

RCPA Quality Assurance Programs Pty Limited
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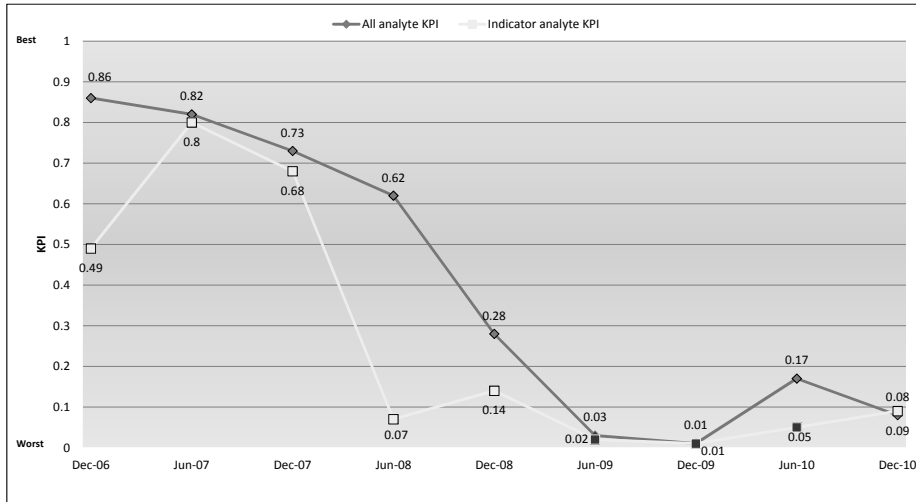
The role of External Quality Assurance in monitoring laboratory performance

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Project Officer – Performance Monitoring Project

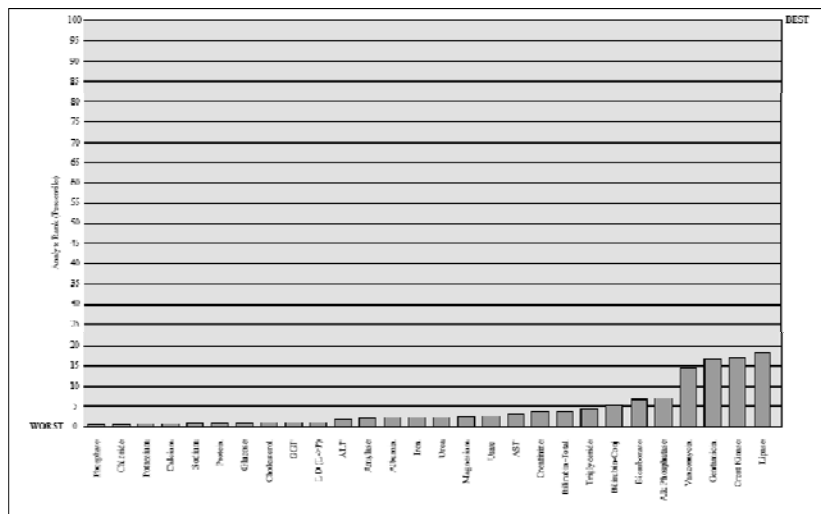
Participant 1

Chemical Pathology QAP



Participant 2

Chemical Pathology QAP



Participant 3

Haematology QAP - Haemoglobinopathy

Case	Actual Diagnosis	Your Diagnosis	Grading
HP9-03	No haemoglobinopathy detected	No haemoglobinopathy detected	Acceptable
HP9-05	Heterozygous Hereditary Persistence of Foetal Haemoglobin	Unacceptable conclusion	Unacceptable
HP9-08	Thalassaemia Intermedia	Unacceptable conclusion	Unacceptable
HP9-10	Heterozygous High O2 Affinity Haemoglobin variant		
HP10-03	Heterozygous Lepore	Heterozygous Beta Thalassaemia	Unacceptable
HP10-05	Heterozygous Alpha Thalassaemia or normal HbA2 Beta	No haemoglobinopathy detected	Unacceptable
HP10-08	Heterozygous Hb D / Alpha Thalassaemia	Unacceptable conclusion	Unacceptable
HP10-10	Heterozygous Hb E / Alpha Thalassaemia	Heterozygous Hb E	Acceptable
	Number of Diagnoses scoring as Unacceptable	5	
	Number of Non>Returns	1	

Participant 4


Haematology QAP - Haemoglobinopathy

Case	Actual Diagnosis	Your Diagnosis	Grading
HP9-03	No haemoglobinopathy detected	No haemoglobinopathy detected	Acceptable
HP9-05	Heterozygous Hereditary Persistence of Foetal Haemoglobin	heterozygous Delta Beta Thalassaemia	Unacceptable
HP9-08	Thalassaemia Intermedia	Unacceptable conclusion	Unacceptable
HP9-10	Heterozygous High O2 Affinity Haemoglobin variant	No haemoglobinopathy detected	Unacceptable
HP10-03	Heterozygous Lepore	Heterozygous Hb Lepore	Acceptable
HP10-05	Heterozygous Alpha Thalassaemia or normal HbA2 Beta	Hb A2 results equivocal, Beta thalassaemia trait not excluded	Acceptable
HP10-08	Heterozygous Hb D / Alpha Thalassaemia	Heterozygous Hb D	Unacceptable
HP10-10	Heterozygous Hb E / Alpha Thalassaemia	Heterozygous Hb E	Acceptable
	Number of Diagnoses scoring as Unacceptable	4	
	Number of Non>Returns	0	

Participant 5

Haematology QAP - Morphology

Case	Actual Diagnosis	Your Diagnosis	Score (max 4)
MO10-02a	Iron Deficiency	Thalassaemia trait	4
MO10-02b	Hb SS (sickle cell anaemia)	Microangiopathic haemolytic anaemia	0
MO10-02c	Acute erythroid leukaemia	Reactive lymphocytosis	0
MO10-05a	Megaloblastic anaemia	Megaloblastic anaemia	4
MO10-05b	Hairy cell leukaemia	Polycythaemia vera	0
MO10-05c	Acute promyelocytic leukaemia-variant	Reactive lymphocytosis	0
MO10-07a	Thalassaemia trait	Congenital macrothrombocytopenia	0
MO10-07b	Acute megakaryoblastic leukaemia	Other congenital neutrophil abnormality	0
MO10-07c	Plasma cell myeloma	Acute myeloid leukaemia with maturation	0
MO10-10a	CLL - Large cell transformation	Chronic lymphocytic leukaemia	2
MO10-10b	Acute myeloid leukaemia with myelodysplasia-related changes	Chronic myeloid leukaemia - blast phase	0
MO10-10c	Mantle cell lymphoma	Acute myeloid leukaemia with minimal differentiation	1
Number of Diagnoses scoring 4 out of a possible 4		2	
Number of Diagnoses scoring 2 out of a possible 4		1	
Number of Diagnoses scoring 1 out of a possible 4		1	
Number of Diagnoses scoring 0 out of a possible 4		8	
Number of Non>Returns		0	
TOTAL SCORE out of possible 48		11	

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Due Date : 14/10/2009	Cycle 9 18 March - 14 October 2009	Laboratory Number <input type="text"/>	
NO RESULTS RECEIVED FOR THIS REPORT			
 RCPA Quality Assurance Programs			

Outline

- Background
- Scope of the project
- Framework

2001

- 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*'.

Report: Chpt 5. External Quality Assurance Programs

- **Recommendation 5.1**
That the DHA and the 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.

- **Recommendation 5.2**
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.

KPI Project

- From this recommendation, in 2004/2005 the KPI project was established by the RCPA and RCPA QAP.

- Key Performance Indicators were setup for Chemical Pathology and Cytopathology with the hope that it could be used as a mechanism to identify unacceptable laboratory performance.

- In 2006/2007 a collaboration was established between RCPA, RCPA QAP and NATA.

- Peer Review Committees were established by NATA to review a limited amount of KPI data.

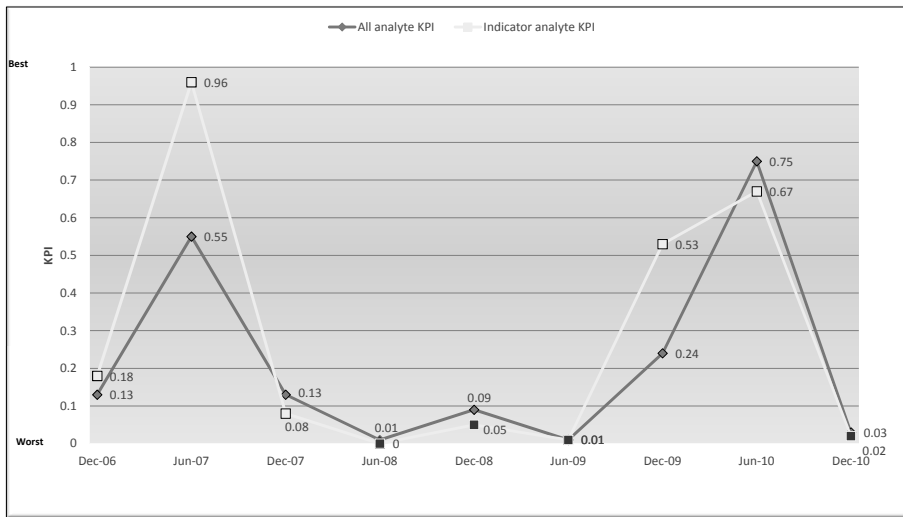
KPI Project conclusions

- 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 NATA assessment.
- The KPIs for Chemical Pathology have continued to be sent to laboratories every 6 months.
- 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.

Department of Health and Aging

“Can we create an early warning system that will help to minimise risk to patients?”

Chemical Pathology QAP



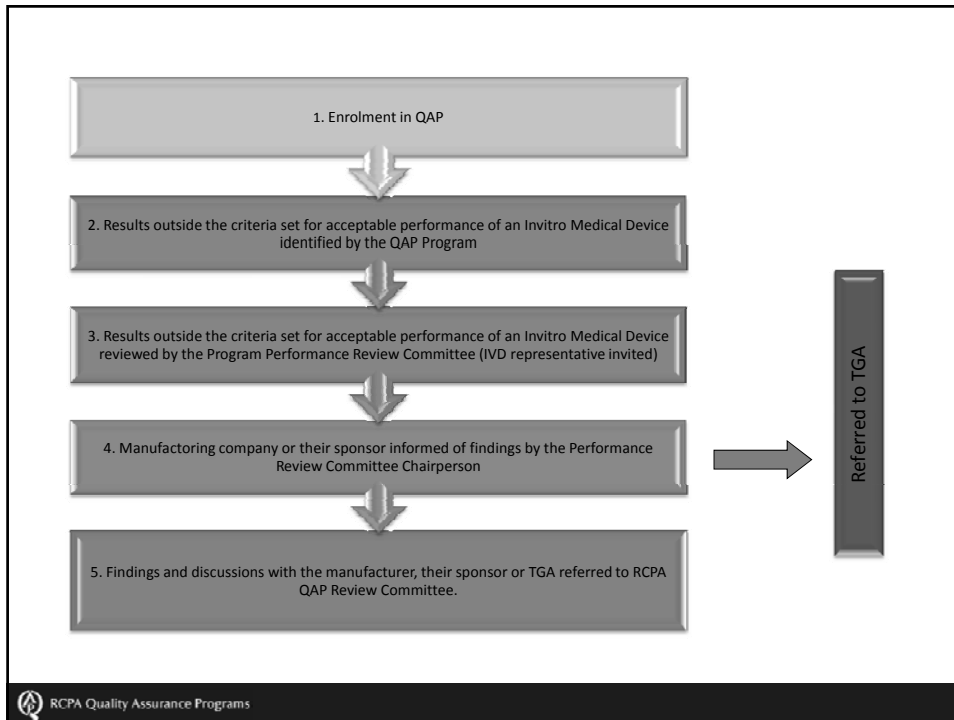
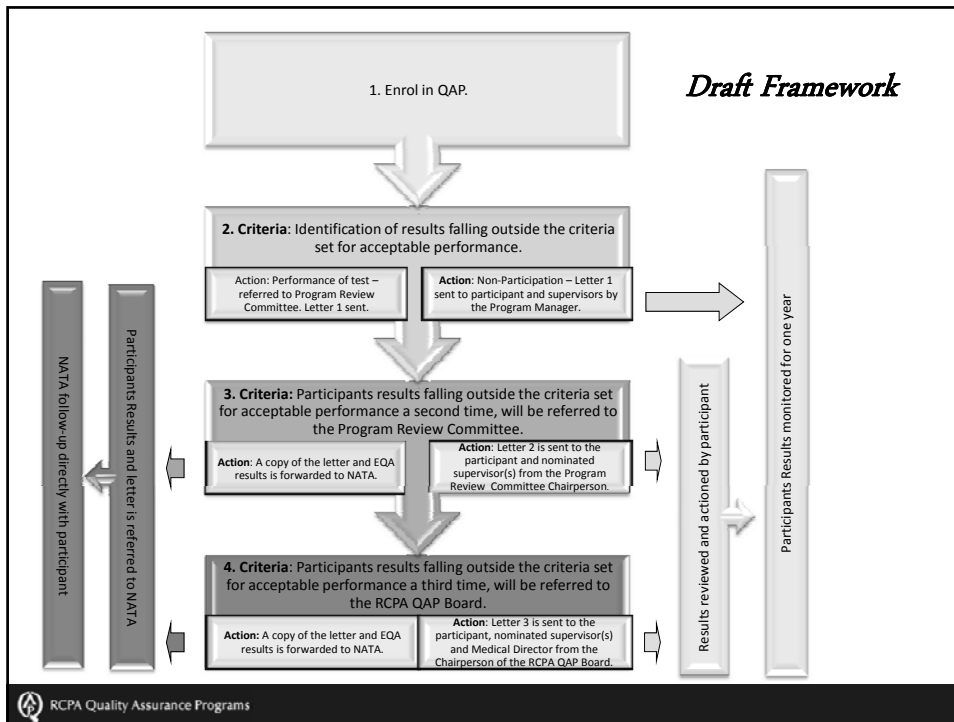
EQA is one aspect of accreditation





‘The role of External Quality Assurance in identifying laboratory performance’

- Review four years of Chemical Pathology KPI data retrospectively
- Develop and evaluate KPIs for :
 - Anatomical Pathology
 - Transfusion Medicine
 - Cytopathology
- Develop triggers of concern using the external quality assurance data
- Trial the protocols to determine whether early indicators of unacceptable performance can be developed around the regular EQA that laboratories perform as part of the accreditation process.
- Establish mechanisms to use EQA data to help monitor quality of test kits



Review process

- Established a methodology / scoring system
- Retrospective data analysis
- Established criteria
 - Test performance
 - Participation
- Reviewed criteria against individual reports
- Assessed fit to framework (workability)

Pilot 2012

- Australian Laboratories
- Programs involved in pilot
 - Anatomical Pathology (General and Breast Diagnostic modules)
 - Gynaenacological Cytopathology
 - Transfusion Medicine (GT Module)
- October 2011 – RCPA QAP company letter to participants
- November 2011 – QA Program letter to participants with details and criteria

Acknowledgments

- Department of Health and Aging - QUPP
- RCPA QAP Program Managers
- RCPA Executive Team
- Program Performance Review Committees

