The road to the latest risk calculations by the RCPAQAP KIMMS Program*

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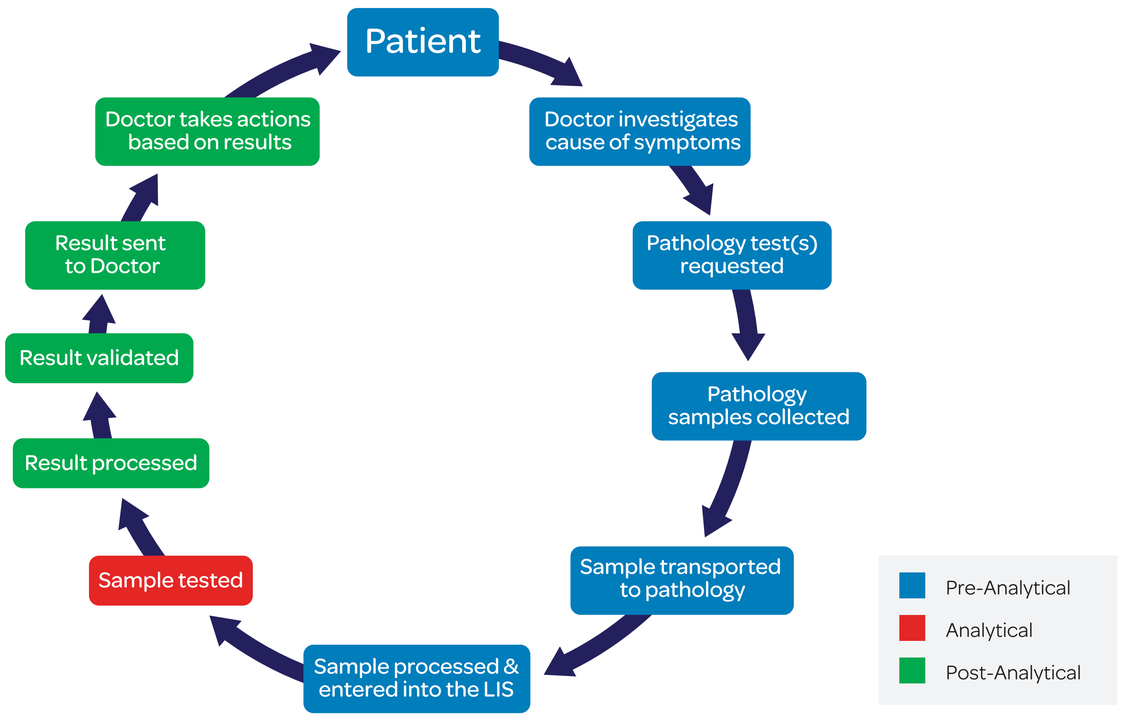
Introduction

Modern Standards documents require that Pathology Laboratories plan and implement actions to address risk. The Royal College of Pathologists Australasia Quality Assurance Programs (RCPAQAP) has been measuring the risks for pre-and post-analytical incidents in its Key Incident Monitoring and Management Systems (KIMMS) since 2011. The calculation has gradually improved as the understanding of risk has matured.

The road to KIMMS new incident risk calculation

- 1996 Khoury, Burnett and Mackay publish "Error rate in Australian chemical pathology laboratories."[1]
- 1999 To Err is Human – a report the Committee on Quality of Health Care in America raised awareness of medical errors in the USA.[2]
- 2007 RCPAQAP develops KIMMS to help monitor the number of incidents that occur in the pre and post-analytical areas of the total testing cycle. Laboratories needed to develop ways to capture this data – primarily via codes added to their LIS's patient record when an incident is detected.[3]

Figure 1. Total testing cycle



- 2010 Not all errors are equal – some pose a greater risk than others. For example, receiving a sample and request allocated to the wrong patient (a rare event) is of higher risk than a haemolysed sample (a common event).
- 2011 A risk matrix is developed – The calculation moved to a Failure Modes and Effects Analysis basis.
- Consequences to the patient multiplied by how easily the incident is Detected equals a risk factor. The risk factor multiplied by the number of occurrences equals the risk.[3]

Consequences	Detection
1 = potential	1 = immediate
4 = recollect	4 = probably
7 = >recollect	7 = unlikely
10 = sentinel event	10 = almost impossible

- 2018 As laboratories improve their pre-and post-analytical processes, more incidents are detected, and the risk increases. This is not correct – the risk should decrease. Thus the risk factor failed to reflect improvements made by laboratories.[4]
- 2020 Risk is based on the consequences to the patient and the Probability that the event will occur and how easy it is to detect the incident. Either a reduction in Probability or an increase in Detectability can reduce the risk.[5]
- 2021 A new 2 phase risk calculation developed
  - Harm factor is equal to Consequences multiplied by Probability
  - The risk score equals o Harm Factor times Detectability.

Scale	Name	Definition
Consequences		
1	Negligible/Minimal	Minimal, Delay, inconvenience
2	Marginal/Minor	Recollect required
3	Significant/ Moderate	Delayed management (non-malignant) and/or medical treatment
4	Serious/Major	Delayed diagnosis (malignant) and/or surgical treatment
5	Critical/Catastrophic	Serious harm to multiple patients and/or patient death
Probability*		
1	Rare	<1/year
2	Unlikely	1 per year
3	Occasional	1 per month
4	Likely	1 per week
5	Frequent	1 per day or more
Detectability*		
1	Detected	Almost all are detected
2	Most detected	
3	Half detected	
4	Most not detected	
5	NOT detected	Almost none are detected

*Each laboratory would need to set its own definition depending on its size.

Examples of how to use the new risk calculation

- COVID-19 tests are a higher risk than other pathology tests, as it has catastrophic consequences because it could affect multiple patients. Assuring the correct result is given to the correct patient in a short TAT is essential.
- A troponin test is of higher risk than a chloride test because the consequence to the patient is higher. Laboratories need to prioritise ensuring the troponin test is robust to reduce the Probability of incorrect results.
- Automatic identification of haemolysed serum samples (using HIL index) and automatically commenting on results affected by haemolysis with algorithms results in a reduced risk due to better detection.
- E-requests, directly entered into LIS systems, are a reduced risk due to a reduction in Probability of patient identification and Missed test errors. They may, however, increase the amount of Mismatched Specimen and Request or Wrong Blood In Tube errors if the stickers are placed on the wrong tubes or containers.

Other risks

- Not all risks lend themselves to this type of risk calculation. They may be better monitored with one-off repeatable audits.
- Risks not covered by KIMMS: Governance structure; Staff competency and ongoing education; Verification, validation and documentation of methods; Reporting results; IT.

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