Internal Quality Assurance Framework

Chemical Pathology

The Royal College of Pathologists of Australasia received funding from the Department of Health, under the Quality Use of Pathology Program (QUPP) to develop a comprehensive framework for internal quality assurance, focused on the morphological disciplines of Histopathology, Cytopathology, Haematology and Forensic Pathology. The overall governance of this project was provided by the College, and was supported by a Steering Committee that included representatives of the morphological disciplines. The Board of Education and Assessment and the Board of Directors further decided to develop separate discipline specific Frameworks for the other disciplines of pathology.

The Chemical Pathology IQA Framework contains activities that will aim to help monitor performance, drive improvement and support collaborative on-going professional practice. The IQA Framework activities focus on peer-review and clinical audit and require documented evidence of a pathologist's involvement in these internal quality activities. The Framework is practice based and the Chemical Pathology Advisory Committee provided guidance with the development of the Chemical Pathology Framework activities.

Implementation of the Chemical Pathology IQA Framework will be undertaken in 2017 in consultation with the Fellowship.

For any queries about the Framework or the project, contact the DCEO, Dr Bronwen Ross at bronwenr@rcpa.edu.au

Framework Features

The Internal Quality Assurance framework divides laboratory activities into 3 specific cycles:

1. *Pre-analytic* phase of the test cycle includes specimen delivery and accessioning, specimen handling and laboratory technical processing.

2. *Analytic* phase of the test cycle, in the current context, relates to the pathologist diagnostic component.

3. *Post-analytic* phase of the test cycle begins with report authorisation through to report delivery, and may include adjunct activities such as billing.

The Framework records these activities under 2 sections:

Section 1: Diagnostic Measures (the analytic phase) relates to peer review activities, participation in 10 hours per annum required.

Section 2: Technical Laboratory Measures (pre-analytic) and Service Performance (post analytic/overview) relate to clinical audit activities, participation in 10 hours per annum recommended.

Please refer to the tables on the following pages for information on examples of suitable activities and further document requirements.

FRAMEWORK Internal Quality Assurance Activities CHEMICAL PATHOLOGY		
Section 1: DIAGNOSTIC MEASURES - (engaging in peer review activities) **Requirement: Minimum 10 hours per annum Diagnostic Measures**		
Activity	**Quality activity monitor related**	**Suggested document requirements**
Case Reviews Using clinical audit techniques	• Internal random case review - Defined number and type of case	Document the review type - Who performed the review - What was reviewed - What cases were reviewed - Time taken Document discordance as - None (agreement) - Minor non clinical - Minor clinical (no impact on patient care) - Major clinical (potential impact on patient care)
	• Internal targeted case review - Specific case types	
	• Internal correlations - *examples could include:* - Audit and review of report comments - Complex testing requiring review and commentary by the Pathologist • Other correlations performed: *examples could include*: - Review of RCPA QAP comments	
	• Inter-institutional correlations - *examples could include:* - Collegiate case reviews - Online interest groups	
	• Intradepartmental correlations - *examples could include:* - Consultations - Case Discussions	
Other Peer Review Activities	• Cross discipline peer review presentations** - *examples could include*: • Any discordant opinions (including discordance with other diagnostic services – eg imaging)	
	• Peer review of corrected/amended reports and complaint resolution	
	• Peer review of compliance with relevant position statements, guidelines and recommendations - *examples could include* - Harmonisation of reference limits - Units of reporting - Utilisation of report templates	
	• Peer review of pathologist initiated discretionary/reflex testing	
Formal Peer Review	• Validated 360 degree peer review completed	Date, time and duration and brief description of activity.

**Collegiate case reviews such as RCPA hosted Chemical Pathology meetings, online interest groups, teleconferences and webinars

Each laboratory must have documented processes for handling diagnostic discordances when detected – eg protocol for the investigation of analytical interference.

FRAMEWORK Internal Quality Assurance Activities CHEMICAL PATHOLOGY		
Section 2: TECHNICAL MEASURES - laboratory based non-conformances (audit activities) **Recommended: Minimum 10 hours per annum combined Technical Measures/Service Performance**		
Activity	**Examples of quality monitors related to lab based non-conformances**	**Suggested document Requirements**
Non-conformance reporting A laboratory non-conformance is an incident that has the potential to cause an error or harm. Documentation of these is a requirement. Laboratories should have existing policies, procedures and processes in place if such an incident occurs. The examples stated in this table should be reported.	• Specimen collection, transport, handling receipt and storage issues* - *examples could include*: - Incorrect identifiers - Labelling errors - Lost specimens • Laboratory techniques issues - *examples could include*: - Methodology reviews and validation/ verification - Performance reviews - Review of laboratories authorisation comments	Incidence +/- % of non-conformances
Section 2: SERVICE PERFORMANCE - suggested examples are provided below of types of service activities that may be monitored and specific data collected		
Audit of Service Performance The goal is to monitor and improve internal laboratory performance using auditable measures and collect acceptable data to develop benchmarks for the future.	• Service Performance - *examples could include:* - Turn Around Time (TAT)** - Whole workload or - Selected case type - ACHS CIs compliance • Report format review – *example could include:* - Entry of erroneous demographic details/clinical notes which may affect reference limits/interpretative comments applied to test results • Design, development and audit of expert systems for - Flagging/prioritising significant results - Applying interpretive commenting to test results - Customising reports according to requester to enhance their clinical utility - Diagnostic criteria/clinical decision points/target values • Billing Errors	Documentation of TAT - Overall - Different phases of reporting process - By different case types % of errors post audit

* Laboratories must have policies for handling detected non-conformances

** Consider criteria from either current ACHS or RCPA recommendations

Establishing a Chemical Pathology IQA Framework that will be used to routinely review processes in the discipline should facilitate improved laboratory practices. It provides a mechanism for peer review, introduces a mechanism for laboratories to benchmark their processes to measure improvements, reduces the risk of aberrant/uninformative/false reports being issued in a clinical environment, thereby improving the quality of patient management and/or outcomes. Completing Chemical Pathology IQA activities under the proposed framework may be a difficult exercise as there are usually 1-3 chemical pathologists in any practice. Therefore, it may be necessary to construct some specific tools for Chemical Pathologists to use as part of the implementation process.

Activities performed from the Chemical Pathology IQA Framework will be linked to the RCPA CPD Program and will likely be an important part of any Revalidation Framework the College may need to adopt in the future.

The completion of these activities could form part of the RCPA audit substantiation for the RCPA CPD Program in the future.