides samples on a quarterly basis to surgeries so that they can test the machine and send the results back to make sure the readings are in range.
What information will you supply to the PCT and with what regularity?	Surgeries will need to supply on a regular basis; <ul style="list-style-type: none"> • Number of patients on Warfarin • Number of tests per patient per year done in the practice • Number of Warfarin patients attending another provider for example Queens Hospital <p>The PCT will need to monitor how many patients attending other providers for their Warfarin tests/dosing</p>
Outline Contractual Arrangements (To be detailed in the Service Level Agreement)	
Proposed period of Contract	19 months (September 09 to March 2011)
Proposed Notice Period	3 months
What Contract Review arrangements do you envisage?	Annually as part of the normal LES reviews
How will Complaints	Via the normal PCT complaints process

be managed?	
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To be Completed by PCT:

Comments received:	Date
Practice Based Commissioning practice/consortia	
Clinical Governance Lead	
Executive Directors	
Professional Executive Committee	

Outcome of Application	Name	Date
Approved – on the basis of:		
Rejected - Reasons for Rejection:		
Passed for Payment:		

