QUALITY USE OF PATHOLOGY PROJECT

The Role of External Quality Assurance in Identifying Poor Laboratory Performance

Final report
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Report prepared by
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ABBREVIATIONS

APA  Approved Pathology Authority
APP  Approved Pathology Practitioner
CPL  Cumulative Performance Level
DoHA Department of Health and Ageing
EOC  End-of-cycle report
EQA  External Quality Assurance
IVD  in vitro diagnostic medical devices
KPI  Key Performance Indicator
NATA National Association of Testing Authorities
NPAAC National Pathology Accreditation Advisory Council
PRC  Performance Review Committee
QAP  Quality Assurance Program
QUPP Quality Use of Pathology Program
RCPA Royal College of Pathologists of Australasia
RCPA QAP Royal College of Pathologists of Australasia Quality Assurance Programs Pty Ltd
TGA  Therapeutic Goods Administration
UKNEQAS United Kingdom National External Quality Assessment Service

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EXECUTIVE SUMMARY

RCPA QAP was engaged by the Department of Health & Ageing (DoHA), in a project to review the *Role of External Quality Assurance in Identifying Poor Laboratory Performance*. The project objectives were to determine if the regular EQA that laboratories perform can be used to identify unacceptable performance earlier than the usual three year NATA accreditation cycle, by establishing a framework and criteria to identify suboptimal laboratory performance, to allow early intervention in order to minimise risk to patients.

An earlier project in Chemical Pathology QAP developed “Key Performance Indicators” for “EQA participation”, “performance of all analytes” and “performance of indicator analytes”. Analysis of data retrospectively from 2006 to 2010 indicated a level of non-submission of results, and a higher level (approximately 25%) of late submission of results by Australian laboratories. A review of the “All Analytes” KPI and “Indicator Analytes” KPI demonstrated that there were probably no diagnostic Australian laboratories considered to be technically poorly performing over this period. These KPIs will need to be reviewed in future. Due to confidentiality concerns, however, this data was unable to be correlated with NATA on-site assessment records.

Key Performance Indicators were developed for Anatomical Pathology in this project. Several scoring methods have been developed, using a novel non-parametric scoring system for measuring participants’ performance for each survey case, and allowing a peer review comparison. Analysis of data retrospectively in the General and Breast diagnostic modules showed significant levels of survey non-participation by laboratories. Performance across surveys indicated a small population of participants that consistently ranked in the lowest 10% of cumulative performance. Benchmarks were developed, although a further period of time will be required to trial and validate these adequately.

Extensive stakeholder consultation with Anatomical Pathologists has identified several key operational issues with the Anatomical Pathology QAP;

- EQA is perceived as educational by many pathologists, so selection of cases should be better suited to assessment of performance rather than educational value
- There are no clear regulatory guidelines (NPAAC) for enrolment of anatomical pathology laboratories; this should be reviewed to allow consideration of a laboratory’s scope of practice
- There are concerns that single pathologist / few pathologist laboratories are at risk of being assessed more rigorously as individuals than large laboratories containing many pathologists,
- Virtual images are not used in routine laboratories for diagnosis

Performance benchmarks have been developed in the Transfusion QAP, including review of performance for a single survey and cumulative performance over a six month period. Trials of the benchmarks to date have been successful, with letters of notification being sent to four laboratories to enable them to complete a timely corrective action.
Existing benchmarks for gynaecological Cytopathology have been revisited, and new benchmarks have been developed which include both EQA results and the National Performance Measures data. Data analysed retrospectively from 2004 – 2010 for the GYN module showed that those laboratories that had major errors in the GYN module had more Performance Measures outside the national standard. Benchmarks have been set at one major error, three unacceptable responses in the GYN module, being outside the national performance measures or non submission of results. Trials have resulted in letters being sent to 10 laboratories. The feedback from participants has been predominately positive, and any negative feedback has been addressed and overcome.

A novel protocol has been developed to monitor EQA results for both laboratory performance and for the performance of in vitro diagnostic medical devices. The framework (Appendix A), has been through extensive consultation, and provides a mechanism of escalation and notification to participants, manufacturers or their agents. The notification of suboptimal laboratory performance makes provision for escalation to NATA. Legal advice received recently prevents RCPA QAP from forwarding any participant results to NATA without the written consent from the participant (laboratory). The capacity to do this is critical for the framework to function effectively, and the regulatory framework needs to be reviewed urgently to overcome this barrier.

Software development for this project has two elements, the development of calculations for the newly developed benchmarks and scoring systems, and the development of a novel electronic platform where both laboratories and NATA can review a summary of results and performance. The development of the first element has been partly completed, whilst the ‘dashboard’ concept is still at the early stages of development. Establishing an early warning system must be balanced with the need to avoid collusion, and the manner in which active notification to participants and NATA is perceived. RCPA QAP prefers an approach to initially assist participants in addressing issues of performance and maintaining accreditation.

Significant effort has gone into this project and establishing an early warning system has been demonstrated to be achievable during this project. However, a pilot phase of six months (Jan- June 2012) is insufficient time to draw any conclusions to the effectiveness of the framework or the benchmarks for performance. RCPA QAP recommends a further minimum pilot phase of two years to test the framework and benchmarks, which will give further time to overcome the barriers of validation of data with NATA and allow resolution of other internal RCPA issues within the Anatomical Pathology QAP.
BACKGROUND

In 2001 the Commonwealth Department of Health and Ageing sought proposals to undertake an evaluation of Australian pathology laboratory accreditation arrangements. This was the first comprehensive evaluation since the introduction of accreditation in 1986. This research resulted in the 2002 Corrs Chambers Westgarth report ‘Evaluation of the Australian Pathology Laboratory Accreditation Arrangements’.

Recommendations from that report included 5.1 ‘That the DHA and HIC seek the cooperation of the RCPA QAP to establish explicit external quality assurance performance criteria, initially in chemical pathology and gynaecological cytology, and a mechanism for the RCPA QAP to identify relatively poorly performing laboratories.’

From this recommendation, RCPA and RCPA QAP established the first KPI project. Key Performance Indicators were setup for Chemical Pathology and Cytopathology with the intention that it could be used as an ‘Early Warning system’ to identify poorly performing laboratories. In collaboration with NATA, Peer Review Committees were established by NATA to review the limited KPI data. It had been intended that a peer review process would be established on an ongoing basis and used as a flag to notify NATA that a laboratory required some form of review. This would have been in keeping with Recommendation 5.2 from the Corrs Chambers Westgarth report, which stated ‘That RCPA QAP and other external quality assurance providers regularly submit to NATA reports identifying laboratories that are poorly performing according to these agreed performance criteria.’

Conclusions from the KPI review process included:

- Chemical Pathology – the KPIs and Peer Review Committee process can identify laboratories with poor EQA performance but this does not necessarily equate to poor ratings at on-site assessment, and therefore, the Steering Committee could not recommend the introduction of KPIs in Chemical Pathology as a formal tool enshrined in NPAAC Standards to help identify poorly performing laboratories.

- Gynaecological Cytopathology – KPIs are not a valid tool to use for identifying poorly performing laboratories and therefore, it was recommended that they not be implemented in the existing format. However, it was thought a large number of Major Errors in a QAP may be a trigger for a review of some variety.

As part of its continual assessment and monitoring program to increase the competency of pathology laboratories and patient safety, Royal College of Pathologists of Australasia (RCPA) Quality Assurance Programs Pty Ltd (QAP) sought QUPP funding for the Role of External Quality Assurance in Identifying Poor Laboratory Performance project. This project is consistent with the DoHA 2009 Budget initiative “to continue the development of key performance indicators and other risk identifiers in pathology service provision”.1
PROJECT DESCRIPTION

The Role of External Quality Assurance in Identifying Poor Laboratory Performance project will examine pathology laboratory performance from a number of perspectives.

Previously the RCPA QAP ran a Key Performance Indicators (KPI) trial. This trial, which showed equivocal results, will be revisited for chemical pathology as this data has now been collected over four years.

In addition, KPIs will be developed for other pathology disciplines, notably anatomical pathology and transfusion serology, and evaluated as indicators. Peer review protocols will be established for each discipline, and individual benchmarks set for adequacy of external quality assurance (EQA) performance as triggers for concern. The protocols will then be trialled in collaboration with the National Association of Testing Authorities Australia (NATA). The trials will determine whether early indicators of poor performance can be developed around the regular EQA that laboratories perform as part of the accreditation process.

Another part of this project will establish a working party with the Therapeutic Goods Administration to develop ways to identify sub-standard tests and kits that can have a direct effect on pathology laboratory performance.

PROJECT OBJECTIVE

1. Review four years of KPI data and correlate with NATA accreditation visits.
2. Establish KPI systems and develop software for transfusion serology and anatomical pathology.
3. Set benchmarks for each KPI discipline.
4. Develop novel protocols to use ongoing EQA results to monitor performance.
5. Establish mechanisms to use EQA data to help monitor quality of test kits.
1. CHEMICAL PATHOLOGY

1.1. BACKGROUND

The Key Performance Indicators were developed during the first KPI project. Limited data correlation was completed during the first project period, which showed that laboratories could be identified with poor EQA performance but this did not necessarily equate to poor on-site NATA assessments. Since this time, the KPIs have continued to be reported to laboratories.

The Key Performance Indicator (KPI) report is a report that summarises the performance of all programs for one laboratory number over a six month period. Two reports are generated per calendar year and issued in February and August.\(^2\)

An objective of this project was to review four years of KPI data and correlate it with NATA assessment reports.

1.2. SCORING SYSTEM

The indicators are derived from End-of-Cycle data from all of the RCPA Chemical Pathology programs that the laboratory is enrolled in. Three indicators are calculated:

- Participation Indicators – results returned, late and amended results
- All Analytes KPI (a ranking of the End-of-cycle %CV for all analytes)
- Indicator Analytes KPI (a ranking of the total error – precision and instrument based accuracy for selected clinically important analytes)

1.3. ANALYSIS OF DATA RETROSPECTIVELY

Results were analysed for 9 KPI reports (December 2006 – December 2010) for Australian laboratories. For this period there were 5 – 18 laboratories, that had an All Analytes KPI of 0.03 or less (i.e. bottom 3%) and 3 – 12 laboratories that had an All Analytes KPI of 0.04 – 0.05. For the Indicator Analytes KPI 6 – 15 laboratories had a KPI of 0.03 or less and 5 – 10 laboratories had a KPI of 0.04 – 0.05.

Participation Indicators include the percentage of results submitted, submitted late or amended. Throughout the study period up to 12 laboratories submitted less than 50% of survey results and up to 46 laboratories submitted less than 80% of survey results.

Over the 4.5 year study period up to 15 laboratories submitted more than 50% of survey results late and throughout the same period there were approximately 25% of Australian laboratories that returned results late more than 10% of the time.

Zero to two laboratories amended more than 20% of results. Twenty-one to forty-nine laboratories amended more than 5% of results in a six month KPI period.
A Performance Review Committee was established and results were reviewed if the All Analytes or Indicator Analytes KPI had been 0.03 or lower twice over the study period. KPI and End-of-cycle reports were reviewed for 23 laboratories. No Australian diagnostic laboratory was considered to be systemically poorly performing over the study period.

1.4. BENCHMARKS

The Performance Review Committee considered the following benchmarks:

- All Analytes KPI ≤ 0.03
- Indicator Analytes KPI ≤ 0.03
- Returned results < 80%; Late results > 10%; Amended results > 5%

Data indicated that benchmarks for results returned should be reviewed. In addition it was suggested that laboratories be screened by the Chemical Pathology QAP if the KPI was < 0.10 consistently.

1.5. STAKEHOLDER FEEDBACK, DIFFICULTIES ENCOUNTERED AND DISCUSSION

1.5.1. Participation Indicators

NPAAC documents outline that participation in EQA is a requirement for accreditation. In setting benchmarks across all RCPA QAP programs, nonparticipation in one survey has been consistently set as a criterion. Survey frequency, however, is higher in Chemical Pathology QAP, than in other programs. The number of letters and workload that would be generated for Chemical Pathology staff and NATA taking this approach would be untenable and therefore, the above benchmarks were considered by the committee and may be further refined in the future.

The KPI reports are generated in February and August and are based on the End-of-cycle reports from the previous six months. It needs to be considered if this is an early enough warning for a laboratory. Participation Indicators could be reviewed more immediately than 6 months, however, software development is a significant barrier required to achieve this. When reviewing the frequency of KPI reports against the Framework, NATA would only be notified of persisting suboptimal performance after one year at the earliest. In addition, laboratories submitting no results for a Cycle will not generate an End-of-cycle report and therefore, under the current system will not be identified as a laboratory with nonparticipation in EQA.

1.5.2. All Analytes and Indicator Analytes Key Performance Indicators

A number of areas remain to be resolved if the KPIs will act as an adequate trigger of concern. These include:

- Esoteric (low volume) tests - indications from NATA are that these are tests of concern.
• One aspect of a laboratory maybe underperforming compared to the overall performance of a laboratory (e.g. backup analyser, blood gas machine).
• Indicator analytes - the possibility of increasing the number of Indicator analytes.
• Frequency of the KPI report - it remains to be determined if the frequency of the reports (every 6 months) is timely enough for a supervisor to be informed of suboptimal performance.
• Usage of the KPI report in the laboratory

1.5.3. Correlation with NATA assessment records

KPI data could not be correlated with NATA assessment records during the period of this project. NATA assessment records are confidential between NATA and the laboratory and therefore could not be released to the RCPA QAP. This resulted in the RCPA QAP being unable to undertake a correlation of records retrospectively. Despite a number of meetings held with NATA this issue could not be resolved.

A number of factors need to be considered when considering a correlation of QAP data and NATA assessment records retrospectively such as:
• Laboratories are currently not required to show the KPI reports to NATA during an inspection
• If EQA is out in the middle of a NATA assessment period it may not have been recorded on an inspection report.
• There are a significant amount of Chemical Pathology QAP results to be reviewed from a three year period at an inspection.
• It may be difficult to correlate the performance of the laboratory (i.e. any major problems in a laboratory) retrospectively at the exact time the KPIs were low.
ANATOMICAL PATHOLOGY

2.1. BACKGROUND

Modelling for Key Performance Indicators was undertaken using the General and Breast diagnostic modules. Both of these modules contain 30 cases per year, distributed by digital microscopy. In Australia glass slides are routinely used for day to day reporting of patient cases, however for use in an External Quality Assurance Program digital microscopy is now considered to be acceptable worldwide.

The advantages for EQA are that:

- it ensures each laboratory receives an identical image,
- each diagnostic feature is capable of being referenced by its X, Y coordinates in the image,
- variability of staining between slides can be eliminated although viewing conditions can be adjusted to suit participants tastes and, of particular relevance,
- Allows performance assessment for all tissue types including small biopsies.
- This eliminates a major element of imprecision in the process.

The Anatomical Pathology QAP has used digital microscopy for 6 years, initially in pilot studies in 2006 – 2007 and then phased into the surveys from 2007 onwards.

A novel non-parametric scoring system for measuring participants’ performance for each survey case was developed in 2005 and presented to participants in early 2006. Individual case scores could be aggregated across all cases in a survey or all cases during a longer period such as a calendar year. It has been used since then with only a few minor changes and the system used for this project is a development of this scoring system.

2.2. SCORING SYSTEM

Anatomical Pathology QAP has now developed several scoring methods for measuring performance and for establishing criteria for identification of unacceptable performance. The scoring methods are:

- Survey Score
- Survey Rank
- Average Survey Score
- Average Survey Rank
- Average Discordant Sum
- Non-concordance Sum

Only participants enrolled as laboratories have their results evaluated by these calculations. The results of participants’ enrolled for educational purposes or individual enrolments are excluded from the scoring system.
2.2.1. Survey Score

Each participant response (10 cases per survey) is classified on the basis to which the response is considered to match a "target diagnosis". The assessments for each case are classified in descending order into the following categories where "Concordant" is the optimal result followed by "Minor discordance", "Differential diagnosis", "Discordant" and "Unable to be assessed" or "No submission received". Within each of these five categories the median value is determined and termed mid-point value.

The purpose of adopting this approach was to reduce to a minimum any subjective element in assessment and making each mid-point value a consequence of the performance in relation to all members of the peer group enrolled for the relevant survey.

Figure 1, for a hypothetical case, graphically shows the distribution of responses for each assessment category and the resulting mid-point values. For example, for results classified as "a minor discordance", responses occupied in the region from 60% to 40% of the total proportion, received the mid-point value of 50%.

![Figure 1. Mid-point values](image)

For each survey the sum of the mid-point values for each case is determined (e.g. for each of the 10 cases in one survey in the General and Breast modules). This sum of mid-point values for each participant, is then expressed as a percentage of the maximum attainable score (i.e. the sum of the mid-point values for the cases where the assessment is "concordant"), in that survey.

The mid-point value in each assessment category, for each case reflects the relative difficulty of each case. As the degree of difficulty increases fewer participants are assessed as concordant and the mid-point value adjusts upwardly in all categories. Discordant assessments in more difficult cases will obtain a higher mid-point value than those in straightforward cases. The size of the gap between the
mid-point value for a concordant assessment and for a discordant assessment could be quite variable and will be influenced by the number of participants assigned to the other assessment categories. Also of note is that, partial submissions including “Unable to be assessed” and “No submission received” assessments (i.e. case nonparticipation) are assessed below "discordant", will adversely affect the survey score and can be minimised with complete participation.

2.2.2. Survey Rank

The Survey Score is converted to a Survey Rank, in percentage, to enable consistent assessment of participant performance between surveys. Participant’s scores are ranked top down, with top performers receiving a survey rank of 100% down to the bottom performers receiving a rank of 0%. Survey non-participation is excluded from the ranking.

Figure 2 shows an example of survey score and survey rank.

![Survey Score vs Survey Rank](image)

**Figure 2. Survey Score vs Survey Rank**

2.2.3. Average Survey Score

The Average Survey Score is the average score of those surveys that results have been returned for, over a three year period. Partial participation, where only some cases in a survey have been submitted, is included in the scoring, while full survey non-participation is excluded.

Over the 3 year period, participants who obtain a majority of concordant assessments will rank higher than those with a greater proportion of minor discordance and discordant assessments.

2.2.4. Average Survey Rank

The Average Survey Score is converted to an Average Survey Rank, in percentage. This reviews performance of a participant over a 3 year period, compared to their peers. Participants’ scores are ranked top down, with top performers receiving an average survey rank of 100%, down to the bottom performers receiving a score of 0%. Survey non-participation is excluded from the ranking.
2.2.5. **Average Discordant Sum**

The number of ‘Discordant’ assessments over a 12 month period is averaged (i.e. the average number of discordant results per survey).

2.2.6. **Non-concordant Sum**

The cumulative value of ‘Minor discordance’, ‘Differential Diagnosis’, ‘Discordant’, ‘Unable to be assessed’ and ‘No submission received’ assessments for all cases in each survey are calculated.

The Non-concordant Sum is an indication of the number of results in a survey that are assessed as not obtaining the target diagnosis. This type of assessment is also used in the RCPA Fellowship Part 2 exams where 4 out of 15 incorrect answers are allowed.

2.3. **ANALYSIS OF DATA RETROSPECTIVELY**

Four years (2007 – 2010) of General and Breast Diagnostic modules data was analysed retrospectively.

2.3.1. **Participation**

Examination of data from both the General and Breast Diagnostic modules demonstrated consistent failure by some participants to submit results. This non-participation fell into two categories.

The first of these was where the participant provided a response to some of the 10 cases but not to others. This has been described as "case non-participation". This is addressed in the criteria where "case nonparticipation" is assigned to the lowest rank category of "unable to be assessed" and would scored as poor relative performance.

The second of these was where there was no response to an entire individual survey (all 10 cases not reported); this has been described as "survey non-participation".

Analysis showed a small number of participants that did not submit some of the 10 survey cases. Of all participants enrolled in the General diagnostic module, between 2008 – 2010 survey non-participation (results for a whole survey have not been submitted) ranged from 7 – 17%. Laboratory participants represented 5 – 11% of survey non-participation.

In the Breast diagnostic module, survey non-participation from 2008 - 2010 ranged from 10 – 21%. Laboratory participants represented 2 – 9% of survey non-participation. In this module there is a higher proportion of individual participant enrolments compared to the general diagnostic module. Historically many laboratories have believed that enrolment in this module can only be by individual participant only, and therefore there are a significant number of laboratories not enrolled.
2.3.2. Performance

To develop criteria for unacceptable performance the subset of data used was the results from Australian and New Zealand participants for the years 2008 – 2010. The results showed a small number of participants that consistently did well at the top, a large population of participants in the middle and a population of participants that consistently were ranked below 10% who required further investigation. Results for both General and Breast diagnostic modules were similar.

When the average discordant sum was compared with the average survey score, the results showed that as the average survey score went down, the average discordant sum went up. In the Breast diagnostic module, the average discordant sum was higher for a larger proportion of participants than in the general diagnostic module. Two reasons for this may be that some participants enrol in the Breast module for educational reasons / interest but do not report breast cases everyday or that day to day participants would refer complex cases seen in the QAP survey.

From extensive modelling of the data retrospectively, empirically derived benchmarks were proposed. Using reviewed data from each laboratory that fell within the proposed benchmark, the Anatomical Pathology Performance Review Committee considered whether the proposed benchmark could be used as a trigger of concern.

2.4. BENCHMARKS

The benchmarks were developed for the General and Breast diagnostic modules. Results for participants enrolled in the program as a laboratory will be reviewed after every survey. If any ONE of the following criteria applies, then a laboratory will be considered to have met the criterion for suboptimal performance. In this situation the RCPA QAP performance monitoring Framework will be activated. Any laboratory judged on this basis of being at risk for suboptimal performance would not have this "at risk" flag reset until two surveys had been completed without there being any results which did not meet any of the criteria of potential unsatisfactory performance.

The criteria are as follows:

**Participation**
- x1 Survey nonparticipation

**Performance of Test**
- **Survey Rank**, x3 in the bottom 10% in a rolling 3 year period
  - Thereafter, if in bottom 10% rank a subsequent time (i.e. x4, x5, etc)
- **Average Survey Rank** ≤10%, in a rolling 3 year period
  - Thereafter, if Average Survey Rank is ≤10% AND less than the Average Survey Rank on the previous survey; or
  - Thereafter reset scoring if Average Survey Rank >10% 3x consecutively
- **Average Discordant Sum** is 1.5+ AND number of surveys completed is 2, in a rolling 12 month period
  - Thereafter, if 1.5+ AND 2 surveys completed AND survey contains Discordant result
- **Non-concordant Sum** 5+ results per survey
The criteria have largely been designed to review results over time, are weighted for case difficulty and compare a participant’s performance against their peers.

2.5. TRIAL OF BENCHMARKS

The trial period ran from January to June 2012. During this period participants submitted results for one survey each, of the General and Breast diagnostic modules. At the time of writing this report, the General survey has recently closed and results have yet to be analysed.

Initial results from the Breast module: Of the 237 participants enrolled in the module worldwide, 159 participants are Australian (85 laboratories). Seven Australian laboratories did not return results for this survey. Four Australian laboratories fell within the criteria, 5 or more non-concordant results, for suboptimal performance. However, one of the 10 cases had a high discordant rate and an overall non-concordance of 87%. It has yet to be decided if this case will be excluded from the scoring and criteria.

2.6. STAKEHOLDER FEEDBACK, DIFFICULTIES ENCOUNTERED AND DISCUSSION

2.6.1. Enrolment

The regulatory requirement for laboratories to be enrolled in external quality control is outlined in the NPAAC document, ‘Requirements for participation in External Quality Assessment (2009)’\(^1\). This is the only regulatory framework, that currently exists, within which the performance monitoring project may operate. It should be noted that the requirement is for laboratories and not individual pathologists.

\(S1.1\) Laboratories must be enrolled, participate and demonstrate acceptable performance continually in appropriate external quality assessment programs.

\(C1.1\) Submission of results must be in a timely manner.

\(S1.2\) Participation must cover all test methods performed in the laboratory.

\(S1.3\) The laboratory must review in a timely manner participation and performance, investigate any aberrant result(s), and document any corrective actions taken to allow assessment of performance.

\(S1.4\) All laboratory staff involved in patient testing must participate in these quality assessment programs.

\(S4.1\) Quality assessment program material must be treated in a manner similar to patient specimen process. Alternative quality assessment, such as virtual microscopy, must be carried out in a manner that is as close as possible to patient testing.

\(C4.1\) It is not always possible to treat the quality assessment samples in exactly the same way as a patient sample e.g. morphology, histopathology quality assessment.

Current practice of what and how laboratories are enrolled in external quality assurance appears to vary substantially across Australia. Participants enrolling in the RCPA QAP can enrol as a laboratory.
participant or as an individual participant. Laboratory enrolment is a requirement for accreditation purposes. Individual enrolment has been seen to be a requirement by some organisations for review of individual competency or for education and interest by some pathologists, particularly in the specialist modules. There is widespread misperception that for the specialist modules (e.g. Breast module) enrolment may only be by individual enrolment. Currently:

- A laboratory enrolls in a module but there are no individual enrolments.
- A laboratory enrolls in a module and its pathologists also enrol individually.
- Pathologists enrol individually but there is no laboratory enrolment.
- A single pathologist laboratory in one instance may be enrolled as a laboratory enrolment but in another as an individual enrolment.
- A large laboratory with many pathologists enrolls as a laboratory in the General module only.
- A large laboratory with many pathologists may enrol as a laboratory in the General module but pathologists enrol as individuals in one or more specialist modules.

Stakeholder feedback also indicates that how QAP surveys are performed in the laboratory is also variable. E.g.

- Pathologists review the QAP separately, each submitting their own answers. One pathologist would have the laboratory enrolment number.
- In a large laboratory QAP samples are distributed to different pathologists. Each pathologist only does 1 – 2 cases per year.
- A laboratory coordinator randomly distributes cases. A pathologist may not receive cases that they would ordinarily report.
- Small laboratories do all of the QAP even if they would not ordinarily report those cases on patients.
- Where there is a requirement by an organisation for pathologists to be enrolled individually, pathologists still get together to discuss cases and then submit a consensus answer.
- A laboratory submits a consensus answer.

Due to the inconsistencies in enrolment the implications for the performance monitoring project are as follows:

- Single pathologist laboratories are effectively undergoing individual assessment.
- Small laboratories with only a few pathologists are being compared with large laboratories.
- Those laboratories, which have been enrolled using only individual enrolments, are excluded from monitoring performance of external quality assurance.

This makes comparing performance across laboratories very difficult.

2.6.2. Scope of practice

In Australia there are single pathologist laboratories and some practices with 40 or more pathologists. The scope of practice within these laboratories varies considerably. Pathologists in smaller laboratories tend to report general cases and may have specialist skills in an area. It is common practice for complex cases to be referred to a pathologist with specialist skills renowned in that area. In large laboratories or specialist laboratories (e.g. Dermatology, Paediatric, Forensic) commonly pathologists work only in their area of specialty.
General or Specialist QAP modules may contain cases that laboratories would not ordinarily see in their day to day practice. The implications for the performance monitoring project are that performance of laboratories is not always being assessed according to the scope of practice of a laboratory.

2.6.3. Selection of cases

Anatomical Pathologists have viewed the diagnostic surveys as being educational rather than for proficiency testing or assessment of performance. The cases in the modules are selected to cover a wide range of pathologies including different organ systems in the general module and new entities, esoteric or difficult cases. Extensive reports including trends of an entity are provided to pathologists for their interest and ongoing education. The value provided to pathologists therefore, is far in excess of a basic proficiency testing program. Historically pathologists have enrolled in a number of specialist modules for their ongoing interest, but in the light of being assessed for performance and the false perception that individual pathologists will be assessed, Australian enrolments for 2012 have decreased.

The implications of the performance monitoring project are that:

- Selection of cases should be better suited to assessment of performance rather than educational value
- Inclusion of complex cases which may have been of particular interest needs to be reviewed and perhaps offered as a separate educational module
- By pathologists and laboratories decreasing their enrolments they may also be decreasing their exposure to cases they would not otherwise routinely see in daily practice.

Digital microscopy is now an internationally accepted medium for external quality assurance. Cases must be carefully selected to suit this medium. There have been several reports of poor image quality, slowness in using the Image Scope software and lack of familiarity with the software. It also is apparent that many laboratories do not have adequate technology to review the cases easily. A meeting has been convened on 27 June 2012, with the Australian agents of Aperio to assist the RCPA QAP in addressing these issues internally and for participants.
3. TRANSFUSION

3.1. BACKGROUND

Transfusion QAP began development of Performance Levels for the General Compatibility module some time ago. This evolved over time and in 2011 the scoring system was changed to the current system where results are deducted for incorrect answers. Performance Levels were communicated to participants before the Performance Monitoring project was piloted in 2012.

The General Compatibility Module contains 6 surveys per year and is designed for laboratories that routinely prepare blood for transfusion for patients with or without allo-antibodies.

3.2. SCORING SYSTEM

During 2011, the Transfusion QAP introduced a performance assessment scheme for the General Compatibility Module, which placed laboratories into 5 operational categories. These categories are:

- Reference 100 – no points lost
- Reference 99 – loss of 20 points, but no critical error made
- Operational – loss of 20 – 49 points but no critical error made
- Review – loss of 50 – 99 points (equivalent to 1 critical error)
- Unsatisfactory – loss of 100 or more points (equivalent to 2 critical errors)

Tests regarded as critical are the ABO blood group, antibody screen and crossmatch reaction.

After each survey has been analysed and discussed by the Transfusion Advisory Committee, each laboratory is placed into a performance level based on the final score attained. This is the survey performance level. From this the cumulative performance level (CPL) is calculated.

The CPL is the performance level calculated from the previous six surveys. Each performance level is given a ranking that is used in the calculation however some exception rules are applied. For example,

- If the performance level for a survey is “Unsatisfactory” then the CPL will default to “Unsatisfactory”.
- A survey performance level of “Review” will default the CPL to “Review”.
- If a participant achieves three consecutive “Reference 100” levels, then the CPL will default to “Reference 100” and CPL calculations will default back to the first “Reference 100”. This exception rule allows highly performing laboratories to regain “Reference 100” status following a loss of points through minor technical reasons or following successful implementation of corrective action.

The CPL therefore, is an ongoing record of performance and this will be recorded on each survey summary report.
3.3. ANALYSIS OF DATA RETROSPECTIVELY

No data has been analysed retrospectively due to the change of the scoring system at the beginning of 2011. However, analysis will be undertaken once enough data has been gathered.

3.4. BENCHMARKS

The Transfusion QAP has adopted the following benchmarks as indicators of unsatisfactory performance, which will trigger a letter of notification to the nominated laboratory and supervisor(s).

**Two critical errors** - 1st letter and Advisory Committee report are sent to the participant and nominated supervisor(s) from the Program Manager. Participant results are then monitored for one year.

**Three critical errors** - 2nd letter and Advisory Committee report are sent to the participant and nominated supervisor(s) from the Advisory Committee chairperson. Participant results, letter and Advisory committee report would have been sent to NATA. Participant results are then monitored for one year.

**Four critical errors** - 3rd letter and Advisory Committee report are sent to participant, nominated supervisor(s) and Director of Pathology from the Chairperson of the RCPA QAP Board. Participant results, letter and Advisory Committee report would have been sent to NATA. Participant results are then monitored for one year.

**Non-participation** - Failure to return results will be treated in the same manner as critical errors above.

3.5. TRIAL OF BENCHMARKS

The trial period ran from January to June 2012. During this period participants submitted results for three General Compatibility surveys. For survey 1, one letter was sent to a participant. For survey 2, three letters were sent to participants. Survey 3 is still being processed however early indications are that there will be some letters sent for nonparticipation of results and incorrect results.

3.6. STAKEHOLDER FEEDBACK, DIFFICULTIES ENCOUNTERED AND DISCUSSION

Very little adverse feedback has been received from participants. The project for Transfusion has gone very smoothly to date. This is probably largely due to the general expectation that performance of EQA in Transfusion should be monitored and that reporting of Performance Levels has been in place for some time.

Some participants have questioned the loss of points, particularly if they cannot rule out an antibody due to the panel they have in their laboratory. This has been clarified by the Program Manager.
4. CYTOPATHOLOGY

4.1. BACKGROUND

While Cytopathology was not specifically outlined in the project agreement with the DoHA, the RCPA QAP felt it would be worthwhile to reconvene a committee and re-examine this area.

The first Key Performance Indicators project established in 2004 investigated the use of KPIs to identify poorly performing laboratories. At that time, the gynaecological data and non-gynaecological data was used in the KPI calculation and the Performance Measures data was not used. The conclusion from this project was that the KPI was not a valid tool to identify poorly performing laboratories. However, it was thought a large number of major errors in a QAP may be a trigger for a review of some variety.

The GYN conventional slide survey has four surveys per year with 5 slides in each survey. The Performance Measures are submitted to the QAP in 2 parts, one year retrospectively.

4.2. SCORING SYSTEM

The Cytopathology QAP used an existing assessment system to define the benchmarks. The GYN conventional slide module uses the following categorisations when assessing results:

- **Target response**: an exact match with the expected (panel) diagnosis.
- **Acceptable response**: not an exact match, but a diagnosis that would not result in an adverse patient outcome.
- **Unacceptable response**: a response which is considered to be a significant deviation from the panel diagnosis but not a major error.
- **Major error**: A significant deviation from the panel diagnosis that may have a significant adverse effect on patient management.

The Performance Measures are a national standard established and documented by NPAAC (2006)4.

- **Performance Measure 1**
  Between 0.5 and 5% of all specimens reported as technically unsatisfactory.

- **Performance Measure 2b**
  Not less than 0.7% reported as high grade or possible high-grade epithelial abnormality, age standardised.

- **Performance Measure 3a**
  Not less than 65% of cytology specimens with a definite cytological prediction of a high-grade intraepithelial abnormality are confirmed on cervical histology, which is performed within 6 months, as having a high-grade intraepithelial abnormality or malignancy.

- **Performance Measure 3b**
  Not less than 33% of the cytology specimens with a cytological prediction of a possible high-grade abnormality are confirmed on cervical histology, which is performed within 6 months, as having a high-grade intraepithelial abnormality or malignancy.
• **Performance Measure 4**
  
  Not more than **10%** of the women with a histological diagnosis of high-grade epithelial abnormality have cells consistent with, or suggestive of, a high-grade abnormality identified on review of slides that were originally reported as negative within the preceding 30 months.

### 4.3. ANALYSIS OF DATA RETROSPECTIVELY

Seven years of data was analysed retrospectively (2004 – 2010) to establish if there was any relationship between the GYN conventional cytology module and the Performance Measures data. The results showed that those laboratories that had major errors in the GYN module had more Performance Measures outside the national standard and vice versa. However there was no absolute correlation of the data and this helped to identify the necessity for separate benchmarks.

Before the analysis of retrospective data was undertaken, the Cytopathology Performance Review Committee considered the use of 2 major errors as the benchmark for the GYN module. The analysis showed that from 2004 – 2010:

- 4 – 14 laboratories had 1 major error per year, whereas 0 – 1 laboratory had 2 or 3 major errors per year.
- 0 – 7 laboratories had 2 unacceptable responses,
- 0 – 3 laboratories had 3 unacceptable responses and
- 0 – 1 laboratory had 4 unacceptable responses per year.

### 4.4. BENCHMARKS

Each laboratory’s results will be reviewed within a rolling twelve month cycle. When a laboratory’s results fail within the criteria for unacceptable performance, the laboratory’s results will be forwarded to the Cytopathology Performance Review Committee for review. If the Committee assesses the results as being unacceptable, a notification letter will be sent from the RCPA QAP to the laboratory suggesting corrective action.

The following criteria relating to unacceptable performance in gynaecological cytology have been developed by the Cytopathology PRC:

- A Performance Measure outside the National Standard set by NPAAC (The committee agreed that Performance Measure 2b is particularly important)
- Non submission of results for Performance Measures
- A major error in a GYN survey
- Three unacceptable responses in any GYN survey in any twelve month period
- Non submission of results for any GYN survey

After results have been reviewed by the Cytopathology PRC, and where appropriate, laboratories results may be highlighted to the RCPA QAP Board of Directors.
4.5. TRIAL OF BENCHMARKS

The trial period ran from January to June 2012. During this period participants submitted results for two GYN conventional slide surveys and one submission of Performance Measures data. There are 50 Australian laboratories enrolled for the GYN module and Performance Measures. Results from the GYN module survey 1 showed three laboratories with a major error. Results from the Performance Measures part 1 submission showed 3 laboratories outside PM1 and 9 laboratories outside PM2b. This resulted in letters of notification being sent to 12 laboratories and a registered letter was sent to the Director of Pathology of each laboratory. Results from the GYN module survey 2 showed 2 laboratories with a major error, however, this still needs to be discussed with the Performance Review Committee.

One response outlining a laboratory’s corrective action has been received by the RCPA QAP to date. However it should be noted that assessment of corrective action is the responsibility of NATA and not the RCPA QAP.

4.6. STAKEHOLDER FEEDBACK, DIFFICULTIES ENCOUNTERED AND DISCUSSION

For the most part feedback has been positive and there has been a lot of interest in the project. As with the Anatomical Pathology community, some people have been hesitant but any reluctance has usually been overcome when the aims of the project are clarified and they realise it is not designed to be punitive, but as a complement to a laboratory’s quality management system.

The vast majority of feedback was related to a lack of transparency of how the program operates. Jenny Ross, Program Manager was able to present some of these aspects at the ASC meetings and this has appeared to have clarified the project goals substantially.

4.6.1 Collusion

There is some concern that the introduction of performance monitoring may lead to collusion. Some laboratories have indicated they would change the way they perform EQA surveys in light of the knowledge that incorrect responses could have been sent to NATA. Any framework should take this into consideration and the proposed framework has.

4.6.2 Review of Performance Measures

It was noted at the last Performance Review Committee meeting in May 2012 that the national Performance Measures are under review and the time line for release of the revised standards is due in 2013.
5. SOFTWARE DEVELOPMENT

Since the initial demonstration of the performance monitoring analysis software in March, work has been continuing to further develop it.

It has been demonstrated that performance monitoring analysis can be performed using a software solution. Feedback from the disciplines regarding the usability and current functionality has been positive.

The performance monitoring application is now working with production data. Since the demonstration in March the “export” function has been developed. A major technical challenge of this project has been to create a system, which can access participant results from any discipline as well as enrolment details as this data resides in several different databases. We now have an excellent solution in place for the performance monitoring software, which in turn can be further easily extended for other purposes.

Several new technologies have been used on this project. Pursuing these technologies has been worthwhile and they will form a good foundation for other key projects. The new technologies are also allowing existing software applications to access the performance monitoring system.

During this report period the software team has completed the following milestones:

- Enrolment software changes are now running on the live system.
- Transfusion analysis designed, implemented, demonstrated and tested.
- Proven integration of QAP Desktop Software with overall architecture.

Overall the software developed for this pilot provides a good architecture for integrating analysis routines for other QAP programs. The architecture developed will also allow future software application growth in areas that will benefit the participant through dashboard control of EQA performance and ease of access to participation for defined levels within an organisation.

(Report prepared by David Bryce, Software Development Manager)

5.1. DIFFICULTIES ENCOUNTERED

One of the objectives of the project was to develop software for Transfusion and Anatomical Pathology. As outlined above, software has been developed for Transfusion. The Performance Levels and Cumulative Performance Level are reported to participants. Internal analysis software has been developed to calculate the cumulative performance level and identify those participants that met the criteria for unacceptable performance.

Software for Anatomical Pathology has not progressed to the same stage as Transfusion Software development could not begin until the scoring systems had been established and finalised. Following this process, requirements and specifications needed to be documented, before software development could begin.
RCPA QAP employed two contract staff dedicated to progress the project. After three months one of these contractors dropped to part-time causing an unanticipated set back.

The RCPA QAP has undertaken a significant transition in software throughout the company. Transfusion had already transferred to the QAP software analysis and reporting platform for the General Compatibility module before the project started. The Anatomical Pathology QAP transition to this software was expected in early 2012 but has experienced some difficulties, delaying this process.

Significant feedback has been received from the Anatomical Pathology community. At the last RCPA QAP Board of Directors meeting in April 2012, it was recommended that the models for Anatomical Pathology be scrutinised again, to take into consideration any proposed changes to the internal running of the APQAP. It would be prudent for this to be done before software is developed for Anatomical Pathology KPIs.
6. FRAMEWORK

One of the objectives of the project was to develop novel protocols to use ongoing EQA results to monitor performance.

Before this project was commenced, RCPA QAP reviewed how performance of EQA was monitored in other jurisdictions. The framework subsequently developed, was modelled on the UKNEQAS approach and adapted for the Australian environment. Extensive consultation was undertaken with Managers and Chairs of programs, with participants throughout Australia and with Fellows and Trainees of the RCPA. The framework will enable the RCPA QAP to offer assistance to participants to enable early corrective action, in the first instance.

The framework has three stages. At each stage a laboratory must meet one of the benchmarks (fall within one of the criteria for unacceptable performance) in order to trigger for a letter of notification to a laboratory.

Performance Monitoring Process for Participants (Figure 3)

1. **Enrolment process**
At the end of every year, participants enrol for the following year. Each participant is given a unique identifying code. When enrolment packages are sent out, participants will be sent a copy of the new framework outlining the process when participants’ results are identified as performing within the criteria for unacceptable performance. As part of the enrolment process, the performance monitoring project will be outlined in the general information with a statement explaining that enrolment in the RCPA QAP acknowledges that performance monitoring of EQA results is now part of RCPA QAP processes. The enrolment process captures participants enrolling for education only, specialisation of Pathologists’ for Anatomical Pathology diagnostic modules and contact details of supervisors including Director of Pathology.

2. **EQA results fall within the criteria for unacceptable performance the first time**
When unacceptable performance has been identified, according to the criteria developed for each module, letters will be sent to the participant and supervisors detailed on the contact page at enrolment. The letter offers assistance to review the QAP results.

   Results within the criteria for ‘participation indicators’
   - The QA Program Manager will send a letter of notification.

   Results within the criteria for unacceptable performance for ‘test performance indicators’
   - The EQA results are reviewed by the Program Performance Review Committee. The experts on each committee will review all EQA results for that module in their context.
   - A letter of notification is sent to those participants / supervisor(s) whose results are considered to fall within unacceptable performance.
- A report prepared by the Program Performance Review Committee will also be sent to the participant and supervisor(s) and is available to the RCPA QAP Board and NATA on request.

Potentially critical situations as defined by the performance criteria
- When the Committee have greater concerns regarding performance of a participant, the EQA report, letter and Committee report are referred to NATA.
- Participants falling within the criteria for unacceptable performance will be monitored for one year, to review the progress of their EQA results.

3. **EQA results fall within the criteria for unacceptable performance a second time**

Those participants whose results fall within the criteria for unacceptable performance a second time will be escalated to the next level of action by the RCPA QAP.

All results within the criteria are reviewed by the Program Performance Review Committee.
- The experts on the committee will consider all EQA results for that module in their context.
- A letter of notification, from the Program Performance Review Committee Chairperson, is sent to those participants / supervisor(s), detailed on the contact page at enrolment, whose results are considered to fall within unacceptable performance.
- A report prepared by the Program Performance Review Committee will be sent to the participant and supervisor(s) and is available to the RCPA QAP Board on request.
- Where appropriate, the Program Manager may also phone the participant to offer assistance to review any problems.
- Results of participants falling within the criteria for unacceptable performance will be monitored for one year, to review the progress of their EQA results.
- A copy of the letter sent to the participant, EQA report(s) and report from the Program Performance Review Committee will be sent to NATA for their consideration and follow-up directly with participants.

4. **EQA results fall within the criteria for unacceptable performance a third or subsequent time**

- After results have been reviewed by the Program Performance Review Committee, the Board of RCPA QAP will formally review all results.
- EQA results from other relevant Quality Assurance Programs will also be reviewed by the Board at this time to ascertain if there is unacceptable performance in other testing or if what has been reported is isolated to one discipline or module.
- The findings of the RCPA Board will be communicated to the Director of Pathology of the organisation concerned.
- Copies of all letters and Committee reports will also be sent to the participant and supervisors detailed on the contact page at enrolment.
- In addition a copy of the letter sent to the participant, supervisors and Director of Pathology, EQA report(s) and report from the Program Performance Review Committee(s) will be sent to NATA for their consideration and follow-up with the participant.
Figure 3.

1. Enrolment in QAP (Identify supervisors in contacts list).

2. Criteria: Identification of results falling outside the criteria for acceptable performance.

   - Action: Performance of test – referred to Performance Review Committee for review. First letter and PRC report sent to participant and supervisor(s).
   - Action: Non-participation – First letter sent to participant and supervisor(s) by the Program Manager.

3. Criteria: Participants results falling outside the criteria for acceptable performance a second time, will be referred to the Performance Review Committee for review.

   - Action: A copy of the letter, EQA results and PRC report is forwarded to NATA.
   - Action: Second letter and PRC report are sent to participant and supervisor(s) from the Performance Review Committee Chairperson.

4. Criteria: Participants results falling outside the criteria for acceptable performance a third time, will be reviewed by the PRC and then will be referred to the RCPA QAP Board.

   - Action: A copy of the letter, EQA results and PRC report is forwarded to NATA.
   - Action: Third letter and PRC report are sent to the participant, supervisor(s) and Director of Pathology from the Chairperson of the RCPA QAP Board.

Participants Results monitored for one year.
6.1 TRIAL OF PROTOCOL

Trial of the protocol from the pilot phase of the project saw the first and second letters of notification sent to some participants and supervisors. Subsequent feedback received after the consultation phase, indicated a requirement for the Director of Pathology to be informed at the first stage of the process, therefore during the pilot phase a copy of the letter was also sent to the Director of Pathology by registered mail, to ensure an audit trail. The process highlighted the need for an automated system to notify appropriate supervisors. During the trial, a report from the PRC was not required to be sent to the participant, as the criteria met by the laboratory for unacceptable performance was clearly outlined in the letter.

At stage two and three of the protocol, when results have fallen within the criteria a second or third time, results would also be referred to NATA for their review and follow-up. This enables results to be reviewed earlier than at a three year accreditation. Legal advice was sought to ensure that the current regulatory framework, including the APA and APP agreements, allows RCPA QAP to send participant information, including results and letters to NATA. The legal advice received stated that RCPA QAP cannot send participant information to a third party, including NATA, without written consent from the laboratory. Due to legal advice received, therefore, RCPA QAP could not refer any results to NATA during the pilot period. Indications from NATA are that it would be useful for them to have this information.

Advantages of the new framework are that:

- Laboratories are actively notified of sub-optimal performance.
- The number of results expected to be referred to NATA should be manageable in terms of workload and highlights those laboratories requiring attention.
- The Performance Review Committee is an expert group of pathologists and scientists that could be used as a resource in the future.
7. TEST KITS

An objective of this project was to establish mechanisms to use EQA data to help monitor quality of test kits.

In collaboration with IVD Australia and the Therapeutic Goods Administration the RCPA QAP developed a framework to manage situations when an IVD is identified in the EQA to be performing significantly different to other IVDs.

**Performance Monitoring Process for Commercial IVDs** (Figure 4)

Data returned to the RCPA Quality Assurance Programs, from time to time identifies test kits or methodologies (in vitro diagnostic medical devices or IVDs) performing outside acceptable levels of performance, or significantly different from other IVDs. This can be identified when a group of participants are seen to be performing significantly different.

IVDs identified as performing outside acceptable levels of performance, are reviewed by the Program Performance Review Committee (PRC). A representative from IVD Australia will be invited to review these findings with the PRC. If these findings are considered of significant concern, manufacturing companies or their sponsors will be notified to enable them to investigate further. The Therapeutic Goods Administration (TGA) will also be advised to enable more rigorous pre-market testing of similar IVDs. Any results released in this instance would not disclose the identification of individual laboratories. Ordinarily participants would be able to view performance of all test kits, in the reports.

For IVDs found to be performing outside acceptable levels of performance, the Performance Review Committee report and any discussions with manufacturers, their sponsors or TGA are referred to the RCPA QAP Board for formal review.

**7.1 TRIAL OF PROTOCOL**

From time to time the RCPA QAP has identified IVDs performing significantly different, however, during this project period no IVDs were identified.
Framework using EQA results for Performance Monitoring of Commercial In vitro diagnostic medical devices (IVDs)

Figure 4.

1. Enrolment in QAP.

2. Results outside acceptable levels of performance or significantly different from other IVDs identified by the QA Program.

3. Results outside acceptable levels of performance for an IVD reviewed by the Program Performance Review Committee (IVD Australia representative invited).

4. Manufacturing company or their sponsor informed of EQA findings.

5. Findings and discussions with the manufacturer, their sponsor or TGA referred to RCPA Board.

Refered to TGA
8. DISCUSSION

External Quality Assurance is one aspect of a quality management system in a laboratory and accreditation requirements. This project was designed to determine if the regular EQA that laboratories perform can be used to identify unacceptable performance earlier than the usual 3 year NATA accreditation cycle, to help to minimise risk to patients. A more ‘real time’ review of performance.

Establishing an early warning system, based on minimum benchmarks that would be expected for corrective action or relative unacceptable performance compared to peers, identifies laboratories of concern early. Review of corrective action of persisting suboptimal performance by NATA at the time it was completed is also beneficial and assists in prevention of risk to patients.

Monitoring performance of EQA brings with it a level of anxiety and this must be balanced with the increased risk of collusion. While EQA is one of the most objective mechanisms of assessing performance, the fear of being ‘penalised’ continues to some degree and needs to continue to be addressed. In addition, stakeholder feedback indicates that enrolments for 2012 (for Anatomical Pathology) have decreased as a direct result of the Performance Monitoring project and therefore has impacted on business revenue. RCPA QAP would not want to be placed at an unfair disadvantage in an open market environment.

A framework was developed and an extensive consultation process highlighted several internal operational issues that need to be addressed by RCPA QAP such as selection of suitable cases for assessment and separate cases for educational purposes. More significantly the issue of enrolment for anatomical pathology laboratories needs addressing urgently and this should be done through the regulatory framework, in particular through NPAAC standards.

One major difficulty encountered during this project was the inability to send or receive any data from NATA, to validate the benchmarks and the process. Correlation of Chemical Pathology KPI data with NATA on-site assessment records could not to be achieved. A further barrier is that RCPA QAP was unable to refer any results to NATA that met the established benchmarks. The Legal view received from Norton and Rose lawyers was that the RCPA QAP is not currently authorised to release quality assurance results of an Australian laboratory enrolled in a programme run by RCPA QAP to NATA. This barrier needs to be addressed at a regulatory level by the Department.

Further work needs to be undertaken to review and make the relevant changes to the Chemical Pathology KPI report by the PRC and key stakeholders. Similarly, anatomical pathology internal processes need to be reviewed and revised to ensure a fair and equitable assessment process for performance monitoring and this should be with key stakeholders. In addition a review of the regulatory requirement for enrolment in EQA for anatomical pathology laboratories/pathologists should be addressed, urgently, by the Department.

If these issues are addressed and barrier are removed then the proposed electronic platform, where the performance data of each laboratory was maintained in one area and both the laboratory and
NATA could have access, would be a resource of great value. Performance issues would be highlighted and corrective actions could be recorded and signed off on the platform. Laboratory Directors, assessors and NATA could all view this information, easily and efficiently, all the while providing laboratories with real time monitoring of performance. This will enable laboratories to address problems immediately they occur and the end result should be improved quality which in turn should increase patient safety. In order to realise this great initiative which the RCPA QAP has had very positive feedback on, a considerable amount of software development is required.

Finally, RCPA QAP recommend that a further pilot phase of a minimum of two years is required to test the framework and benchmarks, which will give further time to overcome the barriers of validation of data with NATA and allow resolution of other internal RCPA issues within the Anatomical Pathology QAP.

Work has also begun in preparing performance benchmarks in Microbiology, Serology, Haematology and Immunology. It would be appropriate that any future continuation of the project includes these areas.
9. CONCLUSION

External Quality Assurance is one aspect of a quality management system in a laboratory and a requirement for accreditation. This project was designed to determine if the regular EQA that laboratories perform can be used to identify unacceptable performance earlier than the usual 3 year NATA accreditation cycle, to help to minimise risk to patients.

Monitoring performance of EQA has been demonstrated to be achievable during this project. How well the benchmarks correlate with what NATA consider “high intensity” laboratories, where additional follow-up of non-conformance is required, requires further investigation. Based on the findings of this study the following recommendations are submitted for consideration:

Recommendation 1
A workshop is convened with key participants (e.g. Biochemistry QA coordinators, Quality Managers) to review the use of Chemical Pathology KPI reports and models for monitoring performance of EQA.

Recommendation 2
A study of Chemical Pathology KPIs and correlation with NATA assessment reports is established prospectively.

Recommendation 3
Working parties are established urgently between the professional organisations of Pathology including RCPA QAP, RCPA, NPAAC and DoHA to consider and advise on matters arising from the Anatomical Pathology review including:

- Enrolment in diagnostic Anatomical Pathology EQA for laboratories
- Guidelines for performing diagnostic EQA in laboratories
- Whether assessing performance rather than just participation results in greater collusion and decrease in exposure of interesting cases.
- Standardisation and documentation of selection of cases and assessment of reports
10. REFERENCES

1. The Role of External Quality Assurance in identifying poor laboratory performance funding agreement

2. RCPA QAP. ‘Notes on Key Performance Indicator Report’

3. NPAAC. Requirements for participation in External Quality Assessment (Fourth edition 2009)

Appendix 1. Presentations at meetings and conferences throughout Australia

The Project Officer has presented the project at meetings and conferences throughout Australia as follows:

- 29 April, 2011, AACB Scientific Education Session, Melbourne
- 23-25 May, 2011, Beckman Coulter Chemistry / Immunoassay User meeting, Gold Coast
- 8-11 August, 2011, AIMS / NZIMLS South Pacific Congress, Gold Coast
- 14-15 September, 2011, NATA forum, Melbourne
- 10 October, 2011, AACB Conference, Sydney
- 31 October – 1 November, 2011, HAA Conference, Sydney (presentation plus poster)
- 3 November, 2011, KIMMS workshop, Sydney
- 4-6 November, 2011, AIMS North Coast Division conference, Coffs Harbour
- 26 – 27 November, 2011, NICE (Transfusion) conference, Albury
- 6 – 7 December, 2011, Beckman Coulter Haematology / Haemostasis / Flow User meeting, Melbourne
- 13 March, 2012, Royal Prince Alfred, Sydney
- 28 – 29 April, 2012, AIMS NSW South West Division, Wagga Wagga (oral plus trade display)
- 5 – 6 May, 2012, AIMS QLD meeting, Toowoomba
- 8 – 10 June, 2012, AIMS Tropical Division conference, Cairns

The Project Officer has presented the project to Anatomical Pathologists at meetings and conferences throughout Australia as follows:

- Tues 31 January, 2012, Douglass Hanly Moir, Sydney, NSW
- Sat 10 March, 2012, Pathology Update, Sydney
- Tues 27 March, 2012, QLD RCPA state meeting, Royal Brisbane Hospital, QLD
- Tues 27 March, 2012, QLD RCPA State meeting , Sullivan Nicolaides Pathology, Brisbane, QLD
- Wed 4 April, 2012, Capital Pathology, ACT
- Tues 17 April, 2012, RCPA State meeting (teleconference with Canberra and Newcastle), RCPA, Sydney, NSW
- Fri 27 April, 2012, Wagga Wagga Hospital, NSW
- Wed 2 May, 2012, WA RCPA State meeting, Royal Perth Hospital, WA
- Tues 15 May, 2012, Wollongong, NSW
- Friday 9 June, 2012, Cairns, QLD
- Tues 19 June, 2012, SA RCPA State meeting, Adelaide, SA
- To date, meetings have been unable to be organised in Hobart and Melbourne.

The Project Officer has presented the project Cytopathology at meetings and conferences throughout Australia as follows:

- 9 October, 2011, Australian Society of Cytology annual conference, Perth
- 6 March, 2012, Australian Society of Cytopathology, Queensland Branch, Brisbane
- 7 March, 2012, Australian Society of Cytopathology, NSW Branch, Sydney
- 1 May, 2012, Australian Society of Cytopathology, WA Branch, Perth
- 29 May, 2012, Australian Society of Cytopathology, TAS Branch, Hobart