

Pathology Governance and Quality Framework

Background

Pathology services provide diagnostic results to clinicians to support in defining diagnosis, prognosis and to effectively manage the care of patients.

The Pathology provision delivered by TDL for the contract with Brent CCG, Harrow CCG and NWLH NHS Trust represent a mid-scale service with 1.654M individual reported items in May 2013.

Quality assurance and governance of Pathology services is a process that is delivered cooperatively between the provider, the customers and external agencies.

This paper describes this governance framework and the interplay between the various organisations at a high level with an intention to offer reassurance that all reasonable measures are in place to ensure quality.

Governance and quality arrangement with the Provider

The provider is bound by a regulatory framework within which they must work. Bodies such as the MHRA and CQC are responsible for monitoring and ensuring compliance at this level.

This regulatory framework is then further consolidated by an accreditation process which is undertaken by the body Clinical Pathology Accreditation UK (CPA) which is now part of United Kingdom Accreditation Service (UKAS).

The standards¹ that CPA/UKAS require the pathology service to evidence compliance with cover a very broad remit and cover all analytical and non-analytical functions of the laboratories:

- A. ORGANISATION AND QUALITY MANAGEMENT SYSTEM
- B. PERSONNEL
- C. PREMISES AND ENVIRONMENT
- D. EQUIPMENT, INFORMATION SYSTEMS AND MATERIALS
- E. PRE EXAMINATION PROCESS
- F. EXAMINATION PROCESS
- G. THE POST EXAMINATION PHASE
- H. EVALUATION AND QUALITY ASSURANCE

The provider also has a range of clinical and operational groups and mechanisms to ensure that quality is maintained and that the services are performing against all of the compliance requirements.

¹ http://www.cpa-uk.co.uk/files/PD-LAB-Standards_v2.02_Nov_2010.pdf

Notable aspects of the quality process with the provider include:

A corporate quality management group

This group facilitates the local laboratory quality management teams with compliance management and monitoring

This group also manage the regulatory and accreditation compliance feeding back to the service users via a number of forums any remedial corrective and preventative actions that have been taken or need to be planned.

Internal and External quality assurance schemes

Every test available in the laboratories has a regimen of internal quality control (IQC) to assess and mitigate issues relating to any day to day variance in results and to ensure that confidence is provided for all patient results undertaken.

Eternal quality assurance (EQA) schemes are also in place whereby special samples are sent by a third party to be run with the results being compared to peer groups of laboratories and analytical methods.

The combination of the two allows the laboratory and its users to have a be comfortable that the results provided are comparable to an expected value (EQA) and consistent over time (IQC).

Clinical, scientific and Operational groups

Forums of clinical and laboratory scientific staff meet regularly to discuss any issues and to identify any changes that need to be made to the services to ensure clinical suitability and analytical quality are maintained within the services.

Governance and quality arrangement with the service users

The service users, Brent CCG, Harrow CCG and NWLH NHS Trust have equally robust mechanisms of ensuring accountability for the delivery of clinically appropriate and analytically correct results.

Consultant led services

The services are termed as 'Consultant Led' services which means that we have invested in procuring a service whereby consultant grade clinicians and clinical scientists are responsible for the clinical leadership and quality of their respective specialities. These act as the patient advocate for all aspects of service delivery and governance including quality.

Transitional governance arrangements

Every test that was transferred from the old analytical platforms to the new equipment had in depth statistical analysis undertaken to assess many elements of the performance of the tests including important areas such as sensitivity, specificity and correlation. Only where assays were shown to perform in a clinically appropriate fashion were they authorised for use.

Consultant Heads of Departments forum

Monthly Consultant Heads of Departments meeting allow for a wide discussion of clinical and technical performance issues to be discussed and to monitor any areas where concern has been raised from other clinical forums.

Information is fed from the Quality Management Group of the provider along with operational and management data which is available within the service to be able to clearly identify and manage any risks.

Contract Clinical Management Committee

A forum is available as part of the contractual management processes which includes representation from Brent and Harrow CCGs and the Consultant Heads of Department to ensure engagement of both Primary and Secondary care clinical service users.

This forum feeds into the Contract Operational Management Committee.

Contract Operational Management Committee

This forum takes clinical and operational leads from all parties to the contract and has devolved authority to implement changes that are required for safe and effective service provision. This group is responsible to the Contract Clinical Management Committee and reports to the Contract Review Committee.

Contract Review Committee

This forum takes recommendations from the Operational Management Committee where financially significant or contractual changes are required to facilitate change and improvement of the services.

Contract Manager

The entire service provision is managed on a day to day basis by the Contract Manager which is a senior scientific post to ensure that any operational issues that arise can be managed appropriately and that continual monitoring of quality and service provision occurs.

CCG Clinical Responsible Officers

Both Brent CCG and Harrow CCG have a named Clinically Responsible Officer tasked with oversight of the services from a Primary Care perspective. These individuals lead a group of GPs within locality groups or other similar structural groups to ensure that information and concerns are passed through to the provider and also likewise back from the provider

Regulatory and clinical oversight framework

Regulatory Framework (CQC, MHRA)		
Accreditation Framework (CPA, UKAS)		
Primary Care Clinical Governance (Clinical Responsible Officers, Locality Groups)	Provider Quality Management Group	Secondary Care Clinical Governance (Consultant Heads of Department)
Laboratory Quality and Management Structures		
Analytical Service		

Clinical governance overview and interdependencies

