HL7 Australia Limited

Australian Digital Health Agency Draft Interoperability Plan

Draft: 10 January 2022

Final: 16 February 2022

Executive Summary

The Board of HL7 Australia is pleased to provide comment on the draft National Healthcare Interoperability Plan (the Plan) and to offer recommendations on how we may assist with its further refinement, adoption, and implementation.

Health Level Seven International (HL7) is the major supplier of data exchange standards supporting health interoperability within Australia and globally. Key standards from HL7 include: HL7 Version 2 (V2); HL7 Version 3 (V3); HL7 Clinical Document Architecture (CDA); and HL7 Fast Healthcare Interoperability Resources (FHIR).

HL7 Australia is an Australian limited company and the official affiliate of HL7 International in Australia.

The state of play and the pace of development of healthcare interoperability in Australia is at an all-time low[1]. This Plan must demonstrate how the Australian Digital Health Agency (the Agency) and other federal, state and territory government agencies intend to drive the required step-change in Australian national health interoperability capability. In its current draft, the Plan lacks a sense national, economic and geo-political relevance. It does not offer a rallying cry for the many stakeholders across the Australian digital health landscape and beyond to really get behind the required uplift in activity and outcomes required.

The Plan should rebuild commitment in national standards and trust in the associated government agencies upon which the Agency must rely. We suggest this can be done by demonstrating how the actions in the Plan will foster a sustainable capability uplift across public and private sectors, not just for potentially time-limited, partisan initiatives. To this end the Plan needs to speak to a broader audience than would appear to be the case in the draft.

We provide five recommendations that we believe will assist in a sustainable uplift in healthcare interoperability standards for Australia, commencing in 2022.

In Recommendation 1, we argue for the establishment of a National Interoperability Standards Governance Group, to provide the oversight, governance and advocacy required to ensure all the moving parts required to achieve interoperability in Australia have been identified, actioned and are effective.

In Recommendation 2, we encourage the Agency to act globally as it looks to accelerate the pace of standards development, by jointly establishing a National FHIR Standards Management Group with HL7 Australia which will be responsible for the development and operation of a FHIR Community Process for Australia.

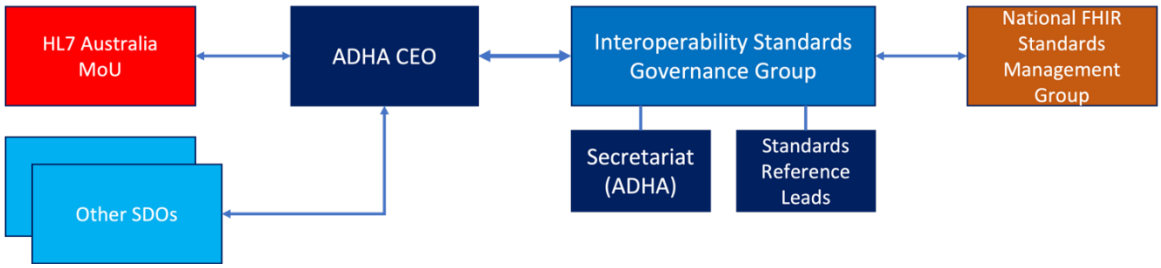
In Recommendation 3, we propose the Agency enter a Memorandum of Understanding with HL7 Australia to support the scaled, sustainable, and timely development, implementation, and maintenance of HL7 standards and to fast track the localisations of Agency defined, HL7 specifications and their joint copyrighting by HL7 International and HL7 Australia.

In Recommendation 4, we encourage the Agency to show leadership on standards conformance through the National Interoperability Standards Governance Group (proposed in Recommendation 1) and through the provision of tooling to support implementation testing.

In Recommendation 5, we outline a roadmap for joint action in 2022.

[1] A Health Interoperability Standards Development, Maintenance and Management Model for Australia, Final, Version 1.1, 28 January 2020. ADHA.

Figure 1: Relationships between the entities referenced in our recommendations.



Introduction

The Board of HL7 Australia welcomes the opportunity to comment on the Draft National Interoperability Plan (the Plan) and to provide recommendations for how we can assist the Australian Digital Health Agency (the Agency) to further shape the Plan such that it may collectively deliver a step-change in health data interoperability for Australia.

Health Level Seven (HL7) International is the major supplier of data exchange standards supporting health interoperability within Australia and globally. HL7 International is a not-for-profit standards development organisation whose mission is to provide standards that empower global health data interoperability.

HL7 Australia is a limited company and the official affiliate of HL7 International in Australia. As an independent legal entity our role as an HL7 International affiliate is to:

- Represent our members at HL7 International and within Australia on HL7 matters.
- Participate in the HL7 International standards development processes.
- Promote the relevance and fitness of the HL7 protocol specifications, HL7 educational material and other HL7 material within Australia.
- Distribute, translate, and localise the HL7 protocol specifications as appropriate.
- Administer and oversee HL7 electronic certification tests as appropriate.
- Promote HL7 standards and educate, inform, and support current and potential users within Australia to promote consistent and widespread usage of the standards.

Importantly, the right to create, reproduce, distribute, and control the use of HL7 V2, V3 and CDA localisations[2] within Australia is exclusively granted to HL7 Australia. Localisations created by other organisations, including the Agency, cannot be regarded as HL7 localisations. Rather, they are proprietary specifications. Further, HL7 International grants HL7 Australia the exclusive right to determine and/or publish the HL7 FHIR Implementation Guides that are considered to be the base FHIR implementation rules for Australia.

The work of HL7 Australia is conducted through a structure of Work Groups, currently covering the domains of Child Health, Orders and Observations, Medications and Patient Administration. In the main these are volunteer run Work Groups, with elected, volunteer, Co-Chairs supporting the development, review, and maintenance of standards with the involvement of HL7 Australia members, clinicians, informaticians and other subject matter experts as required.

Australian localisations of HL7 protocol specifications, requiring a successful ballot by HL7 Australia, are examples of affiliate localisations and are jointly copyrighted by HL7 International and HL7 Australia. No change or additions to the HL7 protocol specifications may be made in Australia without the written approval of HL7 International, except for the production of localisations by HL7 Australia.

Affiliates like HL7 Australia are authorised to enter into formal agreements with third parties to create, reproduce, publish, and distribute affiliate localisations, provided these are balloted by the membership of the affiliate.

With the goal to reaffirm the role of HL7 Australia as a key enabler of interoperability and standards development in Australia, in late 2020, the Board of HL7 Australia convened a series of workshops with members and stakeholders to input into a strategy for the company for the coming three years (2021-2023). Our four strategic objectives for this coming period are to:

[2] Work products made by constraining and/or supplementing HL7 protocol specifications, HL7 educational materials and /or other HL7 material to meet the specific needs within the Affiliate's Territory but not including a translation. Affiliate localizations of HL7 protocol specifications require a successful ballot at the Affiliate level.

1. Position HL7 in the national framework for interoperability standards;
2. Support development of localised standards;
3. Grow our community;
4. Promote adoption and conformance to HL7 Australia standards.

These strategic objectives are well aligned to support the objectives of the draft national interoperability standards plan, which as we propose in our comments and recommendations below, will require genuine collaboration and resourcing.

In addition to the recommendations outlined in this submission, the Board of HL7 Australia offers a side process for a governance review of the Board, with the view of ensuring explicit stakeholder representation capable of ensuring consistency or leadership, governance, and representation.

Responses to Online Questions

1. Interoperability Principles

Do you support the Interoperability Principles in section 3.1, or should some principles be amended, added, or removed?

The concept of interoperability principles is supported because they provide a framework, when adopted, to support a globally consistent approach to interoperability standards development.

If the Plan is to be relevant to the development of all interoperability standards in Australia, these principles need to be universally relevant. As currently written, the principles in section 3.1 are more akin to Agency performance criteria.

We commend the following five principles for interoperability, more details for which can be found in Legg M (2013) and Grieve G (2011)[3]:

- Transmission of data without loss of fidelity
- Information structures and common terminology – structure (data elements), terminology and display of healthcare information is all required to convey meaning. Each are required to support:
    - Records (data capture)
    - Decision support
    - Meaningful communications
    - Analysis and classification of health information
- Identification policies – in a federation that is part of a global digital health economy, identifying people and entities remains a complex and challenging task, particularly because of the need to consistently identify the same entity over time and because of the challenges associated with assigning and then managing an unique identifier, typically involving registries.
- Behavioural agreement (model) – interoperability requires an organised approach to defining what exchanges can happen, when they happen, and how they relate to the business processes they serve.
- Common understanding – documentation (specifications), test schemas, access to the community of standards developers, etc are all critical for ensuring there is a common understanding about what is being implemented and agreement that it has been implemented as intended.

If we regard the 'principles' in section 3.1 as performance criteria for use in evaluating the plan, we offer the following comments and suggestions.

Present each criterion as succinctly as possible with the following information elements:

- Name/Title
- Statement/Description
- Rationale

[3] Adapted from Legg M, Standardisation of test requesting and reporting for the electronic health record, Clin ChimActa (2013), http://dx.doi.org/10.1016/j.cca.2013.12.007; and Grieve G, Healthcare Interoperability [online] Available from: http://www.healthintersections.com.au/?page_id=208

- Implications
- Performance indicators / expected outcomes

We also suggest adding criteria that relate to:

- Open, transparent, and representative collaboration.
- Interoperability success criteria for multiple contexts such as:
    - Care setting (e.g., primary, acute, and aged care)
    - Solution domain (e.g., diagnostics, medication management, continuity of care, patient administration)
    - Region (e.g., international, national, state/territory).

2. Implementation Actions

Are there any key actions missing to promote the objectives of this Plan?

General

- Additional immediate and short-term actions focussed on addressing workforce issues should be included, especially in the areas of standards development, architecture, and software development.

Identity

- Add an action with a short-term timeframe relating to the Health Delivery Modernisation program to support rationalising of the various national/government provider and organisation identifiers in favour of the HI Service HPI-O and HPI-I.
- Add an action with a short-term timeframe to enhance the HI Service by allowing consumers with an Individual Healthcare Identifier (IHI) to have more agency in the use and control of their IHI and those for whom they are an authorised representative (e.g., children).
- Add an action with a short-term timeframe to enhance the HI Service to allow consumers to securely assert their IHI to other digital health services on the web or via mobile applications potentially by associating the IHI with myGovID.
- Add an action with an immediate timeframe to consider the need for additional national identifier types. For example, digital health infrastructure operator organisations e.g., directory operators and electronic prescribing prescription delivery service operators.

Standards and conformance, governance, and incentives to support interoperability

- Add an action with an immediate-term timeframe for the establishment of a national health interoperability standards governance body to orchestrate a sustainable uplift in the development, endorsement, and implementation of national digital standards for Australia. (See our Recommendation 1 below.)

Information Sharing

- Add an action with a short-term timeframe to establish a FHIR registry national infrastructure service for sharing FHIR technical artefacts which support and enable information sharing.

Innovation enabled through interoperability

- Add an action with an immediate-term timeframe to develop a program of incentives for software developers to develop and contribute to open-source projects which implement national standards.
- Add an action with an immediate-term timeframe to develop events which showcase and present awards for excellence in standards development and implementation.

Would you like to see any changes to the scope or timeframe of the proposed actions?

The timeframe of the following actions should be changed from short to immediate term:

- Action 4.1 (HI roadmap).
- Action 5.3 (Terminology mappings).
- Action 7.3 (innovation challenges and connectathon)
    - existing, and in-development specifications and infrastructure is already available to support innovation challenges and connectathon events; and
    - such events require planning and coordination.

The timeframe of the following actions should be changed to short-term:

- Action 5.9 (standards catalogue)
    - the prerequisite for an effective standards catalogue will require orchestrated activities involving several stakeholders and should be prioritised by the proposed national health interoperability standards governance group.
- Action 6.8 (business case for a national publish-subscribe service)
    - Development of a business case should not require 3-5 years.
- Action 6.10 (statutory definitions).
- Action 6.11 (collaboration to harmonise statutory definitions).

The timeframe of the following actions should be changed to ongoing:

- Action 9.2 (update plan from 2025 to 2030)
    - the Plan should be updated frequently in response to the needs of the community, changes in the sector and to demonstrate it is a live plan.

Are there any actions that your organisation would like to be involved in progressing, and what would that involve?

Through our representation on the proposed National Health Interoperability Standards Governance Group (Recommendation 1); the National FHIR Standards Management Group (Recommendation 2); and our proposed Memorandum of Understanding between HL7 Australia and the Agency (Recommendation 3), HL7 Australia would like to be involved in progressing, in whole or in part, the following actions:

- Action 4.1 (HI roadmap)
    - We are particularly supportive of this action, on the basis that consideration will be given to the use of HL7 FHIR interfaces and the review of data elements and permissible values to ensure the Healthcare Identifiers Service remains fit for purpose.
- Priority actions for national interoperability standards: 5.4, 5.6, 5.7, 5.8, 5.9
- Priority actions for safe and secure information sharing: 6.3, 6.7, 6.8, 6.9, 6.10 and 6.11
- Capacity building action 7.1 and 7.3

- Action 8.5 (global interoperability maturity model)
- Action 9.3 (incentives to support and accelerate interoperability)

3. Interoperability Initiatives

Which, if any, of the implementation initiatives in section 7.4 would you like prioritised for delivery and why?

Practice-to-practice record transfer

- We would like to see priority given to enabling practice-to-practice record transfer. Initial work on this initiative has received significant community support by several vendors and standards developers, however, there is the urgent need for: alignment of resources (to reduce the risk of redundancy); alignment on community engagement (clinical and technical); and assistance with balloting and publishing.

Pathology orders and terminology for results

- Many enablers for the digital models of care listed in section 7.4 i already exist and HL7 Australia's Orders and Observations (OO) Work Group is well placed to assist with several of these initiatives.
- Whilst enhancements such as the flagging of abnormal results are supported, we suggest each of these initiatives need to be supported by more explicit and transparent requirements for information governance.
- In Recommendation 1 below, we make the point that each standard requires a plan. A common shortcoming associated with standards implementation, particularly in the pathology domain, is the lack of awareness by health service leaders about the actual level of compliance with information governance requirements for safe implementation of their own systems and services. We provide more information and some suggestions for enhancing the quality and safety of standards, focusing on diagnostics, in Appendix A.

4. General Feedback

Is your organisation leading any activities that should be identified in the final Plan?

We request that the final version of the Plan acknowledge the balloting and finalisation of the next version of the AU Base FHIR Implementation Guide.

Do you have any additional feedback on the Plan?

We offer the following additional comments on the Plan. We have developed our recommendations listed below to help address our comments.

The objectives of the Plan are not well defined. It is not clear how the actions provide a pathway from the current state to the future state or how these would be measured. Public investment in the Plan should provide transparency and accountability for what will be delivered by when and what the value of such delivery will be for the Australian healthcare system and ultimately consumers. We have suggested above the interoperability principles in section 3 should be recrafted as performance criteria for the Plan.

As a national resource, the Plan lacks a sense of importance, urgency and national (economic, geo-political) relevance. The state of play and the pace of development of healthcare interoperability in Australia is at an all-time low[4]. The plan must demonstrate how the Agency and jurisdictions intend to drive the required step-change in Australian national health interoperability capability.

This should be a plan to rebuild trust in the Agency and in the associated government agencies upon which the Agency must rely. This can be done by demonstrating the actions in the Plan are designed so that they foster a sustainable capability uplift across public and private sectors, not just for potentially time-limited, partisan initiatives.

We advocate below on how we believe a sustainable capability uplift can be achieved.

In Recommendation 1, we argue for the establishment of an inclusive, expert, multi-stakeholder governance group to provide the oversight, governance and advocacy required to ensure all the moving parts required to achieve interoperability in Australia have been identified, actioned and are effective.

In Recommendation 2, we encourage the Agency to think and act globally as it looks to accelerate the pace of standards development, by establishing a HL7 FHIR Community Process for Australia and by establishing a National FHIR Standards Management Group.

To tackle the unsustainable dependency on largely volunteer-based standards development organisations, in Recommendation 3 we request the Agency enter a Memorandum of Understanding with HL7 Australia to support the scaled, sustainable, and timely development, implementation, and maintenance of HL7 standards and to fast track the localisations of Agency defined, HL7 specifications and their joint copyrighting by HL7 International and HL7 Australia.

In Recommendation 4, we highlight the need for tools to support implementation testing for key interactions in each clinical domain and for national infrastructure to support the Plan by making accessible, existing or new tools to support conformance testing.

In Recommendation 5, we advocate for the need for agreement on a bold roadmap of joint action in 2022.

[4] A Health Interoperability Standards Development, Maintenance and Management Model for Australia, Final, Version 1.1, 28 January 2020. ADHA.

Recommendations

R1. Establish a Multi-stakeholder National Interoperability Standards Governance Group

As a priority and in collaboration with the Commonwealth Department of Health (DoH), we recommend the Agency establishes a multi-stakeholder national health interoperability standards governance group to bring about a sustainable uplift in the development, endorsement, and implementation of national digital health interoperability standards for Australia.

First and foremost, this governance body must raise the profile and economic value of interoperability standards in Australia by securing sector wide commitment to a coordinated and measurable uplift in the development and safe adoption of standards across the whole of health and social care.

In establishing this governance body, we commend the collaboration and consensus building option (Option 3) detailed in the *Health Interoperability Standards Development, Maintenance and Management Model for Australia* report[5]. We support the Agency to auspice this governance body on the basis that the current leadership recognises that without the collaboration of multiple stakeholders, there will be no sustained and effective progress to deliver interoperability in Australia. As a suggestion, the Agency CEO and DoH First Assistant Secretary Digital Health, or their nominees, should alternate chairing of this governance body.

We see sector-wide engagement and collaboration including digital health agencies in all jurisdictions, national agencies such as Australian Institute of Health and Welfare (AIHW), Independent Hospital Pricing Authority (IHPA) and the Australian Commission for Safety and Quality in Health Care (ACSQHC), clinical and vendor communities, industry, and Standards Development Organisations (SDOs) including HL7 Australia.

The significance of and justification for the urgent establishment of this governance body is three-fold:

A. Standards require a plan – there needs to be a transparent process for what standards are trying to achieve and guiding principles for how this is to be done. This will require the involvement of those stakeholders whose responsibility it is - or should be – for ensuring policies are in place that will support the development, implementation, and incentive for adoption of the standard(s). Ownership of many of the required policies that have a bearing on standardisation are likely to be outside the scope of the Agency and will cover areas such as ethics and privacy, record management, retention, and business continuity[6]:

   Some of these policies and related enablers will rely upon alignment with international standards and agencies. The criteria and obligations for membership of this multi-stakeholder governance body must meet clear and transparent credentials and accountabilities as they relate to the relevant standards, communities of interest and evolving policies.

B. Healthcare standards require clinical leadership – Standards must be appropriate to the clinical setting; implementable; understandable (not the least because they must support the terminology used by clinicians); and they must be acceptable to clinicians. Without informed, contemporary clinical input into the planning for new standards (or the replacement of legacy

[5] A Health Interoperability Standards Development, Maintenance and Management Model for Australia, Final, Version 1.1, 28 January 2020. ADHA.

[6] Legg M, Standardisation of test requesting and reporting for the electronic health record, Clin Chim Acta (2013), http://dx.doi.org/10.1016/j.cca.2013.12.007

standards) there will be risks to driving new standards – the most significant of which is non-adoption and proliferation of variation.

We acknowledge there is an art and a science to ensuring that clinician engagement and leadership is both representative of current medicine and emerging service delivery models; clinically safe and genuinely value based.

A process for selecting and supporting (including through reimbursement) clinical leadership in the standards process needs to be clearly defined, regularly reviewed, and collaboratively managed by the relevant stakeholders (e.g., colleges) and in turn valued by all stakeholders on the governance body.

C. Standards require people, community, and consensus – perhaps the greatest challenge for the Agency in spearheading a renewed era of interoperability in Australia (one that also repositions Australia's relevance on the global digital stage) is in how to genuinely engage the important, rich, technical, and clinical expertise of the informatics community. The broad church of stakeholders proposed for the new standards governance body, particularly, but not in any way limited to HL7 Australia, will be important in helping the Agency to drive a sea change of digital health reform. (We talk further about this under Recommendation 2.)

   We see the role of the new governance body as encompassing:
   - Custodian of the model for national digital health interoperability standards;
   - Custodian of the standards catalogue;
   - Expertise on standards into the Agency's work program and that of other relevant stakeholder programs and policy development (such as AIHW regarding metadata and IHPA regarding classifications);
   - Alignment of products and services with contemporary and best practice for standards development processes;
   - Advocacy on the establishment and adoption of a national digital health infrastructure – particularly in relation to scaling up Australian adoption of HL7 FHIR;
   - Provision of strategic advice to SDOs (including HL7 Australia) on the prioritisation of standards programs, products, and services (including education), having regard for existing work programs;
   - External engagement with the broader standards communities including international standards development organisations;
   - Advice on the development and presentation of digital health education and adoption activities;
   - Support for activities to raise awareness, and promote adoption and use of digital health products, services, and systems nationally; and
   - Evaluation and review of effectiveness of the national health interoperability plan.

In summary: operational must-haves for this new governance body are outlined below:

International Standards Bodies: There must be active, credible, and informed representation of the Australian healthcare needs to international standards bodies. In providing this representation, the governance body must ensure:
- There is a clear and transparent process that prioritises clinical expertise and representation; and
- Such representation can provide continuity over several years – that is, such representation may need to be independent of the Agency and/or the commitment is assumed by the individual[7]; and

[7] For example, a terminology standards expert might be appointed by the Agency on the basis they would continue to be financially supported to ensure active participation even if they were to leave the employ of the Agency. Such mutual obligation is critical for consistency of input and representation and can be expected to be required over a minimum two-year term, ideally longer.

- Expenses associated with active Australian participation and representation in both virtual and in-person activities are paid for; and
- There is effective secretariat support from the Agency to ensure the timely engagement by Australia with international standards bodies in accordance with the standards plans sanctioned by the governance body (ref, point A above).

Multi-stakeholder Involvement: There must be genuine collaboration in the design and establishment of the new governance body. Stakeholders' appointments must be transparent, based on proven standards experience and understanding of the standards development lifecycle at both a local and international level.

The model proposed here, once established using transparent processes, accountabilities (and deliverables), would send a very clear signal to national and international stakeholders that Australia is back in business as a key influencer of healthcare interoperability globally. Equally important, it will make clear that the Agency cannot be both the developer of standards and the consumer of those standards. The model thus ensures there a standards governance structure that is separate from the Agency to ensure the required Australian standards are indeed fit for purpose; safe; and will be maintained.

Paid Standards Reference Leads: The governance body must include a group of paid standards reference leads, modelled on the Agency's clinical reference leads, whose role are to represent the mission of the governance body to ensure the processes required to design, develop, test, ballot, publish and review standards is being undertaken effectively in accordance with clearly defined objectives; and to raise resourcing constraints; and/or to escalate standards governance process issues with the governance body.

The number and appointment of standards reference leads should be clearly defined. Nominations and/or appointments might be invited from, for example:
- HL7 Australia Board
- Australian Institute of Digital Health (AIDH)
- State/Territory jurisdiction
- AIHW
- Open invitation (enabling experts with proven links to international standards to put themselves forward)

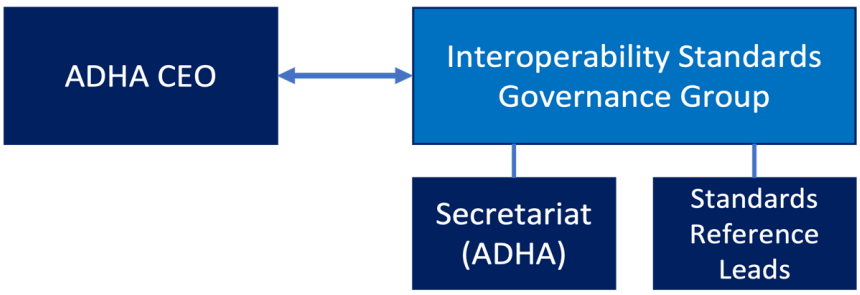


Figure 1: National Interoperability Standards Governance Group

R2. Formal Australian commitment to the HL7 FHIR Community Process

HL7 FHIR presents Australia with the best chance for progressing healthcare interoperability at scale and at pace, but this will require:

1. A clear FHIR roadmap and strategy for Australia.
2. A commitment to building the FHIR community; and
3. Support and funding for national FHIR infrastructure in support of consistent implementation.

Without investment in all three of these Australia will revert to the era of interoperability seen under HL7 V2, where there was proliferation of standards adoption, where no two implementations were the same, and where demonstrating interoperability and conformance becomes challenging and costly.

The core principles required to support scaled adoption of HL7 FHIR include:

- Creating the right environment and circumstances in which to engender maximum adoption of the right standards for the right task (see our first point (A) under Recommendation 1 - 'standards require a plan').
- Confirmation from the users and developers of standards that the standard being specified is fit-for-purpose, i.e., it has been developed using a consensus-based approach involving clinicians and end users; and
- Localisation, where they exist, of international standards (not vice versa or standards that have no relationship to international standards).

PEOPLE AND PROCESS FIRST – THEN TECHNOLOGY

These core principles are enshrined in HL7 International's FHIR Community Process (FCP), which provides quality and conformance guidelines for non-HL7 initiated projects with the aim of setting minimal expectations for all FHIR publications no matter where they originate. It is this global approach to community engagement in the development of FHIR standards that has helped drive the speed of adoption of FHIR particularly in the United States of America.

We recommend the Agency collaborate with the HL7 Australia Board to re-align its FHIR standards co-design process by developing a FCP for Australia, thereby removing the need for a separate Agency-led co-design process. This would enable the Agency and other Australian stakeholders to produce FHIR specifications which can be made publicly available and marketed as Australian FCP Specifications.

In support of this approach, we recommend that the Agency and HL7 Australia enter a formal collaboration to establish a National FHIR Standards Management Group. The role of this Group would be to:

- Define the national FHIR Strategy and Roadmap.
- Develop and establish the Australian FCP which will provide foundational policies and processes which ensure consistent adoption of FHIR in Australia.
- Coordinate the collaborative development of FHIR Implementation Guides and specifications between the Agency and HL7 Australia Work Groups to ensure the outcomes and objectives of both organisations are met.
- Advise the Agency on its use of FHIR and how it can better support the Australian FHIR Community.
- Represent the interests of Australia into the new HL7 International Standards Development Division and into the HL7 International Standards Implementation Division (whose role will be to

support global availability of FHIR publication tooling); and
- Support the growth of the FHIR workforce in Australia.

R3. Memorandum of Understanding Between HL7 Australia and the Agency

To leverage the strength of both organisations and to support the scaled, sustainable, and timely development, implementation, and maintenance of HL7 standards, we recommend the Agency and HL7 Australia enter a Memorandum of Understanding.

We see this MoU addressing some or all the following:
- The relationship between HL7 Australia and the Agency.
- Strategic goals.
- Term (we propose an initial 3 years).
- Collaboration objectives and activities, including:
    - Tasks associated with Agency developed specifications becoming part of the HL7 FHIR AU base
    - Maintenance roadmap of HL7 V2 and CDA standards
    - HL7 Australia collaboration tools: website; confluence sites, registries of all standards, including links to the proposed Agency standards catalogue.
- HL7 Work Groups:
    - Membership
    - Governance (including new governance and operation manual)
    - Remuneration and terms for Co-chairs.
- Infrastructure tools (publication/balloting).
- Conformance schemas for prioritised standards.
- Governance and secretariat support within HL7 Australia for the proposed National FHIR Standards Management Group (Recommendation 2).
- HL7 Australia participation in HL7 International.
- Financial terms and conditions, encompassing:
    - The activities agreed under the term of this MoU
    - HL7 Australia Standards Reference Lead on the proposed national health interoperability standards governance body (Recommendation 1)

R4. National Tooling to Support Implementation and Conformance Testing

We encourage the Agency to show leadership on standards conformance through the national Interoperability Standards Governance Group (proposed in Recommendation 1) and through the provision of tooling to support implementation testing.

Complexity associated with healthcare interoperability arises at the implementation phase. Without access to the tools or help to demonstrate standards are safe, valid, and conformant, there will be variability and potentially risk. Whilst not unique, this is a particular concern for pathology messaging. Greater visibility of compliance of receiving systems is needed to ensure systems in Australia can receive and process complete messages for secondary use and decision support, without introducing commercial disadvantages to sending system providers or punitive measures for receiving system providers.

HL7 Australia does not support software accreditation or consider it an appropriate means for developing and supporting a conformance culture. Instead, we believe Australia requires a plan that identifies the tooling to support implementation testing for key interactions in each clinical domain and national infrastructure to support the plan by making accessible, existing or new tools to support conformance testing.

The plan should identify tools to support the specifications that Australia will require to drive the national digital health strategy and priority implementations of interoperability standards. To help determine these priorities, we propose the Interoperability Standards Governance Group develop an initial transition plan to identify the tools and infrastructure that will be required to support HL7 V2 and HL7 FHIR specifications in those domains known to be associated with clinical risk, such as pathology, medications, and child health.

In partnership with relevant stakeholders on the Interoperability Standards Governance Group, the Agency should fund the creation of national infrastructure (portals, catalogues, technical registries etc) to provide:

- Access to standards materials;
- A range of technical and non-technical means of checking and demonstrating that an implementation is conformant, clinically safe and technically robust.
- In Appendix A we call out a process for the development of quality assurance strategies, with a focus on pathology and radiology standards implementations.

Over time, we envisage the Interoperability Standards Governance Group facilitating an expansion of the national conformance infrastructure to include tools and resources covering all standards including those from GS1, SNOMED International, DICOM etc.

R5. Roadmap for Action 2022

The Board of HL7 Australia acknowledges the obligations of the Agency and of Australian governments to drive a step change in the digital health capabilities of public and private health and social care provision in Australia. We assert that HL7 Australia is a key enabler of this step change through our role in supporting the development, adoption and maintenance of standards and interoperability capability in Australia. To this end, we propose we agree a bold roadmap for joint action for 2022.

Appendix A

Quality Assurance Strategies for Diagnostics Standards Implementation in Australia

Introduction

We suggest there is an important role for the Agency, through the proposed National Health Interoperability Standards Governance Group, to promote the development of quality assurance strategies for information sharing to address the following points:

- Improve information governance and integration architecture for diagnostics provider organisations; and
- Give visibility to the requirements of all information consumers (primary and secondary users of diagnostics information) benefiting from the standard.

We suggest two priority areas for delivery in 2022/23:

- Support pathology providers to comply with the existing HL7 Au v2.4 diagnostic messaging standard together with the Standards for Pathology Informatics in Australia (SPIA); and

- Support medical imaging providers to comply with the existing HL7 Au v2.4 diagnostic messaging standard and develop new Standards for Radiology Informatics in Australia (equivalent to SPIA).

Rationale

The National Pathology Accreditation Advisory Council (NPAAC) accreditation processes reliably produce high quality and repeatable test results in the pathology lab. These requirements for ordering and reporting of results are minimal, and the requirement for digital ordering and results reporting are even more minimal. Responsibilities for message compliance often rests with IT departments and software vendors and may not routinely involve those with clinical governance responsibilities. We believe there is a disconnect between the current digital presentation of results, and the optimal presentation of results for primary and secondary uses (i.e., the results report in document form for primary use, and the atomic form with clinical terminologies for secondary use).

The latest NPAAC Requirements for Information Communication and Reporting includes compliance with the current HL7 diagnostic messaging standard, Royal College of Pathologists of Australasia (RCPA) cancer reporting protocols and the Standards for Pathology Informatics in Australia (SPIA) by August 2022. We suggest that without clear guidelines and support to assist providers to consistently interpret and fully implement the requirements (vs complying with minimal requirements), quality and safety risks will remain; technical debt will be perpetuated and the secondary use benefits from access to high quality atomic data will not be available to health services.

Concept

We suggest the key to safe digital health interoperability practice is to provide support for both IT governance and information governance.

We suggest the proposed National Interoperability Standards Governance Group (Recommendation 1), via the Agency, should publish a set of resources that enable practice managers, business managers, business analysts, project teams, procurement teams, etc to understand Information Governance best practice and compliance guidelines.

These resources[8] should demonstrate the benefits to patient safety, business efficiency and health outcomes, while bridging the gap between the business/clinical context and the interoperability technologies.

Compliance should be incentivised, and non-compliance made visible for consumers.

Oversight might initially be by the Australian Commission for Safety and Quality in Healthcare (ACSQHC).

To complement the above information governance guidelines, we also suggest the development of similar guidelines for clinical software safety which would enable vendors to demonstrate how the information architecture of their products supports compliance with: HL7 standards; clinical terminologies; and national infrastructure.

We suggest that demonstrating compliance with these guidelines should be voluntary.

With industry leaders championing the use of these guidelines, the objective would be to create the market demand for basic visibility that software products are:

- Safe;
- Can identify a patient within the national context;
- Can interoperate with the national healthcare network;
- Can meet relevant compliance requirements; and
- Inform procurement decisions by healthcare organisations.

The development of these quality assurance strategies could be early quick-win assignments for the National Interoperability Standards Governance Group to commission. The current HL7 Au v2.4 diagnostics standard and SPIA already provide a sound baseline to start.

Deliverables for each of the proposed quality assurance strategies could include:

- Overarching quality assurance framework document.
- Transition plan templates for increasing levels of maturity of information governance and ICT governance assurance.
- Business glossaries and data models that link the diagnostics business terms to their information concept, enabling quality assurance of data within the HL7 message structure and correct binding of the clinical terminologies specified in SPIA.
- Practical step by step guidelines to achieve digital maturity, including:
- Best practice patient Identity management using the national Health Identifiers;
- Provider management using national directory infrastructure;
- Presentation of high-quality orders and observations data using HL7 Au v2.4 with transition to FHIR; and
- Where they don't exist, order catalogues and reporting protocols to support best practice in interoperability, e.g., structured, standardised reporting of radiology Investigations.

This could be commissioned work, closely supported by the HL7 Australia Orders and Observations (O&O) Work Group, or a funded assignment for the O&O Work Group.

[8] Resources could be made available via the proposed national standards catalogue