FINAL REPORT

INTERNAL QUALITY ASSURANCE IN MORPHOLOGICAL AND INTERPRETATIVE DISCIPLINES PROJECT

A Report by
The Royal College of Pathologists of Australasia to the
Australian Government Department of Health

Sydney
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### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CAP</td>
<td>College of American Pathologists</td>
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<tr>
<td>CPDP</td>
<td>Continuing Professional Development Program</td>
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<tr>
<td>EQA</td>
<td>External Quality Assurance</td>
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<td>IQA</td>
<td>Internal Quality Assurance</td>
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<td>KAI</td>
<td>Key Assurance Indicators</td>
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<td>KPI</td>
<td>Key Performance Indicators</td>
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<td>LIS</td>
<td>Laboratory Information System</td>
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<td>MDT</td>
<td>Multidisciplinary Team</td>
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<td>NATA</td>
<td>National Association of Testing Authorities</td>
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<td>NPAAC</td>
<td>National Pathology Accreditation Advisory Council</td>
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<td>QA</td>
<td>Quality Assurance</td>
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<td>QAP</td>
<td>Quality Assurance Program</td>
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<td>QC</td>
<td>Quality Control</td>
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<td>QI</td>
<td>Quality Improvement</td>
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<td>QM</td>
<td>Quality Management</td>
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<td>RCPA</td>
<td>Royal College of Pathologists of Australasia</td>
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<td>RCPA QAP</td>
<td>Royal College of Pathologists of Australasia Quality Assurance Program</td>
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<tr>
<td>RCPATH</td>
<td>Royal College of Pathologists, UK</td>
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<td>RCPI</td>
<td>Royal College of Physicians of Ireland</td>
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<tr>
<td>RPR</td>
<td>Regular Practice Reviews</td>
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Executive Summary

Diagnostic “interpretative medicine” is the analysis and integration of clinical information, laboratory data and images for the purpose of establishing a diagnosis (and, or prognosis) in a patient’s case. There are many factors that affect interpretative diagnostic accuracy and error, including knowledge, experience/ training, standardisation of procedures, terminology, and clinical correlation. Although external quality assurance (EQA) activities are well established for diagnostic laboratories in Australia, there has not been a systematic approach to internal quality assurance activities (IQA) to monitor performance locally.

While the need for these is specified in National Pathology Accreditation Advisory Council (NPAAC) documents that govern laboratory accreditation through National Association of Testing Authorities (NATA)/RCPA assessment, a framework against which to make these assessments has been lacking. Likewise, there is a world-wide move towards ‘revalidating’ or monitoring medical practitioners’ clinical performance over time via peer review and clinical audit thereby improving patient safety and outcomes and this will also soon require a formal framework for documentation.

The Internal Quality Assurance in Morphological and Interpretative Pathology Disciplines Project seeks to fill this gap, focussing on the morphological disciplines of pathology, Anatomical Pathology, Cytopathology, Haematology and Forensic Pathology, as these are more difficult to measure in terms of error (such as human errors made via microscopy) than machine-based diagnostic processes. Errors in pathology reports with morphological and interpretative comments also have significant and immediate potential influence on patient management, for example in the treatment of cancer.

The project was an 18 month Australian national project led by the Royal College of Pathologists of Australasia (RCPA), governed by a steering committee of expert Fellows within the morphological and interpretative pathology fields. An initial literature search was conducted to examine best practice standards for IQA in morphological pathology in Australia and elsewhere (see section 5.3). Arising from this review and local experience and reference to NPAAC and other documents, the project team developed a draft IQA framework that included both peer review and clinical audit elements. The Framework was introduced via a workshop to a group of ‘thought leaders’ in these disciplines and was approved by that group to go forward to a pilot stage. The Framework was piloted by volunteer participants from this workshop as well as some additional pilot sites to ensure good coverage of the morphological disciplines, metropolitan and regional laboratories as well as public and private sector. The IQA Framework was designed so that it could be adaptable to suit a variety of local quality management systems.

In developing the Piloted IQA Framework, consideration was given to the three phases in the request-test-report cycle

1. **Pre-analytic** phase of the test cycle is specimen delivery and accessioning, gross examination/cut-up 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 Piloted Framework recorded these activities under 2 sections:
**Section 1:** Diagnostic Measures (the analytic phase) relates to peer review activities, [participation of 10 hours per annum required].

**Section 2:** Technical Laboratory Measures (the pre-analytic) & Service Performance (post analytic/overview) relate to clinical audit activities, [participation of 10 hours per annum required].

The piloted program was designed so the Framework can be both a stand-alone program for IQA in laboratories for the purpose of accreditation and performance measurement and part of the RCPA Continuing Professional Development (CPD) Program. In this way the Framework is intended to pave the way for an appropriate approach to ‘revalidation’ at some stage in the future.

The IQA Framework Pilot included activities for pathologists to participate in, focusing on peer-review and clinical audit requiring documented evidence of individual involvement. The Framework was practice-based providing a collaborative and transparent approach to IQA, and is discussed in detail in Section 5.4. The pilot examined the ability of the pilot sites to complete and document an appropriate amount of IQA in the timeframe and gave an opportunity for feedback on the framework. The Pilot was undertaken over a three month period and focussed primarily on feasibility, acceptability and workability.

Overall the Pilot Program was able to demonstrate the Framework was workable in the Australian laboratory context. It identified elements of the Framework requiring refinement and further support from the College to ensure that the implementation of the Framework will be successful in the morphological and interpretative disciplines. There was variability in practice of internal quality activities between laboratories, and this variability highlighted the need to develop benchmarking capabilities to guide laboratories in measuring improvements in processes.

The feedback from the Pilot Program was also used to further refine the framework, specifically addressing the need to include clearer discipline specific activities. This led to the decision to develop a generic shell model which will be used as the basis to provide discipline specific activity requirements with suggested examples within that discipline. The suggested activities from Section 2 for all disciplines of the Framework require further education and support to improve participation. The findings from the pilot are discussed in detail in Section 5.6 and 5.7.

The Framework was approved by RCPA Board of Directors as a Guideline document, and has subsequently been provided to NPAAC the NATA for possible incorporation into the laboratory accreditation process. The next steps involve systematic implementation across all states for the revised Anatomical Pathology IQA Framework, and using the feedback provided to date to finalise Section 2 activities for Haematology and Forensic Pathology prior to implementation.

It is the view of the College and the Steering Committee that Fellows will benefit from a Framework that has been designed to provide evidence of high standards of professional practice and participation in a quality assurance system and fits within the Australian context and practice. The Framework meets the Project objectives to be a potential warning system for potential errors in a pathology practice, part of an appropriate quality and risk management system to protect patient safety and improve patient outcomes.
1. Introduction

The 2002 Corrs Chambers Westgarth report into the Australian Laboratory Accreditation System identified the need for an early warning system for poor laboratory performance. The current accreditation system and external Quality Assurance programs largely focus on the technical aspects of laboratory performance, but have been unable to grapple with assessment of the diagnostic performance of the pathologists whom provide a morphological and interpretative diagnosis in the disciplines, such as Anatomical Pathology, Cytopathology, Haematology and Forensic Pathology.

In Anatomical Pathology, Cytopathology, Haematology and Forensic morphology the interpretation of slides and composition of an accurate, timely, complete and comprehensible report are the most important steps, which can transcend both excellent and, to an extent, deficient, technical performance by the laboratory. Thus there is a need to be able to monitor the adequacy of these practices and processes in a laboratory.

Quality in a laboratory is dependent on various components, such as personnel and structural factors. Quality assurance and improvements must be woven into all processes and systems of the laboratory to achieve the best possible outcome. Fellows and trainees in the morphological disciplines should be actively involved in their local quality management systems to minimise diagnostic error and ensure timely, accurate and complete pathology diagnosis and reports.

2. Project Statement

2.1. QUPP Objectives

The goal of the QUPP is to achieve improvement in health and economic outcomes from the use of pathology in health care, through the pursuit of better practice amongst requesters (or referrers) and providers of pathology services and knowledgeable and engaged consumers.

The Quality Use of Pathology Program has three sub-programs and objectives:

- **Quality Consumer Services**: to develop and improve consumer-focussed, accessible and coordinated services that promote informed choice and meet consumer needs.
- **Quality Referrals (Requesting or Ordering)**: To support referral practices that are informed and facilitated by best practice professional relationships and protocols between referrers and providers; that:
  - Are informed by evidence
  - Maximise health benefits, and
  - Inform and engage consumers.
- **Quality Pathology Practice**: To support professional practices standards that meet consumer and referrer needs and provide evidence-based, best practice, quality-assured services that are safe, cost effective, and efficient.

This project is in line with Quality Pathology Practice: that is, it supports professional practice standards that meet patient and referrer needs, best practice, quality-assured services that are safe, cost effective and efficient.
2.2. Project Objective

The project objective was to develop an IQA Framework for morphological and interpretative pathology that provides an early warning system for potential performance issues in laboratories. The IQA Framework was to be fair, transparent and robust. It is to be used to assist laboratories and individual pathologists practising in the interpretive and morphological disciplines to:

- Detect problems within interpretative aspects of the practice of pathology at an earlier stage than may currently occur;
- Reduce the risk of reporting errors being issued in a clinical environment;
- Monitor the adequacy of the interpretation of slides, and resulting reports;
- Improve patient management and/or outcomes;
- Monitor performance and support professional practice; and
- Provide a pathway for revalidation.

2.3. How the Project goals were met

The IQA Framework was developed in consultation with pathologists from the morphological and interpretative disciplines to ensure it was fair and that it was able to form part of everyday practice. The proposed Framework model was tested through a Pilot Program. The Pilot Program was created so it could be assessed at various pilot sites that reflected the variety of workplaces Fellows occupied, these being public, private, large or small laboratory, metropolitan and regional sites.

The Pilot was developed using the proposed internal quality activities and carried out over a three month period. The aim of the Pilot Program was to ‘test’ feasibility, acceptability, workability, of the Framework. Subsequent refinements were made to the Framework as a result of the Pilot feedback and other also feedback received from targeted users that specifically addressed issues relating to feasibility and acceptability.

2.4. Project Challenges

Feedback from some of the Pilot respondents indicated the template for Section 2 of the Framework was too complex, and may not adequately represent the requirements of all individual pathologists or their practices, and subsequently a proportion of respondents did not complete Section 2. The Project team responded to this feedback and subsequently modified the Framework to being a generic shell, developing individual discipline specific Frameworks with related activities to overcome the initial lack of participation. This has been completed for Anatomical Pathology and Haematology and Forensic Pathology activities will be developed as part of the implementation phase.

Time constraints and additional workload associated with recording IQA activities was a challenge identified as part of this Project. The results from the Pilot Program, and other feedback collated as part of the Project highlighted there was participation by Fellows in internal quality activities, however it was not common practice for Fellows to fully document their involvement in these practices. This created a level of concern amongst Fellows regarding the additional burdens/requirements to record activities that were already being performed, in particular relating to time management and workload. It is anticipated that the IQA Framework will provide Fellows with a simply means to document their participation in peer-review and clinical audit activities and that
they and their supervisors will see the value for accreditation and professional development that this documentation provides. Workshops and education sessions highlighting the need for Fellows to undertake and document IQA activities have been planned as part of the implementation phase to assist with overcoming this challenge.

The requirement for implementing a system to document IQA activities will be discussed with individuals as part of from part of the implementation phase of the Project, and will take into consideration that a ‘one size fits all’ approach may not be feasible. Templates will be developed and used as guides. The implementation phase will focus on the importance of process improvement, identifying suitable leaders to assist with communicating documentation practices, and using quality-related tools and techniques for best practice IQA to become part of routine clinical practice. Project challenges are discussed in more detail in Section 6.

2.5. Project Outcomes

An appropriate and workable Framework for Internal Quality Assurance in the interpretative and morphological disciplines for the Australian setting that is in line with international best practice was developed and implementation is underway. The Framework has been approved by the RCPA Board of Directors and has been submitted to NPAAC for consideration of inclusion to become part of standards documentation. Project outcomes are discussed in more detail in Sections 5.6 – 5.8.
3. Scope

3.1. Purpose

To develop and establish an IQA Framework that is used to routinely review the morphology and interpretation of slides/cases and composition of an accurate, timely, complete and comprehensible report. The fundamental principle of the Framework that is workable and provides an early warning system of potential performance issues in laboratories.

The IQA Framework activities:

- Provide a workable, simple process to document achievable measurable internal quality activities
- Allow benchmarking in this area of morphological diagnostic pathology.
- Assist evaluate performance and drive improvement and provide a collaborative on-going professional practice process against key quality indicators.
- Provide opportunities for practice quality improvement of the morphological aspect within the Histopathology, Cytopathology, Haematology and Forensic Pathology service.
- Improve patient care and increase confidence in final diagnoses
- Identify good practice and areas for improvement
- Improve communication within and between institutions

3.2. Meeting QUPP Objectives:

The goal of the QUPP is to achieve improvement in health and economic outcomes for the use of pathology in health care, through the pursuit of better practice amongst requesters (or referrers) and providers of pathology service and knowledgeable and engaged consumers. This project addresses the Quality Use of Pathology Program “Quality Pathology Practice”, being to support professional practice standards that meet consumer and referrer needs and provide evidence-based, best practice, quality-assured services that are safe, cost effective and efficient.”

The Framework will be used to routinely review processes in the morphological and interpretative pathology disciplines and aligns with the QUPP objectives to:

- Facilitate improved laboratory practices by providing a mechanism for peer review;
- Introduce a mechanism for laboratories to benchmark their processes to measure improvements;
- Reduce the risk of aberrant/uninformative/false reports being issued in a clinical environment
- Thereby improving the quality of patient management and/or outcome

The Framework will assist in providing evidence where internal quality assurance is needed to improve practices, or where changes are required. The IQA Framework is patient centred to ensure the morphological and interpretative service is safe, displays best practice and that processes are efficient.
3.3. Project Exclusions

The project did not include how or where Fellows and trainees store their evidence of the activities performed under the Framework. The Project suggested this information could be stored within individual laboratory information systems, quality assurance database, diaries or simply in excel spreadsheets. Ideally, wherever this information is stored, it should be easily accessible by the Department Head/Medical Director, pathologist peer or quality officer when required for audit purposes.

4. Governance

4.1 Project structure

The overall governance of this project was provided by the RCPA, and was supported by the Steering Committee, which included representatives of morphological and interpretative disciplines of Histopathology, Cytopathology, Haematology, and Forensic Pathology, together with feedback from RCPA Fellows within these disciplines.

Figure 1 - Internal Quality Assurance in Morphological & Interpretative Disciplines Project Organisation Chart

The above organisational chart represents the structure of how the specific groups worked on this project. Members of the Steering Committee and the disciplines they represent are provided in Appendix A.

The members of the Steering Committee had six formal meetings mainly via teleconference, with some face to face meetings.

Dates of the Steering Committee meetings were as follows;

1. 7\textsuperscript{th} November 2013
2. 30\textsuperscript{th} January 2014
3. 20th March 2014  
4. 8th May 2014  
5. 20th June 2014  
6. 24th November 2014

An agenda for each meeting was sent prior to the meeting date. Minutes from these meetings were taken and distributed to members for review. The RCPA has copies of the Steering Committee minutes and other papers associated with these meetings. Copies of these documents are available from the RCPA Project Management Office on request.

The Chair of the Steering Committee and Project Officer met face to face on occasion, as well as emailing to ensure development of the Framework was reviewed accordingly.

Project updates were emailed in between scheduled steering committee meetings when information was needed to be shared or reminder items were required.

4.2 Project Milestones / Reporting Requirements for the project

The milestones were met for the Internal Quality in Morphological & Interpretative Disciplines Project as stated in the Standard Funding Agreement Schedule under Item F. There were three performance reports required, all of these have been submitted by the due date as stated in the payment schedule.

Deed of Variation 1 was executed in August 2014 to reflect the change of schedule for the Workshop. The Steering Committee agreed that the best use of the Workshop was to demonstrate the Framework once it had been initially tested and was in near final form, thus ensuring the confidence in, and “buy in” from, the thought leaders in the Morphological disciplines closer to the Pilot implementation phase. This change extended the Project from the 01 December 2014 to the 31 January 2015. The Draft Final report was initially due on 01 November 2014, but was varied under Deed of Variation 1 to the 05 January 2015. This change also moved the Final report to the 31 January 2015.

This variation also provided the opportunity to enhance the communication of the benefits of this Framework to a wider pathology audience, at the end of February 2015 at the RCPA Annual conference, “Pathology Update” in Melbourne.
5. Project Activity Details

5.1. Activity Work Plan for this project
An activity work plan was developed to ensure all requirements from the funding agreement were executed and achieved within the project timeline of 18 months (refer to Appendix B).

5.2. Findings from the Literature Review
The project officer conducted a literature review and gap-analysis of IQA programs for medical practice and specifically for the morphological disciplines in Australia and internationally, which provided information to develop the key objectives that form the foundation of the framework (refer to Attachment A - Literature Review, separate to this document).

Findings from the literature review indicated that improving systems and quality management through the use of quality principles and tools to establish benchmarks for practice, creates a robust approach. Monitoring each step in the Request-Test-Report cycle provides a more standardised structure for IQA to ensure there are adequate early warning signs of potential performance issues in laboratories at each stage in the process. Methods such as clinical audit and peer review are used to measure performance of these activities individually, or by group meetings within morphological and interpretative practice.

Quality Assurance

Quality assurance (QA) is not a new concept in pathology and QA activities have been practiced by individual laboratories in both private and public sectors at a variety of geographical settings for many years. However, there is evidence of variability in practice of these activities between laboratories and there is no formal standardised system in place throughout Australia to monitor these activities. Building on the existing local quality systems to establish a consistent framework enables each pathology department to monitor and evaluate their own performance against benchmarks in an effort to assure and improve patient safety.

Quality analyses are well-established in departments such as clinical biochemistry where numerical machine-generated data is obtained. In contrast, histopathology and other morphological laboratory processes where reports contain interpretations, explanations, evaluations of probability and clinical judgments are less easily quantified. Assessment and implementation of quality control in morphological disciplines is not easy as its output is largely qualitative rather than quantitative\(^1\).

A laboratory's technical performance can be assessed to determine where and how changes should be made, and greater focus on internal quality can raise awareness of the level of performance and changes required to lead to improvement.\(^2\)

A review of publications with quality assurance and quality improvement themes indicates the variety of approaches to quality assurance in healthcare. The most commonly reported types of quality assurance systems include;
- Peer review
- Audit and feedback

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\(^1\) Iyengar JN. Quality control in the histopathology laboratory: an overview with stress on the need for a structured national external quality assessment scheme. Indian J Pathol Microbiol 2009;52:1-5

\(^2\) Nakhleh RE. The United States’ approach to Quality Assurance in Surgical Pathology. CAP Vol 12 Issue 4
• Computerised monitoring systems
• Communication

A mixture of the above methods can be used to review quality assurance in the reporting process in a pathology laboratory.

Regardless of the exact quality assurance methods used, the most effective systems shared some common characteristics, including:

• Structured approach
• Regularity of review
• Proactive feedback and education
• Stakeholder buy-in and involvement
• A collaborative approach

Quality and performance indicators provide a quantitative, evidence-based foundation for clinicians, organisations, researchers, and health system planners to monitor and evaluate the functioning of professional and organisational systems.3

Quality measures and metrics can lead to performance improvements at system and provider levels. To increase clinician engagement in the quality agenda, emphasis is placed on the development of indicators that are meaningful to the providers, those that focus on what is being done well, and areas for improvement.4

The best performing health care organisations take local ownership of quality measurement, with involvement from the specialty areas in defining and improving against measures most relevant to the specialty. Even with standards identified, these measures will provide little added value unless they are addressed not only at the population level, but also at the regional and organisational levels.5 A framework approach to establish the baseline to build from to reduce the variation in the IQA methods across the spectrum of pathology laboratories is an appropriate approach in the Australian setting. As pathology is pivotal to health care, actively managing quality of pathology services contributes to avoiding compromised patient care and adverse health events.6

Australian Laboratory Standards

Within the Australian environment, the onus is on individual laboratories to adapt, establish, monitor and periodically review quality indicators for critical aspects of pre-examination, examination, and post-examination processes. The National Pathology Accreditation Advisory Council (NPAAC) plays a key role in ensuring the quality of pathology services in Australia. NPAAC are responsible for the development and maintenance of standards and guidelines for pathology practices. “Requirements for Medical Pathology Services (First Edition 2012)” is the overarching NPAAC document all national medical accredited pathology testing laboratories follow.

5 Mountford J, Shojania, K: Refocusing quality measurement to best support improvement: Local ownership of quality measurement by clinicians. BMJ Qual Safety. doi: 10.1136/bmjqs-2012-000859
These Requirements set the minimum standards acceptable for minimum pathology laboratory practice in Australia. The core requirements come from existing NPAAC publications, Australia Standard (AS) and from International Organisation for Standardisation (ISO) 15189, Medical laboratories- Requirements for quality and competence. The NPAAC document is referred to nationally to unify efforts to improve patient care, and specifies the quality management system requirements, in particular S3.1(b) refers to procedures for internal quality test procedures, including reference intervals, internal quality control, source and External Quality Assessment. Section 3.3 also specifies that “The operations of the Laboratory must be audited as part of the Quality System”. As detailed guidelines currently do not exist in Australia, the approach to date has been variable, and this limits the ability of the accreditation process to monitor compliance with the standard.

**Continuing Professional Development and Revalidation**

Australian medical practitioners engaged in any form of medical practice are required to participate regularly in CPD (Continuing Professional Development Registration Standards pursuant to the Health Practitioner Regulation National Law (2009)). CPD should be relevant to scope of practice in order to maintain, develop, update and enhance knowledge, skills and performance to ensure delivery of appropriate and safe care. CPD must include a range of activities to meet individual learning needs, including practice-based reflective elements, such as clinical audit, peer-review or performance appraisal, as well as participation in activities to enhance knowledge, such as courses, conferences and online learning. The RCPA CPD Program requires Fellows to undertake activities in three categories, which includes participation in group activities/meetings; personal study and quality activities. It is anticipated that participation in activities within the IQA Framework will meet CPD Category C requirement – Quality Activities.


A major challenge facing medical regulatory bodies around the world is how to ensure doctors practice safely and effectively beyond the traditional frameworks of CPD. “Revalidation” is a term that has been used by the General Medical Council (GMC) of the United Kingdom since the mid1990s, and it is closely aligned with the term “recertification”, used in the United States. The International Association of Medical Regulatory Authorities has defined revalidation as “...the process by which doctors have to regularly show that they are up to date, and fit to practice medicine.”

Revalidation in the UK contains some elements in common with the Australian approach to continuing medical education (CME) and continuing professional development (CPD). It also contains elements of peer-review and clinical audit activities. The Medical Board of Australia is currently undertaking a review of international best practice in revalidation and the outcomes of that review will not be known for some time. The Framework developed by this project, while important in terms of standard quality practice, is also likely to form an important part of the approach to revalidation processes for pathologists in the future.

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7 Medical Board of Australia. Continuing professional development registration standard. 2010
Other International findings from the literature review

**Canada** - A Program called *Standards 2 Quality (2009)* has been developed by collaboration between the Ontario Medical Association (OMA) on laboratory medicine and the Ontario Association of Pathologists supported by Cancer Care Ontario to monitor internal quality activities. The Program:

- Aims for best practice guidelines for quality management in surgical pathology professional practice
- Focuses on improving quality management systems that help guide the professional work of pathologists.
- Creates a Framework to look at quality management program components and makes suggestions for how these will be monitored.
- Creates standards or benchmarks against performance which are measured and compared with another group’s performance.

**United States of America (USA)** - The College of American Pathologists (CAP), has a model to monitor internal quality assurance provided by a program called, Q-Probes.

- Since 1989, the CAP has focussed on reducing medical errors and achieving and maintaining excellence by using Q-Probes which was the first major inter-institutional quality improvement evaluation program in anatomical pathology in America.
- Q-probes are part of a laboratory’s compliance for their Quality Management plan in order to comply with the CAP inspection checklist.
- Regulations in the USA require that departments of pathology have a structured and active program of quality assurance and a quality improvement plan.

Q-Probes is an external peer comparison program that addresses process-outcome-structure. It establishes benchmarks through external database comparisons and performance. A feature of Q-Probes is that it is a time comprehensive assessment of key processes in the lab which aim to:

- Build data
- Improve data
- Analyse processes
- Establish laboratory goals
- Improve performance

In the United States, recertification of pathologists takes the form of knowledge based assessment by means of examination.

**United Kingdom (UK)** – There is no equivalent to Q-Probes in the UK to monitor internal quality activities, however, the Royal College of Pathologists (RCPath) implemented a revalidation scheme as a means to address this in December 2012 which:

- Aims to assure patients and the public, employers and other healthcare professionals that licensed doctors are up to date and fit to practice.
- Involves a continuing evaluation of fitness to practise based on local systems of appraisal and clinical governance.

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• Requires at least one appraisal per year (core guidelines based on General Medical Council for doctors)
• Requires documentation to demonstrate how doctors are continuing to meet the requirements, including the following:
  o Qualifications, scope of work done in pathology (include lectures, management, research etc)
  o Annual appraisal by the employer (include development plans, progress objectives)
  o CPD Program
  o Review of practice, showing regular participation in evaluating and improving the quality of professional work
  o Quality improvement activity, such as clinical audit (national / personal and local)
  o Case review (evidence)
  o Clinical incidents / formal complaints
  o Feedback from clinical supervision

The UK also has an online clinical audit scheme, which is peer evaluated and associated with their CPD Program. For pathology, this is associated with the pilot of a ‘Key Performance Indicators in Pathology’ study which examines data collection, deriving national standards based on KPI targets.

Ireland – The Royal College of Physicians of Ireland (RCPI), has a National Quality Assurance Program in Histopathology which was launched in 2009. This is an initiative in enhancing patient safety with timely, complete pathology diagnoses and reports. The program aims to standardise QA systems, identify good practice and areas for improvement, improve communication within and amongst various laboratories, and instil in laboratories processes to collect and review their own performance against national targets. This is done by working through set guidelines and entering this information into a central repository for quality assurance data called the National Quality Assurance Intelligence System (NQAIS). This model is achieved in Ireland through a supported central quality assurance department. It focuses on key quality indicators such as:

• Correlations on certain cases
• Retrospective reviews
• Turnaround times
• Inter institutional consultations
• Intradepartmental consultations

New Zealand (NZ) - The NZ Ministry of Health’s publication Toward Clinical Excellence describes quality tools and processes that can be used by medical practitioners for the purposes of performance assessment. These are flexibly applied by the medical practitioner in order to develop their skills and to achieve ongoing improvement of clinical care.10

The NZ Medical Council has required recertification since 2001. In 2010 the Council described its approach as “supporting and promoting excellence and professionalism” and required attestation to 50 hours of CPD per year, including a clinical audit, 10 hours of peer review and 20 hours of continuing medical education.

A requirement for regular practice reviews (RPR) has also been added to the recertification process recently. Some key principles of regular practice reviews included in the NZ process are:

• It is a formative process

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• It is a supportive and collegial review of a doctor’s practice by peers, in a doctor’s usual practice setting
• Improves the existing high standard of the profession
• May assist in the identification of poor performance which may adversely affect patient care.

5.3. Framework Features and Content

The IQA Framework developed in this project divides activities that can be performed that reflect the three phases of the Request-Test-Report Pathology Cycle;

1. Pre-analytic phase of the test cycle is specimen delivery and accessioning, gross examination/ cut-up 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 Piloted Framework recorded these activities under two sections:

Section 1: Diagnostic Measures (the analytic phase) relates to peer review activities which requires participation of at least 10 hours per annum. This involves recording any case reviews performed and whether it was at a specific clinical meeting such as departmental case review meeting, random internal cases, specific case types or at multi-disciplinary team case presentations, etc. Documentation will include case/patient number and any type of discordance that may have been reviewed.

Section 2: Technical Laboratory Measures (the pre-analytic) & Service Performance (post analytic/overview) relate to clinical audit activities, requiring participation of at least 10 hours per annum. This part of the Framework focuses on internal quality relating to laboratory based non-conformances, specimen handling issues, report format audits and turnaround times.

The key quality activities used in the framework to monitor practice from these specific areas of pathology testing are ‘peer-review’ and ‘clinical audit’.

<table>
<thead>
<tr>
<th>Quality activity</th>
<th>Relates to which area in the framework</th>
<th>Data Collected By</th>
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<tbody>
<tr>
<td>Peer-review</td>
<td>Diagnostic measures</td>
<td>Documented in-house by the individual pathologist (mandated section)</td>
</tr>
<tr>
<td>Clinical audit</td>
<td>Technical Lab Measures &amp; Service Performance</td>
<td>RCPA QAP to potentially host the collection of laboratory based audits</td>
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Peer-review is “the evaluation of the work or performance of an individual by other people in the same field”\(^{11}\). The aim of peer review is to assist in the formulation of informed judgements about

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the professional practice of health care professionals, with the ultimate goal of identifying ways to improve and maintain quality of care\textsuperscript{12}. Peer review involves collection of information regarding the practice of a healthcare professional. This information is appraised by the professional’s peers, often against standards, performance indicators and / or outcome parameters. Professional judgment by a peer is seen as a valid method of making informed judgments on professional practice\textsuperscript{13}. A common element of peer review is performance assessment. Performance assessment can be defined as the evaluation of one or more elements of clinical practice against accepted standards of practice\textsuperscript{14 15}. A paper by Bhatia et al in 1998 indicates peer-review was successful in identifying errors in both procedural and technical pathology\textsuperscript{16}. The Piloted Framework contained quality monitors in the peer–review section to indicate how data should be collected, documented, reported and accessed. 

\textit{Clinical Audit} is "a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change"\textsuperscript{17}. Clinical audits are seen as an important tool in the clinical governance ‘tool kit’\textsuperscript{18}. Overall clinical audits provide a mechanism to:  
\begin{itemize}
  \item Seek to identify areas for service improvement
  \item Develop and carry out action plans to monitor or improve performance
  \item Aim for best practice and competence
\end{itemize}
Conducting regular clinical audit and peer reviews can reduce causes that may contribute to errors in laboratory processes.

This can be achieved by focusing quality improvement activities on factors that affect interpretative diagnostic accuracy and error including;

\begin{itemize}
  \item knowledge
  \item experience/training,
  \item standardisation of procedures
  \item terminology and clinical correlation
\end{itemize}
Sneddon et al (2006) provide an effective summary of the clinical audit purpose and process. Clinical audit is for them “… one of the main tools to establish whether the best evidence is being used in practice, as it compares actual practice to a standard of practice. Clinical audit identifies any


\textsuperscript{17} "www.nice.org.uk", Principles of Best Practice in Clinical Audit 2002.

gaps between what is done and what should be done, and rectifies any deficiencies in the actual processes of care.\textsuperscript{19}

There are many emerging roles for clinical audits, such as national healthcare quality standards (looking at system failures and suboptimal care, patient risk and harm, unwarranted variation in practice), clinician revalidation (assurance of minimum level of competence to safeguard patient safety) and disinvestment (reducing waste and minimising ineffective interventions)\textsuperscript{20}

Evidence that clinical audit and feedback improves professional practice and healthcare outcomes is documented in a Cochrane Database Systematic Review by Ivers et al\textsuperscript{21}, which indicates audit and feedback generally leads to potentially important improvements in professional practice. This paper looked at 140 randomised controlled trials and found that any intervention in which audit and feedback was a core feature, resulted in improvements over time in professional practice.

In developing the Piloted Framework, the Steering Committee proposed two requirements of the Framework for Fellows and Trainees within the morphological and interpretative disciplines:

- Active involvement in 20 hours per annum of internal quality activities from the Framework split between 10 hours from Section 1 (peer review), and 10 hours from Section 2 (clinical audit);
- A link to the RCPA CPD Program when the internal quality assurance activities undertaken by the Fellow/Trainee are within the Framework.

The key quality elements/categories for Section 1 [peer-review] and Section 2 [clinical audit] activities were:

<table>
<thead>
<tr>
<th>IQA Framework Section 1</th>
<th>IQA Framework Section 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inter-institutional consultation</td>
<td>Laboratory based non-conformances</td>
</tr>
<tr>
<td>Intradepartmental Consultation</td>
<td>Laboratory based External Quality Assessment</td>
</tr>
<tr>
<td>Correlation of frozen section diagnosis with final diagnosis</td>
<td>Turnaround Time</td>
</tr>
<tr>
<td>Cytology correlations</td>
<td>Addendum/ corrected reports</td>
</tr>
<tr>
<td>Retrospective Review (focused real time/report completeness)</td>
<td></td>
</tr>
<tr>
<td>Multidisciplinary Team Meetings</td>
<td></td>
</tr>
</tbody>
</table>

Elements included in the Framework contain IQA activities, which reflect different areas of competencies, quality management and overall quality improvement practice. Use of the Framework aims to detect problems with the interpretative aspects of the pathology practice at an earlier stage than may currently occur.


\textsuperscript{20} Scott I, Clinical audit,(Presentation). 2014 Aug

\textsuperscript{21} Ivers N\textsuperscript{1}, Jamtvedt G, Flottorp S, Young JM, Odgaard-Jensen J, French SD, O'Brien MA, Johansen M, Grimshaw J, Oxman AD. Audit and feedback: effects on professional practice and healthcare outcomes. Cochrane Database Syst Rev. 2012 Jun
The responsibility for establishing mechanisms for collecting and storing data on quality indicators for each activity performed resides locally with the laboratory was outside the scope of this Project, however possibilities include being stored within individual laboratory information systems, quality assurance databases or individually via an excel spread sheet. This information should be easily accessible by the Department Head/ Medical Director, individual pathologist or quality officer when required for audit or review. Each laboratory will be able to monitor its own quality assurance performance and compare it over time (in-house or nationally), once agreed benchmarks are established. This will enable laboratories to measure improvements in the quality of work relating to performance and competence. It is hoped that IQA modules will be developed via the RCPA Quality Assurance Programs (QAP), currently the major provider of External Quality Assurance Programs, to allow further simplified data collection both for individual use and, de-identified, for national and international benchmarking purposes.

5.4. Workshop for morphological pathologists and trainees

A Workshop was held on the 31st July 2014 for a number of RCPA Fellows who held leadership positions within morphological and interpretative diagnostic services in Australia and/or held a quality, and or leadership role associated with the College. A senior manager representing the RCPA QAP was also in attendance.

The Workshop provided Fellows with an update on the Draft proposed Framework and an opportunity to obtain feedback on the content and role the IQA framework would provide in on-going professional practice in the morphological disciplines. Prior to the Workshop background papers were distributed to the participants (refer to Appendix C).

Participants at the Workshop were positive and supportive of the Framework, agreeing implementation would most likely be achievable in their workplaces. Participants also agreed the Framework would provide benefits for new pathologists, suggesting these concepts be linked early in the training program to specifically target trainees and their supervisors.

5.5. Pilot program

A Pilot Program for the Draft proposed Framework model was a requirement of the Project. There was a request for Volunteer sites at the Workshop meeting to evaluate the adaptability of the Framework to various types of laboratories and to evaluate the content and overall feasibility of the Framework.

In undertaking the Pilot Program, the Project team sought to:

- Introduce a national stand-alone program that relates to IQA in the morphological and interpretative disciplines
- Test the feasibility of implementation of the Framework
- Obtain feedback on the content of the Framework
- Identify how activities performed from the Framework could be linked to the RCPA CPD Program and possibly form part of any Revalidation Framework the College may need to adopt in the future

The Pilot Program assessed the Draft proposed Framework in a variety of sites that reflected the many workplaces Fellows occupy, that is public, private, large or small laboratory sites. The Pilot was developed using the proposed internal quality activities and ‘tested’ feasibility, acceptability, and workability, of the Framework. The Framework was piloted around Australia in Histopathology, Cytopathology, Haematology and Forensic Pathology settings for a three month period between 25
August 2014 and 14 November 2014. The methodology and the results from the pilot program are detailed in Appendix D

Evaluation of the pilot program

The Framework was piloted at 25 sites, and 14 participants responded to the Pilot Program Survey. Overall the pilot demonstrated the Framework was workable.

Section 1: Diagnostic Measures (peer-review activities)

The data collected under Section 1 was performed in-house by the laboratory and includes activities such as: recording participant time taken and outcomes from peer-reviews.

The results from the Pilot revealed participation in some or all peer-review activities/meetings [Section 1] under the Framework, were dependent on the size of the laboratory, as some participants commented that 10 hours per annum could be difficult to achieve in a solo practice and smaller private labs. If the Framework becomes mandatory, smaller laboratories suggested they would need to discuss how to incorporate peer-review activities with departmental management to achieve the required time, however this was not considered to be an unreasonable requirement.

A formal response to this issue will be part of the implementation plan - that is to support Fellows in smaller labs and offer alternative networks for them so they are not disadvantaged.

Overall Section 1 was well received, and many Fellows in a large private or public laboratory indicated ability to meet the 10 hour per annum requirement, thus deeming Section 1 quite workable: for example, one Fellow reviewed 74 cases in Section 1 for the Pilot within the required Pilot timeframe via multi-disciplinary team case presentations, inter-institutional correlations - second opinions/incoming, internal correlations - frozen section-paraffin, internal case review - specific case types. Half of the respondents reviewed an average of 10-30 cases within the Pilot Program survey time.

A majority of comments received indicated Section 1 activities were relevant to Fellows’ every day clinical practice.

Section 2: Technical Measures & Service Performance (clinical audit activities):

Monitors in Section 2 were not routinely conducted at all sites, as the Draft proposed Framework contained mainly activities relating to Anatomical Pathology and some respondents felt that these activities were not relevant to their clinical practice but were more laboratory system related. Another contributing factor was that Section 2 activities were simply not captured within the laboratory setting, however respondents generally considered that these could be incorporated in the future.

Time was also a contributing factor for not completing Section 2 as some of the activities in the Pilot Program required laboratories to collect specific data where systems were not currently in place to facilitate this. One Anatomical Pathology respondent indicated that this would be possible once the specific activity was set up within their department, or if they had time personally to set up one of the Section 2 activities as a clinical audit topic for their own project. However due to staff shortages in the department at the same time as the pilot was conducted, this was not feasible.

Similarly a Haematology respondent created an alternate internal quality activity that could be used subsequently to the Pilot, however was not able to set it up within the required Pilot timeframe. Forensic Pathology focused on percentage of ‘replacement’ reports issued in this timeframe of the pilot, not amended reports due to the legal aspects applying within this area of pathology.
Some of indicators require further finessing (Haematology and Forensic Pathology) as a result of the decision to create discipline specific IQA Frameworks, using the shell Framework model. Further discussions with the Haematology and Forensic Pathology disciplines will be undertaken to address this.

The Pilot program also identified that departments will need to create or update policies for cases found to be discordant, as some respondents commented that there was no formal process for dealing with discordance. Other comments indicated that Fellows did not currently document all their IQA activities, but were doing some form of documentation at various times, which may be a direct result of time availability and workload.

Overall the Pilot Program was able to demonstrate the Framework was workable in the Australian laboratory context. It identified elements of the Framework requiring refinement and further support from the College to ensure that the implementation of the Framework will be successful in the morphological and interpretative disciplines. There was variability in practice of internal quality activities between laboratories, and this variability highlighted the need to develop benchmarking capabilities to guide laboratories in measuring improvements in processes.

The Pilot Program was able to validate the adequacy of Framework activities under Section 1 “Diagnostic Measures” however the College will seek to provide further input and examples of activities that can be undertaken to complete activities under Section 2 – “Technical Measures & Service Performance”. The completed survey results were disappointing for this Section and the Project Officer followed up all respondents who did not participate in activities under Section 2, and identified that time constraints and clarity around the activities required were the main contributors to non-participation.

The Pilot Program highlighted that particular assistance is warranted for the implementation of the Framework for regional laboratories, smaller isolated laboratories, and part-time pathologists to enable achieving participation of the required guideline of 20 hours per annum (that is minimum requirement for 10 hours from the ‘peer review’ section and 10 hours from the ‘other’ section).

The practical difficulty for smaller, rural laboratories is a key feature to be addressed in the implementation plan, and options to investigate could include the provision of practice visits from senior Fellows, structured network support via webinar (or similar), or development of suitable online tools.

5.6. Framework refinements/finalisation

Feedback from the Pilot Program lead to subsequent refinements of the Draft proposed Framework. Participants required better explanation of what was required and relevant for each discipline, rather than presenting a “one size fits all disciplines” Framework approach. The shell of the Framework model remained, however it was agreed each discipline specifically would have their own Framework so the activity requirements and examples suggested within the Framework were relevant and presented clearly presented. The refined IQA Framework developed for Anatomical Pathology is at Appendix E. Further refinement of some of the quality activities is required for Haematology and Forensic Pathology. Subsequent discipline specific Frameworks with discipline specific activities are being developed for clearer presentation of Section 2 requirements. However these results requiring refinement of Section 2 did not ultimately impact the feasibility, acceptability and workability of the Framework, and further education and promotion will address this initial deficiency.
The College proposes to work with the RCPA QAP in the near future to specifically target activities such as clinical audit and pre-analytical processes whereby data can be captured to assist with the development of benchmarks. Better implementation of Section 2 of the Framework will require the assistance of the RCPA QAP to develop a specific IQA module containing questions relating to the activities in this Section and possibly activities around peer review. It is possible that RCPA QAP will perform the data collection for this Section that is de-identified and can be subsequently used to develop benchmarks. Fellows and laboratory managers may then be able to receive reports with correlated data to assess comparative performance for these activities. This will be further investigated as part of the implementation phase.

5.8 Approval by the RCPA Board of Directors

The RCPA Board of Directors approved the IQA Framework to become a RCPA Guideline. The Guideline in principal states that Fellows within the morphological and interpretative disciplines to be Actively and individually involved in 20 hours per annum of internal quality activities from the Framework. Subsequent refinements of the Framework will be taken back to the Board for further approvals.

5.9 Benefits of the IQA Framework

The structure of the internal quality activities in the IQA Framework will direct and focus the pathologist to review and measure the processes of reporting cases. It is envisaged that a planned, systematic approach to implementing the IQA Framework will support and enable organisations/departments to successfully improve organisational effectiveness in best practice in morphological and interpretative reporting and improve patient safety and outcomes.

The IQA Framework will provide the mechanism for each discipline to identify and implement effective risk and quality management processes consistently. Implementing effective risk management and quality improvement programs where staff are keen to participate and share their experiences can provide networking and discussion with peers, which can help to identify problems and potential solutions to improve outcomes and reduce risk.

Continuous improvement and risk management are data driven, are dependent upon relevant information being provided to the executive, clinicians, managers and the governing body. The data and information provided should reflect the issues that are most significant, rather than just for the process of data and information collection itself.

The IQA Framework will provide risk management benefits for pathologists and laboratories which include:

- A tool for pathologists for selecting cases for second opinion;
- Clinical performance management and early intervention for individual practitioners
- Reduction and/or prevention in the number of critical incidents; which leads to
- Overall improvement in patient safety and improved risk management safety.

Use of the Framework will assist in providing ‘early warning signals’ of poor performance. Likewise the peer review activities allow laboratories to identify error patterns between individual pathologists, serving as a starting point for re-education or professional development activities. The collection of data over time will provide information to develop performance benchmarks amongst laboratories,
as well as in time (as data matures) national benchmarks. IQA activities are also an important tool to assist in standardising morphological protocols that may prevent unnecessary additional tests being performed. The IQA Framework offered a structured approach, which although likely to impact on the time spent and the cost associated with such procedures, are also likely to improve the existing quality standards.

The IQA Framework was developed in consultation with pathologists who will use it to improve their own practices and those within their laboratories and this peer consultation will be beneficial with driving acceptance and uptake. It is the view of the College and the Steering Committee that our Fellows will best benefit from an IQA Framework that has been designed based on evidence and understanding of the Australasian context and practises, rather than using tools developed in other overseas contexts. This approach will assist with ensuring a uniform Framework is implemented nationally that is transparent and transferable as the workforce moves between laboratory locations and types, resulting in better patient safety.

The IQA Framework should benefit new pathologists so they are introduced to these concepts early in their professional lives, and linked to trainees through their supervisors. In the near term, pathologists will be able to link these activities to their mandatory RCPA CPD Program activities which are used for registration and employment purposes. In the longer term, pathologists and practices will have the opportunity to monitor performance and be well placed to provide evidence of their ongoing competence to bodies such as AHPRA should revalidation be introduced in Australia. The information collected may be able to be used as part of EQA and accreditation activities and hence be of benefit to other pathology stakeholders such as NATA and NPAAC.
6. Challenges and Next Steps

The issues identified by the Project are detailed below; however these issues did not compromise the delivery of contracted obligations. An issue encountered in the Project was an inability to allocate pathologists’ fees, which were ultimately given *gratis*. The College has requested permission from the Department to reallocate these funds to assist with the implementation of the framework. A number of activities have been identified under “Next Steps” in Section 6.2, and the RCPA Board of Directors support a detailed implementation plan and also to expand the framework to involve other disciplines. The Department has subsequently supported this request, and work on the implementation phase has commenced.

The other main issue identified was the structure of the Framework. The IQA Framework consists of two Sections: Section 1: “Diagnostic Measures (Peer Review)” and Section 2: “Technical Measures & Service Performance” (Clinical audit). Section 2 focused on clinical audit activities and feedback from some respondents indicated the template for this section was too complex, and may not adequately represent the requirements of all individual disciplines, and subsequently a proportion of respondents did not complete this section.

The College acknowledged the need to address this deficiency, and agreed that the development of more discipline-specific lists of examples and will assist with providing participants with a greater level of useability. The revised Framework for Anatomical Pathology has been completed and work is underway to replicate this for Haematology and Forensic Pathology. Further work is still required, however the fact that this issue occurred does not mean that the elements of the “Technical Measures & Service Performance” Section are not valuable IQA tools (as demonstrated by the literature review) but reflects either their less widespread use by pathologists in Australia at this stage or their inability to document these activities due to the timing of the pilot. The implementation phase will involve education and support for pathologists in the use of these tools to facilitate uptake and greater usability.

Another ongoing challenge will be to educate pathologists and trainees in the importance of internal quality assurance in everyday practice, rather than an unstructured approach. The focus is on improving a process in the long term, and not handling procedures and process problems on an ad hoc basis when they occur. Process improvement will require leaders to ensure the culture of laboratories is one of support and encouragement providing the necessary resources of people, time and training.

The IQA Framework was developed into an RCPA Guideline, factoring in necessary refinements identified in the Pilot Program. The College will continue to seek feedback from Fellows to ensure its workability. The finalised Framework will be implemented in stages within the morphological and interpretative disciplines over the next twelve months.

The initial focus for implementation will be on the histopathology and cytopathology disciplines, as the College was reasonably satisfied with the results from the Pilot Project for these disciplines. Haematology and Forensic Pathology disciplines will undergo refinement of quality monitors, based upon feedback from the Pilot, before being deemed suitable for implementation. The staggered implementation will allow the College time to make any suitable adjustments for subsequent discipline development and roll-out.
A communication strategy will be developed to assist with the implementation and uptake of the IQA Framework amongst the Fellowship. This strategy will focus on promotional activities in the first instance, and will be followed up by more interactive uptake opportunities.

The first of these promotional activities will be to discuss the IQA Project and Framework at Pathology Update in February 2015. The Project Officer will be at the RCPA booth to demonstrate how to use the Framework. Fellows will be continually encouraged to provide feedback on their experience and to act as advocates within their own laboratories to increase uptake.

The RCPA will also publish the Project information on the RCPA website to ensure it is easily accessible to all Fellows. Pathology Today, the fortnightly College newsletter, will be used inform the Fellowship of the IQA Framework, and as a means of conveying new updates, tips etc to assist with implementation.

The Project Officer will identify discipline specific conferences within Australia, such as the International Academy of Pathologists (IAP) and Haematology Society of Australia and New Zealand (HAA) to attend to demonstrate the Framework and to inform the Fellowship of the IQA Framework requirements, and specifically how these link to RCPA CPD. In addition to attendance at conferences, a number of smaller, discipline specific workshops will be planned around a number of metropolitan cities and regional centres by state and area to rollout the Framework.

The College proposes to approach the RCPA QAP to initiate involvement in developing QAP programs that can be used with the IQA Framework to develop benchmarks for particular activities. This body of work will involve working closely with a number of key stakeholders within the RCPA QAP.

The RCPA Board of Directors endorsed the Framework in principle and is supportive of the implementation within the morphological and interpretative disciplines; however the Board also wants to broaden the Framework to include other disciplines. As there is not a current round of QUPP funding available, it has not yet been decided if the College will seek further funding for this expansion into other disciplines via a further grant application.
7. Conclusion

To achieve a standardised, fair internal quality assurance system a framework is needed to measure (by peer-review and clinical audit), document and record processes so as to meet and compare competencies between laboratories and pathologists.

An integrated coordination between technical and managerial activities along with highly skilled pathologists is essential for the continuous, unimpeded high quality, efficient and effective laboratory operations. This Framework will provide a mechanism which will help monitor changes for ongoing improvement in the interpretative and morphological disciplines.

The Framework encourages learning and sharing which are key drivers for quality improvement. It aims to assist in reducing unwarranted variation in diagnostic reports that have a morphological and interpretive component, and create an expectation of transparency throughout the laboratory with established measures of performance.

It is the view of the College and the Steering Committee that Fellows will benefit from a Framework that has been designed to provide evidence of practice and participation in a quality assurance system and fits within the Australian context and practice. The Framework meets the Project objectives as a warning system for potential errors in a pathology practice, and could also be suited to future requirements regarding the introduction of recertification/ revalidation into Australia as well as incorporation into accreditation processes via NPAAC standards.

The RCPA Board of Directors supported the IQA framework and the College plans to adapt the framework to incorporate the remaining pathology disciplines in the future.

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References


Breen K, Revalidation - what is the problem and what are the possible solutions? MJA 2014; 200 (3) Feb

College of American Pathologists


Nakhleh RE, Diagnostic error in pathology, Diag Histopathology.2013;Vol 19 Iss12:433-437


Royal College of Pathologists of Australasia (CPDP Program)

Royal College of Physicians of Ireland


Standards2Quality*: Guidelines for Quality Management in Surgical Pathology Professional Practices. A Proposal; for Laboratory Physicians in Ontario

The Royal College of Pathologists

The Royal College of Pathologists (website –Clinical effectiveness), Online scheme for certification of high quality audit. (Viewed document on website 10th July 2014)
Appendix A – Steering Committee

Associate Professor Adrienne Morey (Chair)
Anatomical Pathologist
Director of Anatomical Pathology, St Vincent’s Pathology NSW

Professor Jane Dahlstrom
Anatomical Pathologist
Senior Staff Specialist, ACT Pathology

Dr Stephen Fairy
Anatomical Pathologist
Douglass Hanly Moir Pathology NSW

Associate Professor Margaret Cummings
Cytopathologist
Pathology Queensland Royal Brisbane & Women’s Hospital QLD

Dr James Daly
Consultant Haematologist
QML Pathology QLD

Associate Professor Neil Langlois
Forensic Pathologist
Forensics SA

Dr Jeanne Tomlinson
Pathologist
QAP Representative

Project Team:

Dr Bronwen Ross
Deputy CEO, the Royal College of Pathologists of Australasia

Lynda Saunders
Project Officer, the Royal College of Pathologists of Australasia
This is the Activity Work Plan from the Royal College of Pathologists of Australasia (RCPA) to the Department of Health as required by the Funding Agreement for the development of the framework for the RCPA Internal Quality Assurance in Morphological and Interpretative Pathology Disciplines Project. **Activity Work Plan**

<table>
<thead>
<tr>
<th>Date due</th>
<th>Activity</th>
<th>Date completed</th>
</tr>
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<tbody>
<tr>
<td>23.08.2013</td>
<td>Set up Governance and Management for Project</td>
<td>20.08.2013</td>
</tr>
<tr>
<td></td>
<td>- Project Officer and Chair of the Steering Committee for the project</td>
<td></td>
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<tr>
<td>10.09.2013</td>
<td>Finalise appointment of Steering Committee members</td>
<td>10.09.2013</td>
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<tr>
<td>12.09.2013</td>
<td>Commence comprehensive literature review and gap-analysis to develop</td>
<td>25.11.2013</td>
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<td></td>
<td>potential areas for a framework for Internal Quality Assurance</td>
<td></td>
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<tr>
<td>01.10.2013</td>
<td>First Performance Report to Department of Health</td>
<td>01.10.2013</td>
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<tr>
<td></td>
<td>Accounts to submit invoice</td>
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<tr>
<td>28.10.2013</td>
<td>Organise and summarise the data collected from Australia and internationally resulting from the literature review and gap-analysis in readiness for the Steering Committee to assess and consider (draft ver. 1)</td>
<td>28.10.2013</td>
</tr>
<tr>
<td>14.11.2013</td>
<td>First meeting of Steering Committee</td>
<td>07.11.2013</td>
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<tr>
<td></td>
<td>- Present literature review and gap-analysis and overall data findings on other pathology Colleges and Quality Assurance agencies here in Australia and internationally to the Steering Committee</td>
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<td></td>
<td>- Discuss and draft objectives, on potential areas for the framework agreed by the Steering Committee</td>
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<tr>
<td>19.12.2013</td>
<td>Project Officer and Chair of the Steering Committee meet to discuss the outcomes from the first Steering Committee meeting and progress of the project.</td>
<td>19.12.2013</td>
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<tr>
<td>30.01.2014</td>
<td>Second meeting of Steering Committee</td>
<td>30.01.2014</td>
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<td></td>
<td>- Review items that require revision in the framework</td>
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<td>- Discuss the proposed options of quality activities, and confirm the format the framework will be delivered</td>
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<td></td>
<td>- Discuss the workshop and develop a Communication Strategy for Fellows which will be used in the implementation of this framework</td>
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<tr>
<td>01.02.2014</td>
<td>Second Performance Report to Department of Health</td>
<td>31.01.2014</td>
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<tr>
<td></td>
<td>Accounts to submit invoice</td>
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<tr>
<td>28.02.2014</td>
<td>Project Officer to draft the</td>
<td>03.03.2014</td>
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<tr>
<td></td>
<td>- Potential tools and options that were agreed at the Second Steering Committee meeting, which will be presented at the Workshop to the RCPA Fellows attending</td>
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<tr>
<td></td>
<td>- Information/ fact sheets on the content &amp; format of the framework for the Internal Quality Assurance in Morphological and Interpretative Disciplines</td>
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<tr>
<td>Date</td>
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| 21.03.2014    | Third meeting of Steering Committee  
- Project update  
- Approve any revisions to the developing draft content in the framework before the workshop and Fact Sheets to be reviewed by Steering Committee                                           |
| 14.04.2014    | Call for Expression of Interest for Laboratories to be pilot sites for proposed program                                                                                                                                     |
| 15.04.2014    | Project Officer visits Canberra Hospital ACT                                                                                                                                                                          |
| 29.04.2014    | Project Officer visits DHM- NSW                                                                                                                                                                                             |
| 02.05.2014    | Pilot sites identified                                                                                                                                                                                                     |
| 08.05.2014    | Fourth meeting of Steering Committee  
- Project update                                                                                                                                                                                                                 |
| 12.05.2014    | Pilot Program Commences                                                                                                                                                                                                    |
| 19.05.2014    | Project Officer visits Forensics SA                                                                                                                                                                                           |
| 26.05.2014    | Project Officer visits SNP/QML/ Royal Brisbane & Women’s Hospital QLD                                                                                                                                                       |
| 01.06.2014    | Third Performance Report to Department of Health  
Accounts to submit invoice                                                                                                                                                                                                     |
| 20.06.2014    | Fifth meeting of Steering Committee  
- Project update                                                                                                                                                                                                                  |
| 27.06.2014    | Project Officer develops questionnaire in aide to obtain documented feedback from participants at the Workshop regarding the evaluation of current practice before the Pilot Program of the framework |
| 31.07.2014    | Workshop  
- Information presented on the proposed for the Internal Quality Assurance in Morphological & Interpretative Disciplines  
- Project discussed with Fellows to finalise the final content of the framework                                                                                                                                     |
| 15.08.2014    | Evaluation Survey / Pilot Program sent to Pilot sites                                                                                                                                                                           |
| 25.08.2014    | Pilot Program begins                                                                                                                                                                                                       |
| 29.09.2014    | Project Officer contacts Pilot sites for updates on any issues                                                                                                                                                               |
| 24.10.2014    | Sixth meeting of Steering Committee  
- Project Officer present findings from the Evaluation Surveys  
- Steering Committee review survey feedback from Fellows and pilot sites  
- Steering Committee evaluates content of framework, make changes as required  
- Committee approve final version of the framework in readiness to submit to the RCPA Board of Directors                                                                 |
| 14.11.2014    | Pilot Program Completed                                                                                                                                                                                                     |
| 19.11.2014    | Briefing paper prepared. Submit to the RCPA Board of Directors for update on framework project and consideration for Guideline                                                                                          |
| 24.11.2014    | Project Officer correlates Evaluation Surveys                                                                                                                                                                              |
| 19.12.2014    | - Final framework presented at the RCPA Board of Directors meeting for Guideline approval  
- Submission to NPAAC for development as a Standard                                                                                                                                                                         |
<p>| 05.01.2015    | Draft Final Report to Department of Health                                                                                                                                                                                  |
| 09.01.2015    | - Publication of framework on RCPA website                                                                                                                                                                                  |
| 02.03.15      |                                                                                                                                                                                                                           |</p>
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<tr>
<th>Date</th>
<th>Activity Description</th>
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<tr>
<td>30.01.2015</td>
<td>Final Report to Department of Health</td>
<td>30.01.15</td>
</tr>
<tr>
<td></td>
<td>Finance Dept to raise invoice</td>
<td></td>
</tr>
<tr>
<td>13.02.2015</td>
<td>External auditor to commence audit</td>
<td></td>
</tr>
<tr>
<td>16.02.2015</td>
<td>Prepare presentation information for the Pathology Update</td>
<td>20.02.2015</td>
</tr>
<tr>
<td></td>
<td>- Chair of steering committee and DCEO RCPA to review</td>
<td></td>
</tr>
<tr>
<td>27.02.2015</td>
<td>Pathology Update meeting – framework presentation</td>
<td>27.02.2015</td>
</tr>
<tr>
<td>06.03.2015</td>
<td>Final Financial Acquittal Report to Department of Health</td>
<td></td>
</tr>
</tbody>
</table>
Appendix C - Background Paper

PROPOSED DRAFT FOR THE INTERNAL QUALITY ASSURANCE FRAMEWORK
FOR DISCUSSION AT THE WORKSHOP

INTERNAL QUALITY ASSURANCE IN MORPHOLOGICAL AND
INTERPRETATIVE DISCIPLINES PROJECT

THE ROYAL COLLEGE OF PATHOLOGISTS OF AUSTRALASIA

JULY 2014
BACKGROUND
The 2002 Corrs Chambers Westgarth report into the Australian Laboratory Accreditation System identified the need for an early warning system for poor laboratory performance. The current accreditation system and external Quality Assurance programs largely focus on the technical aspects of laboratory performance, but have been unable to grapple with assessment of the diagnostic performance of the pathologists in the morphological and the interpretative disciplines, such as Anatomical Pathology, Cytopathology, Haematology and Forensics. Standards currently mandate that Internal Quality Assurance activities are undertaken, but there is limited detail on how they should be performed in regard to morphological diagnosis. The Royal College of Pathologists of Australasia (RCPA) sought funding through the Department of Health, under a Quality Use of Pathology Program (QUPP) initiative to develop a comprehensive framework for internal quality assurance, focused on the Histopathology, Cytopathology, Haematology and Forensic disciplines for their interpretative and morphological processes involved in pathology diagnosis.

AIM
The aim of this project is to establish a national internal quality assurance framework that ensures patient safety and care with timely, accurate and complete pathology diagnosis and reports. The draft framework contains key elements of quality management, focusing on internal quality assurance (IQA) activities, which reflect different areas of competencies. This system will aim to detect problems with the interpretative aspects of the practice at an earlier stage than may currently occur.
IQA activities should be undertaken in parallel with participation in appropriate external quality assurance (EQA). Recently, the RCPA Board of Education and Assessment (BEA) and Board of Professional Practice and Quality (BPPQ) have indicated support for a move to individual enrolment in appropriate EQA modules, although this aspect does not form part of the framework under discussion. EQA activities should be appropriately documented.
It is acknowledged that many pathology laboratories will already have in place policies and procedures that satisfy some of the recommendations of this document. There is no suggestion that they modify these practices, if the key elements outlined in this draft framework are being accomplished and recorded in some other manner. In contrast, it may be that some laboratories do not have in place policies and procedures to participate in some of the internal quality assurance activities being recommended. In this case there will be a small amount of planning within individual departments to align with these required activities under the framework.

The draft framework includes a suite of options for pathologists to participate in with a focus on peer-review and clinical audit, and requires documented evidence of a pathologist’s involvement in these internal quality activities. The draft framework is practice based and provides internal quality assurance mechanisms for the individual pathologist when undertaken in a collaborative and transparent manner. It is accepted that different laboratories will have different requirements and approaches to IQA, and that the one size fits all approach may not be feasible.
This document describes a number of quality management components and makes suggestions for how those areas should be monitored. The final agreed framework will be used to review performance and drive improvement in the various processes of developing pathology reports.
A component of the framework is clinical audit. In the UK the Royal College of Pathologists have a document called, ‘Scheme for Certification’. It outlines criteria for a high quality clinical audit and explains the benefits of them. The guidelines state that a good clinical audit contains a set of criteria that consists of; acceptable rationale, conducted against agreed standards, appropriate sample size
and selection, appropriate analysis and interpretation, identification and implementation of any changes required, re-audit stage/cycle and outcome.

The content of the framework, the quality activities proposed and suggested document requirements are listed on page 9-10. These quality activities will be linked in some way to the RCPA Continuing Professional Development Program (CPDP). The current Category C: Quality Activities section of the CPDP may be extracted and combined with this framework to create a new tool (yet to be named) that may provide a solution for the need to create a Revalidation pathway. Specific codes for the internal quality assurance (description) activities within the framework are to be confirmed. Page 11-14 contains a list of quality monitors with key indicators within the draft framework and how the activities are recorded, as well as references that support these recommendations. For further information on definitions for quality activity monitors see the end of this document, Appendix 1.

PROJECT OBJECTIVES

The key objectives of this project are:
1. Creation of draft framework
1.2 Development of a communications strategy for the framework
1.3 Presentation of the draft framework to RCPA Fellows for discussion, feedback and further recommendations
1.4 Pilots of the proposed model in a number of laboratories
1.5 Evaluation of the pilot study
1.6 Steering Committee to review pilot study outcomes and make changes to the framework as/if required
1.7 Presentation to the RCPA Board of Directors for approval as a Guideline document (in line with CPDP requirements)
1.8 Liaison with NPAAC regarding appropriate modification of standards

GOVERNANCE

The overall governance of this project is provided by the Steering Committee and the RCPA College, together with feedback from RCPA Fellows.

Project Steering Committee:
Associate Professor Adrienne Morey (Chair)
Anatomical Pathologist
Director of Anatomical Pathology, St Vincent’s Pathology NSW
Professor Jane Dahlstrom
Anatomical Pathologist
Senior Staff Specialist, ACT Pathology
Dr Stephen Fairy
Anatomical Pathologist
Douglass Hanly Moir Pathology NSW
Associate Professor Margaret Cummings
Cytopathologist
Pathology Queensland Royal Brisbane & Women’s Hospital QLD
Dr James Daly
Consultant Haematologist
QML Pathology QLD
Dr Neil Langlois
Forensic Pathologist
Forensics SA
Quality Assurance

Quality assurance (QA) in is not a new concept in Pathology and QA activities have been practiced by individual laboratories in both private and public sectors and a variety of geographical settings for many years. However, there is evidence of variability in practice of these activities between laboratories and there is no formal standardised system in place throughout Australia to monitor these activities. Building on the existing local quality systems to establish a consistent framework enables each pathology department to monitor and evaluate their own performance against benchmarks in an effort to assure and improve patient safety.

Improving quality systems and quality management by using principles from evidence-based medicine creates a more robust approach to a pathology reporting that will encompass the many processes within the laboratory. Monitoring each step in the Request-Test-Report cycle provides a more standardised structure for internal quality assurance which will ensure there are adequate early warning signs of potential performance issues in laboratories.

A comprehensive review of information on the current practices in place in Australia and internationally formed the foundation for the development of the set of objectives for the proposed draft framework. This information was further developed by the Steering Committee. The workshop aim is to present the draft framework for consideration and refinement as/if required with a key group of RCPA Fellows.

The National Pathology Accreditation Advisory Council (NPAAC) documents (Requirements) set the minimum standards acceptable for good pathology laboratory practice in Australia. The requirements for the competence of medical laboratories are described in ISO 15189:2012, Medical laboratories—Particular requirements for quality and competence. The standard for internal quality assurance is quite general and it states….”The laboratory shall design quality control procedures that verify the attainment of the intended quality of results”.

………….”The laboratory must establish, monitor and periodically review quality indicators for critical aspects of pre-examination, examination, and post-examination processes”. While ISO 15189 has a requirement for Internal Quality Assurance activities to be undertaken, the approach to date has been variable. The standards do not currently address the necessity for internal quality assurance and performance monitoring in the morphological and interpretative disciplines.

The Draft Framework

The draft framework provides guidance to pathologists for the implementation of the Internal Quality Assurance in Histopathology Cytopathology, Haematology, and Forensic disciplines by defining key quality activities and associated key quality indicators that should be monitored by these departments.
These quality assurance activities are practical, focus on the work of the pathologist and relate to improving patient care. Data collecting on quality indicators, identified for each activity is performed locally by the laboratory. This information may be stored within individual laboratory information systems, quality assurance database or simply in an excel spreadsheet. This information should be easily accessible by the Department Head/ Medical Director, pathologist or quality officer when required for audit or review.

Each laboratory will be able to monitor its own quality assurance performance and compare it over time (in-house or nationally), once agreed benchmarks are set to improve the quality of work relating to performance and competence. Such benchmarks would be de-identified for comparison purposes.

Quality activities outlined in this draft framework will be linked in some way to the RCPA CPD Program, combining with the Quality Activities section of CPDP to create a new entity/pathway suited to possible future requirements regarding the introduction of recertification/ revalidation into Australia.

The College has recognised significant changes in the regulatory environment and acknowledges that recertification may at some stage become formalised requirement for Fellows in Australia and New Zealand.

In the United States, recertification takes the form of knowledge based assessment by means of examination. In the United Kingdom (UK) they are taking a more global view of performance assessment, believing that actual practice is more important than what might be demonstrated in the examination option. It is more likely that Australia and New Zealand will follow a model similar to the UK, where demonstrating appropriate performance is the fundamental principle of the recertification process.

It is the view of the College and the Steering Committee that our Fellows would best benefit from a framework that is designed based on evidence and understanding of the Australasian context and practises, rather than potentially being imposed by regulation.

The New Zealand Medical Council has required recertification since 2001. In 2010 the Council described its approach as “supporting and promoting excellence and professionalism” and required attestation to 50 hours of CPD per year, including a clinical audit, 10 hours of peer review and 20 hours of continuing medical education.
A requirement for regular practice reviews (RPR) has also been added to the recertification process recently, some key principles of regular practice reviews included in the NZ process are;
  • It is a formative process
  • It is a supportive and collegial review of a doctor’s practice by peers, in a doctor’s usual practice setting
  • Improves the existing high standard of the profession
  • May assist in the identification of poor performance which may adversely affect patient care

There is a level of controversy and debate over the best method for revalidation, presupposing the purpose is to detect underperforming doctors to enable remediation. In an MJA article by Dr Kerry
Breen published in February 2015, it states, “there are good reasons to argue that existing processes and databases should be used to determine more accurately what the weaknesses in Australia’s medical regulatory regime are and to tailor improvements to those weaknesses”.

It has been agreed by Murphy et al (BMJ Qual Saf 2012; 21: 649-656) that individual performance limitations can be identified by the measurement of ‘insightful practice’. The role of ‘insightful practice’ is to act as the centre or hub within a continuous cycle to generate, monitor and maintain evidence of personal accountability and responsibility for quality improvement. This insight into your own practice helps individuals build, collect and reflect within these actions or set activities to independently verify outcomes for professional improvement.

Demonstration of the use of these internal quality tools along with general information (qualification, scope of practice, CEPD fulfilment) and enrolment in appropriate external QAP program modules could ultimately form the basis of a credentialing/revalidation process, although the design of such a process is not the aim of the current project.

It is BEA policy that we should move toward individual enrolment in EQA modules pertinent to our area of practice, although it is acknowledged that transparency and fairness must be assured with respect to case selection and assessment of non-concordances if the scheme is to be a useful tool for individual performance assessment. Technical issues with image quality and data-entry software also need to be addressed. [Not part of this IQA framework, but the RCPA QAP is aware and will be reviewing]

**Framework Features**

The Internal Quality Assurance framework divides activities into 3 specific cycles: pre-analytic, analytic and post-analytic.

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

*Pre-analytic* phase of the test cycle is specimen delivery and accessioning, gross examination/cut-up and laboratory technical processing.

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

Performing peer-review activities, clinical audits and participation in accredited/approved External Quality Assurance Programs, The framework sections below are quality improvement processes that reflect the above phases.

(A) Diagnostic Measures (the analytic phase)

(B) Technical Laboratory Measures (the pre-analytic)

(C) Service Performance (post analytic/overview)
**FRAMEWORK: INTERNAL QUALITY ASSURANCE ACTIVITIES**

### (A) DIAGNOSTIC MEASURES (relates specifically to the pathologist)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Quality activity monitor related to your discipline</th>
<th>Discipline</th>
<th>Suggested document requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Case Reviews</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Using clinical audit techniques</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>(A) Internal random case review</strong></td>
<td>Internal random case review - Defined % of cases</td>
<td>All</td>
<td>Document the review type - Who performed the review - What was reviewed - What cases were reviewed - ~ Time it took</td>
</tr>
<tr>
<td><strong>(B) Internal target case review</strong></td>
<td>Internal target case review - Specific case types</td>
<td>All</td>
<td></td>
</tr>
</tbody>
</table>
| **(C) Internal correlations** | Internal correlations  
   i) Frozen section – paraffin  
   ii) Non gynae cytology – histology  
   iii) Bone Marrow aspirate - trephine  
   iv) Other | Histo Cyto Haem | Structure discordance as;  
   - None (agreement)  
   - Minor/ typo error  
   - Minor discordance/ no effect on patient care  
   - Major discordance/ potential impact on patient care |
| **(D) Inter institutional correlations** | Inter institutional correlations - 2nd opinions (incoming and outgoing) | All | |
| **(E) Intradepartmental correlations** | Intradepartmental correlations  
   - Formal 2nd opinions  
   - Informal 2nd opinions | All | |
| **(F) Multi Disciplinary Team case presentations** | Multi Disciplinary Team case presentations  
   - Any discordant opinions | All | Document discordance  
   - None (agreement)  
   - Minor/ non clinical  
   - Minor/ clinical  
   - Major/ clinical |
| **(G) Audit of corrected/ amended reports** | Audit of corrected/ amended reports | All | |
| **(H) Compliance with / utilization of structured report templates** | Compliance with / utilization of structured report templates  
   - Other (where available) | All | |

**The MDT meetings are the responsibility of the individual laboratory, and are expected to be documented and records maintained with the above criteria mentioned. Record any disagreement which may arise between the original diagnostic report and the MDT review. Issue an addendum post MDT if required and follow-up according to your individual laboratory policy for such incidents. Each laboratory must have documented processes for handling diagnostic discordances when detected.**

**Correlation results:**  
Agreement – represents frozen section/ histopathology/ cytology/ BM cases where all present agree with the report.  
Deferral rate- represents the cases where frozen section diagnosis was deferred until final diagnosis was reached on paraffin sections.  
Minor disagreement/ discordance- represents where there is a small change in diagnosis but there is minimal or no clinical impact.  
Major disagreement/ discordance- represents a significant difference between original diagnosis and the final diagnosis where potentially there is a significant impact on a patient’s treatment or outcome.
### FRAMEWORK: INTERNAL QUALITY ASSURANCE ACTIVITIES

#### (B) TECHNICAL MEASURES: laboratory based non-conformances

<table>
<thead>
<tr>
<th>Activity</th>
<th>Examples of quality monitors related to lab based non-conformances</th>
<th>Discipline</th>
<th>Suggested document Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-conformance reporting</strong></td>
<td>Specimen receipt issues**</td>
<td>All</td>
<td>- Incidence +/- % of non-conformances</td>
</tr>
<tr>
<td></td>
<td>- Incorrect identifiers</td>
<td></td>
<td>**Laboratories must have policies for handling detected non-conformances</td>
</tr>
<tr>
<td></td>
<td>- Labelling errors</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Lost specimens</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Specimen handling issues</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>e.g. - Cut-up</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Laboratory technique issues</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>e.g. - Embedding</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Cutting</td>
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<tr>
<td></td>
<td>- Staining</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Special stains</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Frozen section TAT</td>
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</tbody>
</table>

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.

Data collection of audits of this type will be hosted by the RCPA QAP as part of the laboratory “technical” module to allow benchmarking between laboratories.

### FRAMEWORK: INTERNAL QUALITY ASSURANCE ACTIVITIES

#### (C) SERVICE PERFORMANCE: activities that you should currently monitor in-house

<table>
<thead>
<tr>
<th>Activity</th>
<th>Examples of quality monitor</th>
<th>Discipline</th>
<th>Suggested document Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Audit of Service Performance</strong></td>
<td>Turn Around Times**</td>
<td>All</td>
<td>Documentation of TAT</td>
</tr>
<tr>
<td></td>
<td>- Whole workload or</td>
<td></td>
<td>- Overall</td>
</tr>
<tr>
<td></td>
<td>- Selected case type</td>
<td></td>
<td>- Different phases of reporting process</td>
</tr>
<tr>
<td>** For Histology consider criteria from either current ACHS or the UK RCPATh criteria or RCPA recommendations</td>
<td></td>
<td>- By different case types</td>
<td></td>
</tr>
<tr>
<td></td>
<td>** Forensics to advise suggested indicator Report format review</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Typographical/ transcript errors</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- SNOMED coding</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Billing Errors</td>
<td></td>
<td>% Errors concluding check</td>
</tr>
</tbody>
</table>

The goal is collecting acceptable data to develop benchmarks for the future to compare nationally, hosted by the RCPA –QAP technical module. (presented as de-identified information, similar format to the RCPA-QAP are already doing with their results)
<table>
<thead>
<tr>
<th>Quality Activity Monitor</th>
<th>Discipline</th>
<th>Key Quality Indicators</th>
<th>References (supporting evidence)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(C i) Frozen Section / Paraffin Correlation</td>
<td>Histology</td>
<td>Number of cases reviewed</td>
<td>Correlation results</td>
</tr>
<tr>
<td>---</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>(C ii) Non Gynae Cytology/ Histology Correlation</th>
<th>Histology Cytology</th>
<th>Number of cases reviewed</th>
<th>Correlation results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(E) Intradepartmental Consultation</td>
<td>All</td>
<td>% Total of cases reviewed</td>
<td>Association of Directors of Anatomic and Surgical Pathology. Recommendations for Quality Assurance and Improvement in...</td>
</tr>
<tr>
<td>(F) MDT meetings with Clinical Teams</td>
<td>All</td>
<td>Surgical and Autopsy Pathology. <em>Am J Clin Pathol.</em> 2006;126:337-340.</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>-----</td>
<td>------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>All</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(H) Compliance with use of Structured Reports</td>
<td>Histology</td>
<td>Cancer resections shall be reported using a template or proforma</td>
<td>RCPath KPI Proposals doc. 2013 July; KPI 5.2 Cellular pathology reporting of cancer resections</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>----------</td>
<td>---------------------------------------------------------------</td>
<td>------------------------------------------------------------------</td>
</tr>
<tr>
<td>Laboratory Non conformance reporting Lab service reporting</td>
<td>All</td>
<td>All non-conformances</td>
<td>National Pathology Accreditation Advisory Council (NPAAC). Requirements for Quality Management in Medical Laboratories (2007 Edition)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>National Pathology Accreditation Advisory Council (NPAAC). Requirements for Medical Pathology Services (First Edition 2013)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>RCPath KPI Proposals; 2013</td>
</tr>
</tbody>
</table>
Other jurisdictions have used a subset of these KPI's.

As previously mentioned, local protocol will determine how this framework is adapted but it is recommended that systems are developed to correlate with the required quality activity monitors outlined.

Developing this draft framework provides opportunity for better measures to detect problems early within laboratories as well as monitor any performance issues that may be occurring. This framework will potentially create a positive discussion forum to promote shared learning's, exchange ideas and introduce uniformity. It will also drive improvement in interpretative practices leading to a higher standard in pathology reporting.

It is suggested that some form of peer review audit activity is mandatory for all morphological pathologists (NZ requires 10 hours per annum minimum). Selection of other audit activities would be dependent on the requirements / practice profile of the different laboratories.

It is anticipated that the RCPA QAP may assist in hosting the collection of data on laboratory based audits, but not data on individual peer review.

Overall, the framework for internal quality assurance encompasses a wide range of options including clinical audits, peer review activities and systems review.
References:

Barnes I, Pathology Quality Assurance Review 2014

Breen K, Revalidation - what is the problem and what are the possible solutions? *MJA* 2014; 200 (3) Feb

College of American Pathologists


Royal College of Pathologists of Australasia (CPDP Program)

Royal College of Physicians of Ireland

Standards2Quality*- Guidelines for Quality Management in Surgical Pathology Professional Practices. A Proposal; for Laboratory Physicians in Ontario

The Royal College of Pathologists

The Royal College of Pathologists (website –Clinical effectiveness), *Online scheme for certification of high quality audit*. (Viewed document on website 10th July 2014)

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Addendum/Supplementary Report</td>
<td>Amended/Corrected report - is issued when the final report diagnosis changes. The reason for the issue of amended reports should be documented and reviewed in-house via clinical audit. Supplementary/Addendum report - is issued when new information becomes available after the final report has been submitted e.g. immunohistochemistry or molecular results.</td>
</tr>
<tr>
<td>Competence</td>
<td>The ability to do what we have been trained to do. That is; competence encompasses what we have learned and what we are able to do. This involves acquiring and maintaining clinical, technical knowledge, and skills.</td>
</tr>
<tr>
<td>Correlation</td>
<td>Correlation can involve separate interpretations on the same specimen or initial and subsequent specimens from the same patient.</td>
</tr>
<tr>
<td>External review</td>
<td>Requested by a pathologist (not the original reporting pathologist), clinician or patient for case review by another pathologist external to the original reporting pathologist.</td>
</tr>
<tr>
<td>Internal audit</td>
<td>A review of results or cases within a laboratory.</td>
</tr>
<tr>
<td>Interpretation</td>
<td>A professional diagnosis or opinion</td>
</tr>
<tr>
<td>Interdepartmental consultation</td>
<td>Case review providing an additional diagnostic opinion for evaluating diagnostic accuracy by the original reporting pathologist or department. A useful peer review process when there is diagnostic uncertainty by the original pathologist. Or if a regional lab where a pathologist arranges for assistance to meet the framework requirements.</td>
</tr>
<tr>
<td>Intradepartmental consultation</td>
<td>Is when a pathologist seeks a second opinion from another pathologist within their own department, or company network. If the second opinion is not stated in the original report, documentation in house must occur, within the laboratory information system or per department protocol.</td>
</tr>
<tr>
<td>Laboratory based non-conformances</td>
<td>Is a lab incident that has the potential to cause harm to the analysis of the specimen being diagnosed by the pathologist within the pathology test cycle.</td>
</tr>
<tr>
<td>Performance</td>
<td>Is what actually is done day-to-day practice. Performance depends on the level of competence; however it is also influenced by individual and system-related factors within the laboratory.</td>
</tr>
<tr>
<td>Clinical audit</td>
<td>A quality improvement process that seeks to improve patient care and outcomes through systematic review.</td>
</tr>
<tr>
<td>Peer review</td>
<td>A case reviewed by another pathologist/s within the same practice, or nominated ‘expert’ in a specific area. Peer review is one of numerous performance measures and quality and safety strategies which can be undertaken alone, or as part of a wider framework.</td>
</tr>
<tr>
<td>Turn-around time (TAT)</td>
<td>Usually measured from the time the lab receives the specimen to the time the final report is authorised.</td>
</tr>
</tbody>
</table>
Appendix D: Pilot Program Survey Summary

IQA Pilot Program
Survey Report

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1  Introduction................................................................................................................. 2
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3  Survey results...........................................................................................................5-10
4  Issues Arising from the Project Pilot Program......................................................11-12
5  Next Steps...............................................................................................................13-14
6  Conclusions.............................................................................................................15
1. Introduction

Under the Quality Use of Pathology Program grant for the *Internal Quality Assurance (IQA) in Morphological and Interpretative Pathology Disciplines* project it stated that a Pilot Program for the proposed framework model is required in laboratories (pilot sites). The purpose for the pilot study was to assess feasibility, acceptability, and reliability in adapting the framework to the various public and private laboratories around Australia using quality assurance tools- peer-review and clinical audit.

The pilot program was designed explaining the content, indicating types of case reviews and quality activities to participate in from the framework, and the duration of the pilot program. It also required participant to document their findings locally.

The objectives of the pilot was for pathologists at pilot sites to document their involvement in IQA, record the activities required in each section of the pilot program and provide evidence of this involvement (if required). Pathologists were asked to record this information locally via their normal methods such as, log book, excel spreadsheet etc. There were two sections within this pilot; ‘peer review’ and the ‘other’ quality activities section, each having a 2.5 hour requirement of participation time.
2. **Methodology**

The pilot program was designed by the Project Officer and Chair of the Project, with comments made by the project steering committee.

The pilot program participants were sourced from the IQA Workshop on the 31<sup>st</sup> July 2014. At the conclusion of the workshop meeting, pathologists were asked to be the pilot sites for the framework’s pilot program. The pathologists were from public and private laboratories representing disciplines in Histopathology, Cytopathology, Haematology and Forensic Pathology. 24 pathologists currently working in laboratories were present at the IQA Workshop meeting. The pathologists came from Victoria, New South Wales, South Australia, Western Australia, Queensland, Tasmania, the Australian Capital Territory, and New Zealand. The sites represented a combination of public and private laboratories, various scopes and size, as well as locations (metropolitan and regional).

Further to the pilot sites obtained from the Workshop meeting, an independent laboratory was contacted before the pilot started and was informed of this IQA project via phone and email. This site agreed to participate and provide feedback to the program as well via the survey. This site/pathologist did not attend the Workshop. This meant there were a total of 25 participating sites for this pilot.

The pathologists from the participating sites were emailed an instructional paper with framework details a week before the pilot program was to begin. This was to allow pathologists to contact the Project Officer, or project team if they could not participate or if any questions or clarification relating to the pilot program was needed before the pilot was to begin. Two pathologists made contact during this period with minor queries. No other pathologist made contact with the project team for further clarification, or to discuss any problems relating to the pilot program during this period.

The pilot program offered a suite of options to choose from allowing pilot sites to participate in the specific quality indicator that related to their size and scope of laboratory. There were two sections in the pilot program. Firstly, there was the ‘Diagnostic Measures’ (peer review) section where it was the pathologist’s option to choose what activities/case reviews they wished to record as having been involved with for the 2.5 hours. Pathologists were asked to document the review type, who performed the review, what cases were reviewed, time it took and findings such as discordances. The pilot survey did not collect the peer-review data from the quality activities/indicators that each pathologist completed. This information was recorded individually within their own laboratories.

Secondly, there was the ‘Technical Measures & Service Performance’ section (using clinical audit as the quality tool) where there were four quality monitors to choose from relating to each discipline, which required documenting the quality monitor chosen. This was to demonstrate examples of the type of clinical audit that could be performed in the future from this section of the framework. The aim of this section is to display the types of activities that will be sought and the data that is hoped to be captured.

Once the two sections of the pilot program with the specific quality activities were completed by the individual pathologist from the pilot site, they recorded their results as per their normal procedure when documenting their Continuing Professional Development Program (CPDP) activities.

The pilot program started on the 25<sup>th</sup> August 2014 and concluded on the 14<sup>th</sup> November 2014 giving time for sites to participate and obtain the required 2.5 hours for each of the ‘peer-review’ and ‘other’ sections of the pilot.
To obtain feedback from the pilot program a survey relating to framework user experience was
developed and conducted by the Project Officer. Question design and input was sort from the
General Manager, Innovation & Development at the RCPA QAP, the Chair of the IQA project and
the Director of Education and Accreditation at the RCPA who help ensure the survey worked and
questions were designed to obtain ultimate feedback from the program. To gather this feedback
participants were sent an email on the 13th November 2014 with a link to the survey and were
given up to four weeks to submit their responses.

There were a total of 22 questions in the survey. The online survey was constructed using
Survey Monkey (http://www.surveymonkey.com/). Participant did not have to answer all of these
questions as the survey design had skip-logic. Skip-logic is a feature that changes what question
or page a respondent sees next based on how they answer the current question. The survey
(taking no more than 10 minutes to complete) asked the respondents questions on their quality
activity findings, the process related to peer-review and clinical audit, difficulty in achieving the
required hours for each section, experience with discordance and any further comments, or
suggestions relating to the content of the framework.

Individual responses were confidential to the project team, and respondents were not obliged to
supply any information that they believed may identify them, it was thought this may encourage
open feedback in the comments section at the end of the survey.

This pilot program represented 25% of the proposed 20 hours per annum (that is 10 hours from
the ‘peer review’ section and 10 hours from the ‘other’ section) which is the minimum requirement
for the complete model of the Internal Quality Assurance in Morphological & Interpretative
Disciplines Framework.
3. Survey Results

The survey was sent to the 25 morphological and interpretative Fellows who indicated their interest in participating in the pilot.

Total number of Fellows = 25
Total number of surveys sent to Fellows = 25
Total number of responses received from this survey = 14.

Questions and responses from the survey:-
Section One: Peer review

Q1. Did you complete the required 2.5 hours?

Yes = 9
No = 5

Total answers = 14

Q2. What prevented you from completing the required 2.5 hours?

Respondents answered this question = 4
Respondents skipped this question = 10

<table>
<thead>
<tr>
<th>Answer Choices</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Too many other commitments</td>
<td>1</td>
</tr>
<tr>
<td>Did not understand the requirements</td>
<td>1</td>
</tr>
<tr>
<td>Did not find it worthwhile</td>
<td>0</td>
</tr>
<tr>
<td>Forgot about it</td>
<td>0</td>
</tr>
<tr>
<td>Was on leave at the time</td>
<td>0</td>
</tr>
<tr>
<td><strong>Other (please specify)</strong></td>
<td>2</td>
</tr>
</tbody>
</table>

The **other responses were stated as follows;

- ‘Am now working 7.6 hours per week and no time has been available for working on this’
- ‘I was not allocated enough cases to take me long enough to take up 2.5 hours. I was allocated less than 10 cases’

Q3. For the 2.5 hour diagnostic case review, please state the number of cases reviewed.

Respondents answered this question = 8
Respondents skipped this question = 6

<table>
<thead>
<tr>
<th>Answer Choices</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 10 cases</td>
<td>2</td>
</tr>
<tr>
<td>10 - 19 cases</td>
<td>0</td>
</tr>
<tr>
<td>20 - 29 cases</td>
<td>3</td>
</tr>
<tr>
<td>30 - 39 cases</td>
<td>0</td>
</tr>
<tr>
<td>40 - 49 cases</td>
<td>1</td>
</tr>
<tr>
<td>50 or more cases</td>
<td>2</td>
</tr>
</tbody>
</table>

If respondent indicated 50 or more cases they were asked to state the total number of cases reviewed, for these two responses case numbers were as follows;
**Q4.** For the diagnostic measures activities, from which quality monitor did you do your 2.5 hours? If more than one, please indicate.

- Respondents answered this question = 7
- Respondents skipped this question = 7

<table>
<thead>
<tr>
<th>Answer Choices</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal random case review</td>
<td>2</td>
</tr>
<tr>
<td>Internal case review - specific case types</td>
<td>3</td>
</tr>
<tr>
<td>Internal Correlations - frozen section-paraffin</td>
<td>4</td>
</tr>
<tr>
<td>Internal Correlations - non-gynae-histology</td>
<td>5</td>
</tr>
<tr>
<td>Internal Correlations - bone marrow aspirate-trephine</td>
<td>Not performed</td>
</tr>
<tr>
<td>Inter-institutional correlations - 2nd opinions/ incoming</td>
<td>Not performed</td>
</tr>
<tr>
<td>Inter-institutional correlations - 2nd opinions/ outgoing</td>
<td>Not performed</td>
</tr>
<tr>
<td>Multi-disciplinary Team case presentations</td>
<td>1</td>
</tr>
<tr>
<td>Audit of corrected/amended reports</td>
<td>Not performed</td>
</tr>
<tr>
<td>Compliance with the utilization of structured report templates</td>
<td>Not performed</td>
</tr>
<tr>
<td>* Other, please describe</td>
<td>6</td>
</tr>
</tbody>
</table>

The *other response = core biopsy review

* = activities performed were ranked for responses to this question, (1) being most common activity the respondents chose, down to (6), the least common activity.

Please note: respondents were allowed to elect more than one specific activity from the answer choices list to make up their 2.5 hours.

**Q5.** If you performed case reviews using compliance/utilization of structured report templates, please indicate the type(s) of template used.

- Respondents answered this question = 7
- Respondents skipped this question = 7

<table>
<thead>
<tr>
<th>Answer Choices</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not review these type of cases in the 2.5 hour requirement</td>
<td>5</td>
</tr>
<tr>
<td>All RCPA templates</td>
<td>1</td>
</tr>
<tr>
<td>Some RCPA templates, please specify</td>
<td>0</td>
</tr>
<tr>
<td>In-house department templates, please specify</td>
<td>1</td>
</tr>
<tr>
<td>Other, please specify</td>
<td>0</td>
</tr>
</tbody>
</table>

Comments made by respondents to this question:

- ‘These are based on RCPA templates’
- ‘No structured reports for bone marrow yet’
**Q6.** If any of the cases revealed discordance, please indicate the type(s) observed.

Respondents answered this question =8  
Respondents skipped this question =6

From the 8 respondents that answered they indicated the following

<table>
<thead>
<tr>
<th>Answer Choices</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>There were no discordances</td>
<td>2</td>
</tr>
<tr>
<td>Minor discordance (non-clinical)</td>
<td></td>
</tr>
<tr>
<td>- typographical error</td>
<td>2</td>
</tr>
<tr>
<td>Minor discordance (clinical)</td>
<td></td>
</tr>
<tr>
<td>- no effect on patient care</td>
<td>4</td>
</tr>
<tr>
<td>Major discordance (clinical)</td>
<td></td>
</tr>
<tr>
<td>- impact on patient</td>
<td>0</td>
</tr>
</tbody>
</table>

Comments made by respondents to this question:
- ‘typos difference in Furhman grade hyperplastic polyp vs cystic fundic gland polyp colon polyp: adenoma instead of tubular adenoma’
- ‘Clinical note typos. Billing’

**Q7.** Does your department have policies for dealing with any of the discordance stated in this pilot, that being minor-typographical/ minor–clinical/ major-clinical)?

Respondents answered this question =7  
Respondents skipped this question =7

<table>
<thead>
<tr>
<th>Answer Choices</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>5</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
</tr>
</tbody>
</table>

**Q8.** Did you follow your department policy on handling any discordances?

Respondents answered this question =8  
Respondents skipped this question =6

<table>
<thead>
<tr>
<th>Answer Choices</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>5</td>
</tr>
<tr>
<td>No, the policy was not followed</td>
<td>0</td>
</tr>
<tr>
<td>Not relevant as there was no discordance</td>
<td>1</td>
</tr>
<tr>
<td>Not relevant as the department has no applicable policy</td>
<td>2</td>
</tr>
</tbody>
</table>
Q9. If you reviewed a case which resulted in you finding a major discordance, did you consult with the department head about your discovery?

Respondents answered this question = 3
Respondents skipped this question = 11

<table>
<thead>
<tr>
<th>Answer Choices</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>2</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
</tr>
</tbody>
</table>

Q10. Did this pilot program make you review your current policies on discordances?

Respondents answered this question = 6
Respondents skipped this question = 8

<table>
<thead>
<tr>
<th>Answer Choices</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>0</td>
</tr>
<tr>
<td>No</td>
<td>6</td>
</tr>
</tbody>
</table>

Q11. Please indicate the extent to which you agree or disagree with the following statements.

Respondents answered this question = 7
Respondents skipped this question = 7

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>The requirements for this pilot were easy to achieve</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>This is a useful activity for monitoring the quality of our work</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>The activities were relevant to my work</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>This type of activity has potential to enhance or improve our practice</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>It would be reasonably easy to meet a requirement of 20 hours per annum</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>7</td>
</tr>
</tbody>
</table>
Q12. Please comment on any aspects of the peer review activities, including the outcomes for any discordances revealed, and any actual or potential implications for procedures or practice.

Respondents answered this question =6
Respondents skipped this question =8

Comments made by respondents to this question:
- "Weekly internal QAP is routine practice in our department."
- "The audit template (supplied as appendix 1 from the pilot instructions) is too complex and time consuming and records data under Case Details which don't need recording if there is no discordance."
- "This degree of review was achieved without making any change to our normal practice."
- "We are probably all doing this sort of stuff anyway - the difference is making the effort to record it and categorise any discordances formally."
- "Discordances have all been minor so far, so have not resulted in our Department developing policies for discordances. We have rather reviewed the slides in a group, so discussed findings and agreed on approaches to particular problems identified. These meetings have been documented and I'm not sure that we need a policy other than to say "should be discussed in Department meetings". Could try to formulate policy for a major discordance, although such a discordance would be capture in our "Riskman" system."
- "We tend to review cases that are in our own area and there is therefore less potential for change as it is less independent. When we review cases for clinical meetings with cases that everyone reports, there is less general interest in quality as people somehow feel they have less ownership of that work (organ system)."

Section Two: Technical Measures & Service Performance

This section of the survey overall indicated the following comments:

Responses from this section were stated as follows:
- "Nominated quality monitors were not particularly applicable to haematology. We monitor numbers of PBs processed, $ film reviews and % film review by haematologists as well as bone marrow TATs. Did not take 2.5 hours to over these bits of information. (Perhaps 0.5-1hour max) I was not allocated enough cases to take me long enough to take up 2.5 hours."
- "I do not work in Anatomical Pathology/Cytology."
- "Nil."
- "Nil."

From the 14 respondents in this section one pathologist skipped this section completely; 6 participants just stated, ‘did not participate’, 4 indicated the above comments with no activities performed, 2 participants performed alternative quality activities (which were not stated in the pilot program, but were acceptable-they being a core biopsy review and an internal random case review). 1 participate chose a re-staining activity due to poor staining.

None of the respondents in this ‘other’ section of the framework who performed a clinical audit indicated the number of cases reviewed for the audit, or indicated if they met the timeframe requirement of 2.5 hours or not.
7 respondents from this section of the framework did state their reasons from the answer choices below for not participating, which are in the table below:

<table>
<thead>
<tr>
<th>Answer Choices</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not wish to do so</td>
<td>0</td>
</tr>
<tr>
<td>Considered it irrelevant</td>
<td>0</td>
</tr>
<tr>
<td>It was too difficult</td>
<td>1</td>
</tr>
<tr>
<td>Lack of time to follow up this section for the pilot</td>
<td>1</td>
</tr>
<tr>
<td>The laboratory does not utilise these types of quality monitors</td>
<td>2</td>
</tr>
<tr>
<td><strong>Other (please specify)</strong></td>
<td>3</td>
</tr>
</tbody>
</table>

**Other comments made by respondents to this question:**
- ‘Did not complete’
- ‘Working at multiple sites made coordination difficult’
- ‘Monitoring repeat H&E for example would be very hard to do, as the reasons for this vary so much. It would be almost impossible to tease out. A further H&E may be because of technical errors in the initial slide, a recut for teaching, photography, for a slide set, to see more into the tissue- could not work these things out from the computer system’

At the end of the survey final comments or suggestions about the framework were asked for, and are stated below;

Respondents answered this question =5  
Respondents skipped this question =9

Comments made by respondents to this question:
- ‘The range of options is good - we could easily do a lot more of these’
- ‘Suggest Appendix 1 as a simpler table rather than a form for each case. Much quicker’
- ‘The review took 16 hours (conservative estimate)’
- ‘We modified the form in Appendix 1 to be more useful to us - more room for comments on reports which we have used to try and develop a uniform approach to particular diagnoses in terms of reporting terminology, special stains ordered etc. We would need to consider more quality monitors in order to achieve the 2.5 hours required in this area. This would involve development of systems to capture the required information, which would be relatively time consuming in the beginning. We do not have the problem of having to include pathologists who are not at the central laboratory in our audit process, as all the haematologists are housed here. For AP, more complicated systems might be required in order to cater for regional pathologists. Again, this would require time and resources at the beginning. If this framework were to be implemented, an appropriate lead-in time would need to be considered’
- ‘It is hard to know with the "other" sections, how that would count for cpdp eg turn-around time in non-gynae cyto: that is something the laboratory scientists would do, and would apply to all those in the department doing non-gynae cytology, so why would it relate to one person's cpdp?’
4. Issues Identified in Project Pilot Program

The objectives of investigating the acceptability, and reliability in adapting the framework to the various public and private laboratories through the pilot program were performed.

The peer review section of the survey showed this part of the framework was well received. Acceptability and useability was demonstrated. Comments in this section indicated that many pathologists were doing aspects of this internal quality activity, but not documenting the activity as often as they should to provide the evidence that they have performed this peer review process.

Section one, ‘Diagnostic Measures’ of the survey which contained peer-review activities, showed that the hours required for this section of the framework is achievable (minimum of 10 hours per annum) and are not unreasonable. Comments included in the survey suggest that there will be a need to provide some lead-in time for some laboratories (smaller and regional laboratories) to achieve the specific outcome but by providing time to adapt to the framework with planning, education and communication, it is workable.

The survey also showed that some laboratories do not have policies in place if discordances were discovered in the review of cases. A general guideline in dealing with discordance should be developed and available in all laboratories. It is important to note the response for question 9 of the survey showed there were 3 responses indicating a major discordance, even though question 6 asked if a major discordance was revealed in this pilot and the responses indicated none. A possible explanation for this variable could be that the responses to question 9 were taken as a previous experience in finding discordance, and were not related to the pilot program.

The assessment of the pilot program also indicated that the quality indicators for Haematology and Forensic Pathology could be improved. It proved difficult to obtain specific quality indicators for Haematology and Forensic Pathology, thus the options for quality indicators in the framework were not as specific to these disciplines. Reviewing the published literature on internal quality assurance in pathology showed more developed quality indicators were available in Histopathology and Cytopathology.

Post pilot program the Project Officer and the pilot site for Forensic Pathology discussed their quality indicators further and it was decided the ‘replacement reports’ as per question 13 in the survey would not be ideal moving forward. It was discussed that recording / reviewing ‘discussions’, would be more relevant. In terms of the report, if forensics had a ‘Critical Conclusion Check’, which is an overall assessment it would be beneficial for this discipline not concentrate on the details, but consider if the final conclusion is sustainable from the report. The Forensic Pathology steering committee member suggests the possibility of developing a template that could be used if required and will discuss further with the Forensic Pathology Advisory Committee as well as requesting specific peer review and clinical audit activities.
Section two of the survey looked at the ‘other’ areas of internal quality assurance activities relating to the framework. It focused on IQA activities accounting for the remaining component of the framework and was designed for pathologists to engage in clinical audit activities and was included to encourage all pathologists to be aware of issues in all phases of the pathology cycle. This section was designed to show various types of audit topics pathologists could do in their work practice and to perform individually which would meet the 10 hour requirement for this section.

In the instructional paper sent to pilot sites was a clinical audit template (as an appendix) which was included to provide guidance in performing and documenting a clinical audit process. Several respondents felt that the template example for recording was too complex and this may either be modified or not included in the implementation phase of this project. Laboratories could also develop their own template that suits their pathologists and practice.

The low response to this section may be due to the belief by some that the quality activities listed as potential topics of audit are not a pathologist specific internal quality issue or it may be that this section of the framework required further explanation about the purpose and desired outcome.

Survey feedback also suggested that some laboratories are capturing this type of information and others are not, such as frozen section correlations with paraffin diagnosis, turn-around times, and bone marrow aspirates and trephine correlations etc.

As previously discussed with the RCPA QAP, it is hoped that they can assist us and host / correlate a small part of the data required for this section of the framework, that being the data associated with the service performance (such as turn-around times, report format, billing codes etc) and the technical performance data (staining quality/repeats required, identification errors etc). It has been discussed that a similar format may be developed in a similar style to the current RCPA QAP Anatomical Pathology technical module, but will relate to all disciplines under a module called, ‘IQA framework’, to capture this data. It is envisaged that this will be achieved when the framework is formalised and becomes a requirement for regular participation. The purpose is to establish benchmarks that could be compared nationally for IQA in the morphological & interpretative disciplines.

Some respondents found that participation in this section was either too time consuming for them or did not fit with part-time practice or with low case loads. These factors will need to be addressed in the implementation phase.
5. Next Steps

The IQA Project and survey has identified that the Framework is workable in the Australian laboratory context. Key focuses for ensuring successful implementation will be to identify and establish benchmarks that will assist and guide laboratories in their IQA practices and the adoption of the framework, to specific circumstances.

Going forward the IQA project will focus on the following;

- The Framework be developed as a RCPA guideline
  - The Steering Committee/ RCPA Board may need to consider a strategy for particular circumstances such as isolated practices, part-time pathologists etc. It may require specific support from the Project Officer and/or the College for implementation of the Framework in these circumstances.
  - Seek further feedback regarding the low uptake of the “Other” section of the Framework and provided specific resources and educational support to pathologists to assist them with participating in the activities in the “Other” section.

- Communication to the Fellowship of the IQA Framework will be required, commencing with promotion at Pathology Update in February 2015. The RCPA booth will have the Project Officer available to discuss the Framework with Fellows.

- Publish project information on the RCPA website.

- The management team of the IQA project is also investigating other meetings in 2015 suitable for promotion of the Framework.

- Meetings with the new CEO and senior management of the RCPA QAP will be carried out in February to provide an update on the IQA project and the pilot and next steps.

- It is recommended that implementation of the Framework is carried out in stages over the next 12 months. Due to the relative success of the pilot in Histopathology and Cytopathology disciplines, the implementation of the framework in these disciplines should be first. The framework will be introduced to laboratories in the metropolitan and regional areas by state / areas as follows;
  - South Australia and Northern Territory
  - New South Wales
  - Victoria
  - Queensland
  - Western Australia
  - Tasmania
  - Australian Capital Territory
  - New Zealand

As the Project Officer resides in South Australia it is recommended that the implementation commence in the relevant pathology network there (i.e. SA Health as this network also has laboratories in the Northern Territory).
- Haematology and Forensic Pathology will follow. This will allow time for the advisory committee members from these disciplines to review and refine where necessary, and identify more specific quality indicators for their areas.

- The remaining disciplines to follow with the adaption of the framework. In the meantime discussions will be required with the advisory committees from these disciplines.

- Discussions with the RCPA BEA on how best to integrate with CPDP, and the RCPA approach to revalidation.
6. Conclusions

The pilot program showed variability in practice of internal quality activities between laboratories. Elements of the framework require refinement for certain individual circumstances and for the different morphological disciplines. Further assistance and refinement is also required of the “Technical Measures & Service Performance” section of the Framework to assist with implementation.

By developing a collaborative approach and open discussions the core framework will be adapted to all disciplines. Using quality assurance tools, such as peer-review and clinical audit, will allow the gathering and possible sharing of data and improve uptake of best practice in pathology by individual pathologists.
Appendix E – Anatomical Pathology IQA Framework

FRAMEWORK
Internal Quality Assurance Activities
ANATOMICAL PATHOLOGY

Section 1: DIAGNOSTIC MEASURES - (engaging in peer review activities)

Requirement: 10 hours per annum Diagnostic Measures

<table>
<thead>
<tr>
<th>Activity</th>
<th>Quality activity monitor related</th>
<th>Suggested document requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case Reviews</td>
<td>• Internal random case review&lt;br&gt; - Defined % of cases&lt;br&gt;• Internal target case review&lt;br&gt; - Specific case types&lt;br&gt;• Internal correlations&lt;br&gt; v) Frozen section – paraffin&lt;br&gt; vi) Non gynae cytology – histology&lt;br&gt; Or other types of correlations performed&lt;br&gt;• Inter institutional correlations&lt;br&gt; - 2nd opinions (incoming and outgoing)&lt;br&gt;• Intradepartmental correlations&lt;br&gt; - Formal 2nd opinions&lt;br&gt; - Informal 2nd opinions&lt;br&gt;• Multi Disciplinary Team (MDT) case presentations**&lt;br&gt; - Any discordant opinions&lt;br&gt;• Audit of corrected/ amended reports&lt;br&gt;• Compliance with / utilization of structured report templates&lt;br&gt; - Other (where available)</td>
<td>Document the review type&lt;br&gt; - Who performed the review&lt;br&gt; - What was reviewed&lt;br&gt; - What cases were reviewed&lt;br&gt; - Time it took&lt;br&gt;Structure discordance as;&lt;br&gt; - None (agreement)&lt;br&gt; - Minor/ typo error&lt;br&gt; - Minor discordance/ no effect on patient care&lt;br&gt; - Major discordance/potential impact on patient care&lt;br&gt;Document discordance&lt;br&gt; - None (agreement)&lt;br&gt; - Minor/non clinical&lt;br&gt; - Minor / clinical&lt;br&gt; - Major / clinical</td>
</tr>
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</table>

** The MDT meetings are the responsibility of the individual laboratory, and are expected to be documented and records maintained with the above criteria mentioned. Record any disagreement which may arise between the original diagnostic report and the MDT review. Issue an addendum post MDT if required and follow-up according to your individual laboratory policy for such incidents. Each laboratory must have documented processes for handling diagnostic discordances when detected.

For example:
- **Agreement** – represents frozen section/ histopathology/ cytology where all present agree with the report.
- **Deferral rate** - represents the cases where frozen section diagnosis was deferred until final diagnosis was reached on paraffin sections.
- **Minor disagreement/discordance** - represent where there is a small change in diagnosis but there is minimal or no clinical impact.
- **Major disagreement/ discordance** - represent a significant difference between original diagnosis and the final diagnosis where potentially there is a significant impact on a patient’s treatment or outcome.
**FRAMEWORK**  
Internal Quality Assurance Activities  
ANATOMICAL PATHOLOGY

### Section 2: TECHNICAL MEASURES - laboratory based non-conformances (audit activities)

**Requirement:** 10 hours per annum combined Technical Measures/Service Performance

<table>
<thead>
<tr>
<th>Activity</th>
<th>Examples of quality monitors related to lab based non-conformances</th>
<th>Suggested document requirements</th>
</tr>
</thead>
</table>
| Non-conformance reporting | • Specimen receipt issues*  
                          - Incorrect identifiers  
                          - Labelling errors  
                          - Lost specimens  
                          • Specimen handling issues  
                          - Cut-up  
                          • Laboratory technique issues  
                          - Embedding  
                          - Cutting  
                          - Staining  
                          - Special stains  
                          - Frozen section TAT | - Incidence +/- % of non-conformances |

*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.*

### Section 2: SERVICE PERFORMANCE - suggested examples below of types of service activities that may be monitored and specific data collected

**Audit of Service Performance**

The goal is collecting acceptable data to develop benchmarks for the future to compare nationally, hosted by the RCPA QAP technical module. (Presented as de-identified information, similar format to the RCPA-QAP are already doing with their results)

- Turn Around Times**  
  - Whole workload or  
  - Selected case type  
- Report format review  
  - Typographical/ transcript errors  
  - SNOMED coding  
- Billing Errors  

**Documentation of TAT**  
- Overall  
- Different phases of reporting process  
- By different case types  

% Errors concluding check

*Laboratories must have policies for handling detected non-conformances

**For Histology consider criteria from either current ACHS or RCPA recommendations*