Implementation of standard pathology messaging:
supporting patient care and a bridge to HL7 FHIR

This paper, developed by IHE Australia, with the support of the Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP) continues a consultation with the pathology governance, service delivery and information system sectors. It is a response to renewed interest in cross-industry adoption of existing Australian Pathology communication and vocabulary standards and proposes a pathway to support industry to implement products that are capable of using these standards reliably.

This pathway will:

- support industry in moving from use of multiple different implementations of HL7 version 2 messaging and various laboratory-based vocabularies to the adoption of the Australian standard message (ADRM 2021.1) and use of standard vocabularies e.g. RCPA Standardised Pathology Informatics in Australia (SPIA)
- improve patient care and streamline communications outside the traditional referrer-laboratory relationship
- provide a focus on the adoption of standard order and result terminologies, within the familiar HL7v2 framework and prepare industry for the anticipated move to use HL7 FHIR based laboratory messaging
- enable pathology laboratories to meet accreditation against communication standards in their inbound and outbound messages.
- provide patient care benefits and support clinician's EMRs with enhanced capacity to use and interpret pathology messages.

While laboratories and referring doctors have been communicating effectively with the current approach to messaging, this has required considerable "translation" effort by messaging intermediary services. Use of non-standard messages and codes has placed limits on the capacity:

- to exchange pathology results with all interested clinical recipients,
- to communicate electronically with quality assurance programmes, cancer registries, and the National Notifiable Diseases Surveillance System (NNDSS),
- to interact with Australia's My Health Record.
- to use pathology information to support clinical care

Moving from development of IT standards to widespread adoption takes a community-wide approach, and a range of tools and methods to support industry adoption. An approach which has worked in many countries and health domains involves foundational work on suitable standards, followed by a refinement and organisation of these standards to meet specific business needs and workflows, along with implementation support, testing and verification.

Internationally, this community co-design and collaboration approach is overseen by Integrating the Healthcare Enterprise (IHE) . IHE's mission to improve healthcare for patients though IT system interoperability, building on and extending the work of numerous standards organisations whose products must be integrated to deliver functional outcomes. IHE's method involves cross-industry collaboration and co-design, industry led standards selection, and integration of existing standards and workflows into a single implementation guide/profile. Profiles that incorporate an agreed set of existing but constrained standards have been demonstrated to support widespread, rapid and less costly deployment. IHE's approach has been widely used internationally within many healthcare specialities and is published by the International Standards Organisation (ISO) as an ISO technical framework. IHE profiles are embedded in many vendor applications and national infrastructures. Domains using IHE profiles include diagnostic imaging systems, medical devices and medical records, lab systems, and health information exchange (HIE), with Australia's MyHealth Record being a prominent local example.

For readers not overly familiar with IHE, these links to short videos may introduce IHE and IHE's methods and IHE's Connectathon events.

IHE Australia, in association with industry sponsors, will be conducting short consultation and education sessions to seek industry input, along with an invitation to join a local IHE Pathology and Laboratory Medicine (PaLM) working group.

The working groups will deliver an integration of ADRM2021.1 and RCPA SPIA coding resources into a single implementation guide (consistent where possible with international IHE standards) and industry access to a technical message testing service supported by RCPAQAP tooling, and end to end testing and fine tuning of vendor implementations in an IHE Connectathon.

Way forward?

The pathology laboratory sector is now expected to meet reporting and quality assurance and accreditation requirements; IHE Australia, RCPA QAP and associated industry sponsors have the capacity to assist in this transition should IT vendors commit to this goal. Other sectors who originate pathology referrals and receive results will be involved as the lab industry moves to adopt standard messaging in order to maintain accreditation. , These include communication services and clinical information system vendors and their respective health service-provider customers.

It is likely that by working collaboratively as an industry, supported by IHE that the time and cost to implementation will be minimised, provided this work occurs in a well governed environment.

The next step will be a series of workshops with key industry sectors to explore their perspectives on these issues, and interest in working with IHE and industry sponsors to address this issue over the next 12 months.

The first workshop focusing on the pathology sector will be held on Thursday 28th November and further consultation with the communication services and community EMR sector will occur through collaboration with the Medical Software Industry Association.

Further background to this proposal is in the associated attachment.

We look forward to working with all users of pathology messaging.

Vince McCauley	Tony Badrick
Chair IHE Australia	CEO RCPA QAP
	Dept Chair NPAAC

For further information or comment, please contact:

Peter MacIsaac
Secretary IHE Australia Admin.australia@ihe.net
www.ihe.net
0411403462

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Attachment A - Background:

Current situation in pathology messaging – proposed direction

Every day, many tens of thousands of pathology results[1] messages are sent between laboratory information systems and clinical information systems using many variations of HL7 version 2 messaging standard and a wide variation of codes for orders and results. Despite the creation of a standard message format and orderable and result codes by HL7 Australia and the RCPA, there has not been widespread uptake or implementation of the standards by message senders (laboratories), messaging intermediaries (transport services) or message receivers (clinical information systems).

The fact that thousands of results appear to be reliably transported, received and interpreted by clinical systems is a testament to the strengths of HL7 version 2 and the capacity of current message services (messaging intermediaries) to transform results messages as they pass through their gateways into formats that are acceptable to the receiving clinical system. Sorting out disparate message formats is just one of the key roles that messaging services play, along with customer engagement and identification, end to end security, and quality assurance of the communication delivery service. The additional cost of maintaining this message transformation system is included in the overall costs paid for by the health system in ensuring the quality and fidelity of electronic communication. Given the key role of messaging services in delivery of HL7 messages, the standardisation of messages will not remove or alter the need for these services; their task will be simplified when message quality improves, and the potential for messaging services to interconnect will enhance overall healthcare for the individual, the population, and the healthcare system for its practitioners and payers.

Barriers to standards adoption in pathology messaging

Other than marginal inefficiency and additional costs, are there real problems to be addressed through driving uptake of standards, and why address these now? The following view represent a generalised perspective on the business case for action. Not all comments are intended to apply to every member of the respective communities covered.

A common barrier to change in the health sector is the imbalance between those who bear the costs of change and those receiving the benefits. Achieving standardisation of messaging comes at a cost to vendors and providers as standards must be implemented, tested, and incorporated as software upgrades. The benefits from standardisation are mostly gained by patients through quality improvement, other vendors who receive the standard messages, and system efficiencies for funders and the health system in general. In the market driven health system, vendors will generally consider upgrading software when their customers or

[1] While this paper refers to laboratory messaging, the same issues apply to radiology result messaging.

other parties are demanding change and are prepared to pay for it. Even then, there are competing corporate priorities and typically, limited internal resources to undertake the required work. The main exception to the market rule is meeting regulatory or health funder change requirements. For the past 20 years, the pathology and clinical information systems vendor industry have not seen sufficient value in pursuing the standardisation of messages or adoption of standardised terminology, while alternative approaches existed; system-wide change appeared to be unachievable.

Green shoots for adoption of standard pathology messages

There have been few examples of standardisation occurring, mainly in areas where regulatory pressure exists. Electronic delivery of results, while primarily aimed at communication with referrers and clinicians, is also needed in reporting results to registries and for quality assurance reporting on test samples (QAP). As these types of systems have become computer based, the value of only dealing in standardised messages is recognised in the interests of quality and to reduce the cost burden on the public purse. The Australian Bowel Cancer registry has the legislative authority to require delivery of reports in a standard form for a limited set of cancer results; this has been adopted by the pathology industry, demonstrating the capacity for change. The RCPAQAP External Quality Assurance (EQA) program sends out regular standardised samples for testing and is moving to extend its results management system to support receipt of EQA test results by standardised HL7 messages and workflows. The RCPAQAP also recognises that the quality use of pathology extends further than the walls of the laboratory, and has a strategic interest in supporting wider implementation of the standards that the industry has set for messaging and terminology.

In 2022, the regulatory environment changed significantly with the National Pathology Accreditation Advisory Council NPAAC) of the Australian Healthcare Quality and Safety Commission publishing the 5th edition of the Requirements for information communication and reporting in pathology. This edition has moved from supporting the adoption of standards, to one requiring standards adoption, which must now be demonstrated during the laboratory accreditation process[2]. Laboratories are audited and accredited against the NPAAC standards by the National Association of Testing Authorities (NATA) Australia and are required to meet all the NPAAC standards including the standards outlined in the Requirements for information communication and reporting. Failure to achieve accreditation precludes pathology laboratory access to Medicare participation. It appears that the NPAAC 5th edition came into force in the federal health insurance act covering accreditation of pathology laboratories in August 2023. NATA is in the first year of formally assessing laboratories against the NPAAC information technology standards. While there appears to be ambiguity in the standards relating to the requirement to adopt SPIA terminologies, this is not regarded as the

[2] Section 4 – Conformance with electronic messaging standards p 19

intention of NPAAC in that terminologies "must" be implemented to the extent that they can be.

Other changes in the digital health landscape are looming for the pathology industry that have the potential to impact on electronic messaging delivery. These include the potential changes to the required level of upload of pathology results to the **My Health Record** where electronic reports and data will need to be submitted (moving on from text-based document formats) to adopt a new standard for laboratory reports based on HL7 CDA and HL7 FHIR. The Australian Digital Health Agency (ADHA) has announced a strategy to deliver a nationwide **Health Information Exchange** (HIE) which will also impact on pathology services and their information system vendors.

Based on IHE's understanding of standardisation adoption and organisational change, it is likely that moving to HL7 CDA or FHIR standards will be facilitated and more safely achieved where messages for results and requests are already in the coded ADRM2021.1 format, also with implementation of the RCPA SPIA terminologies, and reference standard identifiers for individuals and organisations.

One of the areas where HL7v2 shares with HL7 FHIR is HL7v2's ability to support and consume complex standard terminologies or vocabularies. By focusing on facilitating the ADRM and SPIA implementation now, the Australian medical software industry will benefit by adoption of the toolsets and methods needed to move from simple code-sets used in current products, to complex terminologies such as LOINC and SNOMED-CT. Implementation of these within HL7v2 messages will rapidly identify any gaps or issues that need to be addressed before they become part of HL7 FHIR pathology standards. With uptake of terminology standards, it is imperative for systems to update and validate terminologies originating in the ADHA's National Clinical Terminology Service.

Finally, it appears that a viewpoint exists that HL7 version 2 is a legacy and obsolete standard. This view may be more common in policy than delivery-focused parts of the health IT community and has led to underinvestment in maintaining the core version 2 backbone of our current systems. In 2003, HL7 version 2 (created for enterprise-wide interoperability) was to be replaced by Version 3 (created to support data workflows between providers); in 2005, v3 was to be replaced by CDA, due to perceived complexity; in 2014, HL7 FHIR was launched using web standards, as an "easier to implement" alternative to CDA. As Mark Twain might have said were he here now – "the rumours of HL7v2's demise are greatly exaggerated". The adoption of new standards is a medium to long term proposition, with HL7 v2 messages likely to remain the backbone of pathology-clinical system communication for some time yet.

Even as new approaches based on FHIR begin to be implemented, HL7v2 can provide a bridge to the adoption of HL7 FHIR in many sectors.

As a result of the pathology accreditation changes and other influences towards pathology messaging advancement, is there sufficient consensus among a critical mass of clinical and IT stakeholders to standardise HL7v2 implementation in pathology messaging?

If so, there are as many approaches to change as there are stakeholders; however internationally, there is one "stand out" approach that delivers widespread adoption, collaboratively, relatively quickly, and cost effectively – IHE (Integrating the Healthcare Enterprise), but of course we would say that!

Call for support

We would ask stakeholders to indicate their interest in working with IHE Australia to support the adoption of the ADRM 2021.1, common vocabularies for order and result codes (RCPA SPIA Resources), use of standard identifiers, and a standard method for industry deployment (IHE – Integrating the healthcare Enterprise).

Way forward?

Applying the elements and products of IHE standards development for lab messages involves:

1. Industry **education and consultation** regarding the problems to be solved and drivers for change.
2. The formation of **an IHE Australia Pathology and Laboratory Medicine domain strategy and technical committee** to steer the strategy and have industry experts create the technical solutions based on IHE principles, international standards and ADRM2021.1, and SPIA. The RCPAQAP has agreed to sponsor this committee, which will be looking for additional sponsors and active participants.
3. Analysis of the implementation problem from the perspective of **leveraging existing profiles** and the **international experience** and industry capability.
4. The development of a **white paper** describing the IT actors, use-cases, and workflows as a consultation and prioritisation tool.
5. Development of **Interoperability profiles** (also known as Implementation Guides) that draw on, and integrate existing standards (e.g. messaging, vocabulary and identifiers) to address agreed workflows, while constraining standards to remove optionality and ambiguity. The profile must be capable of being implemented consistently and able to achieve the required outcomes.
6. A prioritisation and scoping exercise to develop a staged set of **implementation cycles** determined by industry capacity to adopt change and the logical order of change. Not all journeys can be completed in one step. IHE operates a rolling 14-18 month cycle of profile development, testing and implementation.
7. Provision and adaptation of **validation/test tools and plug-a-thons** to enable vendors to test their products as they develop the profile implementation.

8. Re-establishing a local capability for testing, including adoption of RCPAQAP's testing tools (partially developed using the Caristix toolset), and IHEs testing and connectathon management environment **IHE Gazelle**.
9. Use of formal and regular **IHE Connectathon testing events** to bring vendor engineering teams together for a few days to test and troubleshoot their profile implementation with other vendors who are collaborating actors (e.g. Message sender, message intermediary, message receiver). Successful vendors can promote their achievements at Connectathons, whereas those who require more time are able to do and achieve demonstrable interoperability at a subsequent testing event.
10. Enabling **customers to specify compliance with IHE profiles** in their tenderings and purchasing processes.
11. Reliance by regulators on IHE Connectathons certificates or product related conformance testing as **meeting accreditation standards** for communication, in a similar vein to RCPAQAP role for testing quality.

The success of IHE is based on a reproducible and reliable method building on a genuine and open community of interest with governance based on Standards Development practices to avoid dominance by any stakeholders or sectors and to achieve sufficient, but not always total consensus, within a specified timeline.

One of the core rules of IHe engagement is a commitment by all parties to declare conflicts of interest –there will always be actual and perceived conflicts or sectoral interest that must be balanced. Conflicts and concerns about potential advantage or disadvantage resulting from change are expected to be discussed and resolved early in the process.

Can the same outcome be achieved some other way or by some other leadership group? Of course, the answer is yes and it happens often enough, particularly where:

- priority is given to a "home grown" approach ('we are different"),
- there is limited focus on understanding or willingness to use prior work and international standards,
- there is a reluctance to co-design interoperability solutions with industry
- money is plentiful and technical resources are available.

We argue the case that looking at the long history of IT change and adoption, IHE's middle out model is a good fit for our Australian system, as it has been successfully proven elsewhere.

Experience tells us that other approaches such as top down, bottom up, professional body, academic, project based or consultant led approaches can be more disruptive, more likely to fail, may achieve lesser results, take longer to implement, and are usually more expensive. A project focused or sectoral approach to solution design tends to result in a siloed solution

that meets narrow success criteria, do not inherently look to integration and reuse of what has been done before, or adopt a broad architecturally consistent approach.

This is the reason why IHE is widely adopted by industry and why national digital health bodies collaborate with IHE.

IHE's methods are open for anyone to emulate – but why forgo the capacity to leverage the extensive library of IHE profiles, international and national community, IHE's toolsets, and our accumulated expertise.

For further information or comment

Peter MacIsaac
Secretary IHE Australia Admin.australia@ihe.net
www.ihe.net
0411403462