

InformatICS External Quality Assurance (IEQA) Down Under: Evaluation of a pilot implementation

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Background

External Quality Assurance (EQA) provides ongoing evaluation to verify that laboratory medicine results conform to quality standards expected for patient care. While attention has focused predominantly on test accuracy, the diagnostic phases, consisting of pre- and post-laboratory phases of testing, have thus far lagged in the development of an appropriate diagnostic-phase EQA program. One of the challenges faced by Australian EQA has been a lack of standardisation or “harmonisation” resulting from variations in reporting between different laboratory medicine providers. This may introduce interpretation errors and misunderstanding of results by clinicians, resulting in a threat to patient safety.

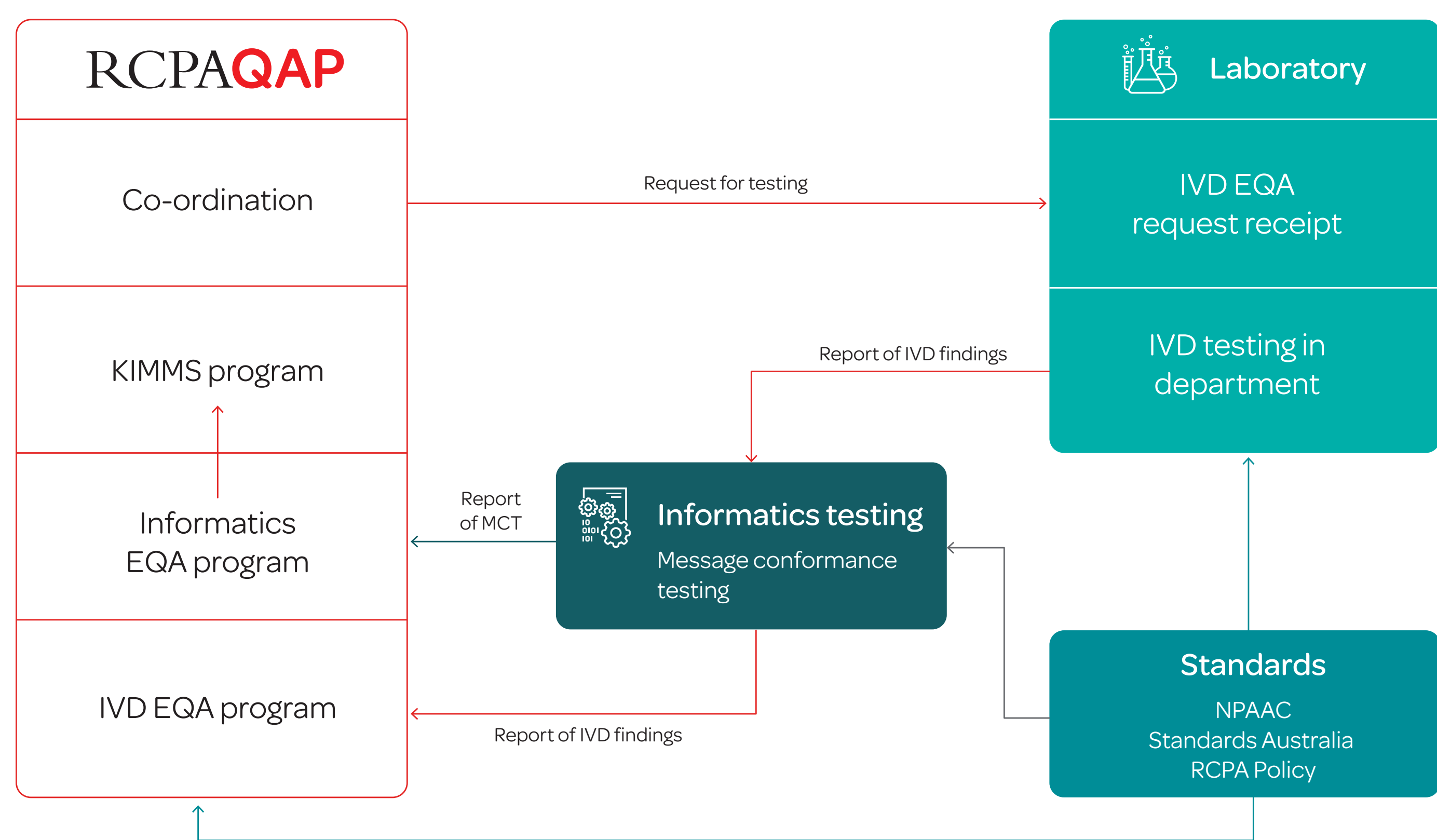
One of the major post-laboratory areas that has been under urgent pressure for improved EQA measures has been laboratory reporting, especially given the widespread adoption of electronic health records which aggregate reports from multiple laboratories, such as MyHealth Record in Australia. The importance for standardisation of the formats and styles used in clinical chemistry reporting are key to interoperability and safety for electronic health records. Significant variations in reporting policies between different Australian laboratory medicine providers, or even within the same provider result in different styles of reports for different customers.

The Australian Pathology Units and Terminology Standardisation (APUTS) project¹, began in 2011 and was the first of 3 projects completed in a program of laboratory medicine informatics standardisation led by the RCPA but which had active involvement from many organisations and individuals. This sub-project endeavoured to create a system to perform quality assurance on the electronic laboratory message when the laboratory sends a result back to the EQA provider itself.

A trial implementation of the IEQA Program

Compliance and standardisation of laboratory medicine terminology are needed to maintain integrity of data shared between sending (laboratory medicine providers) and receiving (physicians, MyHealth Record, registries) organisations’ digital health information systems. The RCPA PITUS (Pathology Information, Terminology and Units Standardisation) 16 Project Working Group 6 collaborated with RCPAQAP to design and analyse a system for reporting data using an IEQA Program, the architecture of which is outlined in Figure 1.

Figure 1. High-level IEQA architecture



In 2015, as part of the RCPAQAP Liquid Serum Chemistry Program (LSC), laboratories were invited to supply a routine paper report displaying results. The LSC program is a commutable frozen patient serum program used to assess method differences. The RCPAQAP then analysed these reports against the Standards for Pathology Informatics in Australia (SPIA, formerly known as the RCPA APUTS v2.3 standard)², and variations were identified³. This provided validation for the rationale for development and trial of an IEQA protocol to test compliance of existing Health Level-7 (HL7) reporting standards with reporting standards developed by the RCPA⁴. The system built was capable of sending standardised electronic request messages and receiving electronic report messages and then analysing the message received. Message services supported Secure Message Delivery (SMD)-based secure messaging. Two laboratories volunteered to send HL7 v2 report messages with atomic clinical chemistry results for the RCPAQAP Liquid Serum Chemistry Program.

Key milestones of the IEQA trial

1. Development of the software by Medical Objects. Two new software modules for the trial implementation, including:
 - a. Multi-component test requests (e.g. liver function test) (electronic requesting of clinical chemistry request orders)
 - b. Quality assurance – compliance rule checking module for HL7 v2.4 report messages against HL7 Messaging Standard v2.4 and AS4700:2:2012 standard; Atomic data in HL7 v2.4 report messages against SPIA, including checking LOINC code, preferred term, reference interval, flagging, alignment and units.

2. Installation, setup, and verification of the system software and communication services
 - a. Medical Objects’ “Explorer” software application installed on computers used for compliance testing.
 - b. Medical Objects’ “Eclipse” communication services used during the trial implementation to electronically send HL7 v2.4 request messages to the participating laboratories as well as receive HL7 v2.4 report messages from the participating laboratories.
3. Implementation of the IEQA Program and compliance testing of the received HL7 v2.4 report messages
 - a. Using Bulk orders module, a clinical chemistry test request for Liquid Serum Chemistry Program was created and an electronic HL7 v2.4 request was electronically transmitted to the two laboratories. Also sent a PDF version of clinical chemistry request form via email.
 - b. The participating laboratories electronically transmitted HL7 v2.4 report messages with the results to RCPAQAP for analysis.
 - c. Quality Assurance module performed compliance rule checks on each received HL7 v2.4 report messages. Assessed:
 - i. Compliance of HL7 v2.4 report message against the HL7 Messaging Standard v2.4 and AS4700:2:2012 standard, including to conformance points in and AS4700:2:2012 standard.
 - ii. Compliance of atomic result data in the HL7 v2.4 report messages against terminology standards (LOINC code, preferred term, reference interval, and units) and harmonised reference intervals described within SPIA (15) (Figure 2).

In the Quality Assurance Module, windows were also provided for the tester to perform manual comparison of the rendered clinical chemistry report against the expected SPIA format, which is important for certain SPIA standards that require manual checking (Figure 3).

Figure 3. Example of Quality Assurance software windows, with report format using SPIA rendered report rules (left) and rendered clinical chemistry report from the HL7 v2.4 report message (right).

The figure shows two side-by-side screenshots of the Quality Assurance software. The left window displays the SPIA rendered report rules, and the right window displays the rendered clinical chemistry report from the HL7 v2.4 report message. Both windows show a table of test results with columns for Test Name, Units, Ref. Range, and Flag. The right window also includes a 'Time' column. The tables list various clinical chemistry tests such as Sodium, Potassium, Chloride, Urea, Creatinine, Bilirubin, and Glucose, along with their respective units and reference ranges.

4. Compilation of a draft Informatics Program Survey Report. These were provided to each laboratory that participated, to assist them in identifying compliant areas and areas requiring further improvement.
5. Review of trial implementation. Presentation of report showing the compliance checking tool to each participating laboratory.

Issues around the implementation

The lack of a significant industry driver to encourage laboratories to configure their laboratory information systems to receive a standardised electronic request message remains a barrier. This barrier would be overcome if there was an IEQA in place to identify those laboratories that were not using the SPIA standards.

Conclusions

For laboratory medicine services to provide quality post-laboratory services to clinicians and patients, it is essential that programs are in place to ensure ongoing proficiency of test result reporting as well as standardisation of test results.

The described IEQA model could be used in any country where there is electronic transmission of requests and results. In Australia there are guidelines for the format of reports and the transmission of results, these would need to be in place as well. This is a key initiative to reduce this under-recognised post-laboratory error. We believe that EQA providers in each country could develop a similar IEQA in the interests of patient safety.

References

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