Australian Digital Health Agency

A Health Interoperability Standards Development, Maintenance and Management Model for Australia

Final, Version 1.1, 28 January 2020

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Related Documents

1. A Health Interoperability Standards Development, Maintenance and Management Model for Australia, Executive Summary Report, Final, Version 1.0, 30 June 2019.
2. A Health Interoperability Standards Development, Maintenance and Management Model for Australia, Supplement, Final, Version 1.0, 30 June 2019.

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The author (David Rowlands) greatly appreciates the support of the following people in the development of this report:

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- Mr Jeff Parker, Managing Director, JP Consulting (Aust) Pty Ltd

Share information.

Not just medical information but whatever else may help me as a patient, perhaps about peer support groups, self-help groups or other agencies in the community that may help me.

Importantly though, this information needs to be in a format I can understand.

Twanny Farrugia,
Chronic condition consumer.
Consumers Health Forum of Australia's journal, Health Voices, Issue 17, 2016

1 Introduction

This report was commissioned by the Australian Digital Health Agency (ADHA) to provide advice on how interoperability standards development, maintenance and management can be improved to meet health sector needs in Australia.

The report comprises three parts:

A. Analysis of the problem. This addresses why standards are needed (the benefits), the nature of standards and standardisation, and lessons from our own recent past in Australia as well as learnings from other countries, industries and the literature.

B. Current state analysis. This considers demand for and supply of standards for interoperability, and provides high-level stakeholder analysis.

C. Recommendations.

In addition

- A separate Executive Summary Report provides a strategic overview of findings, conclusions and recommendations.
- A Supplement includes finer detail concerning the proposed Health Interoperability Standards Office, and several one-page responses to key questions.

1.1 Methodology

The project methodology featured:

- Widespread consultation with standardisation stakeholders. Stakeholders consulted are listed at Appendix A.
- Literature review.
- Qualitative hypothesis testing.
- Report writing.

1.2 Definitions

The following definitions apply for the purposes of this report.

Interoperability

"The ability of a system or product to transfer meaning of information within and between systems or products without special effort on the part of the user. Interoperability is made possible by the implementation of standards" (GDHP, n.d.).

Standard

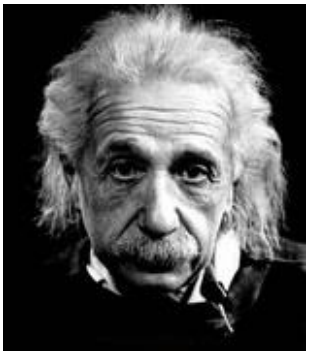
Codified knowledge that provide, for widespread and repeated use, rules, guidelines or characteristics for activities or their results, aimed at ensuring fitness for defined purposes.

(Refer to section 3.1)

Standardisation

The processes via which specified domains (e.g. the public and private health sectors) achieve a targeted level of consistent implementation of specific standards, to achieve a defined purpose.

PART A: ANALYSIS OF THE PROBLEM



“If I had an hour to solve a problem, I'd spend 55 minutes thinking about the problem and 5 minutes thinking about solutions” (Albert Einstein, as quoted by Goodreads, n.d.)

2 The need for standards

Standards pervade virtually every aspect of our lives, whether we realise it or not. They are embedded in virtually every product and service we consume. There are very good reasons for this, including interoperability, safety and economy.

However, standards are also often, indeed mostly, invisible. Consumers may, from time to time, look for evidence that a product or service is standardised. For example:

- A child's car seat is compliant with Australian and New Zealand Standard AS/NZS 1754 Child restraint systems for use in motor vehicles.
- A bike helmet is compliant with AS/NZS 2063:2008—Bicycle helmets.

More commonly though, people don't think about the way standards affect their lives because they are more concerned about the performance or suitability of the product or service they are consuming or wish to consume than how that performance or suitability is delivered.

Determining the best model for standards development to support health system interoperability in Australia starts with understanding the need, in terms of the nature and quantum of standards development required.

2.1 Interoperability is impossible without standards

The driver for ADHA's interest in standards and the context for this report is interoperability, which was simply defined by ADHA in 2017 as "… the ability to move information easily between people, organisations and systems" (ADHA, 2017, p. 29).

ADHA also defined semantic interoperability as:

"The capability of two or more systems to communicate and exchange information, and for each system to be able to interpret the meaning of received information and to use it seamlessly with other data held by that system" (p. 29).

The criticality of semantic interoperability in health care is that it requires meaning to be preserved from one context to another so that information can be interpreted in the same way – i.e. what was meant by the author is the same as what is understood by the reader.

More recently, however, the Global Digital Health Partnership (GDHP), which was initiated by ADHA in 2018, has agreed on the following definition (adapted from the Institute of Electrical and Electronics Engineers):

> "[Interoperability is] the ability of a system or product to transfer meaning of information within and between systems or products without special effort on the part of the user. Interoperability is made possible by the implementation of standards" (GDHP, n.d.).

The need for appropriate, effective and efficient digital health standards development in Australia is justified solely in the GDHP's final sentence, which is definitional in nature. Turning this sentence around:

Interoperability is impossible without standards.

This is agreed by the public and private sectors alike, as illustrated by recent statements from leading US stakeholders:

- The US Government recently articulated six principles for the trusted exchange of health care data, the first of which is standardisation – "Adherence to industry and federally recognized standards, policies, best practices, and procedures" (ONCHIT, n.d.a, p.2).
- Microsoft, Amazon, Google, IBM, Oracle, and Salesforce recently issued a joint statement on healthcare interoperability, agreeing that "Open standards, open specifications, and open source tools are essential to facilitate frictionless data exchange (Mandel, 2019).

2.2 Drilling down

However, it is not just "standards" that are required. The characteristics of good standards are elaborated in section 3.1, but three that merit early articulation are:

1. The requirement is standards that are fit for purpose. Implementing standards entails additional private cost[1], and this can be substantial. It is unlikely to be undertaken unless there is a high likelihood that additional private benefit[2] will exceed this cost, or conformance to the standard is required for some other reason, such as being mandatory through regulation. Neither case is likely unless the standards concerned have been demonstrated to be fit for purpose.
2. Standards are not static. Even if initially delivered with high quality, they are products that require ongoing maintenance. They evolve as user and implementer requirements evolve, as technologies evolve, as experience with them matures, as they are evaluated over time in terms of their contribution to their intended purpose, etc. They have lifecycles, and quality must be maintained right across these lifecycles. If they are not well-maintained, their ability to meet evolving interoperability and other requirements decays. Figure 1 below illustrates that:
    - Standards, at the completion of their initial development, deliver nothing more than the requirements agreed at the initiation of their design and development (at best).
    - Requirements evolve, but without ongoing maintenance, the capabilities enabled by standards do not.
    - The more standards are used, without maintenance and implementation support, the less likely they are to deliver even to their theoretical capabilities, because:
        - The more widely they are implemented across a highly fragmented, complex system such as health, the more likely they are to be implemented by inexperienced people who just have the standard in

[1] In Economics, private cost is the cost borne by an individual or firm directly involved. In the case of a software developer, this would entail the cost of changing or writing new code, etc.

[2] In Economics, private benefit is the benefit derived by the individual or firm directly involved. In the case of a software developer, this would entail revenue or some non-monetary benefit such as reputation.

front of them and not the full knowledge likely to be required for successful interoperability.

- As changes are made in other complementary standards or in other parts of other systems, the all-important contexts for individual standards decay.

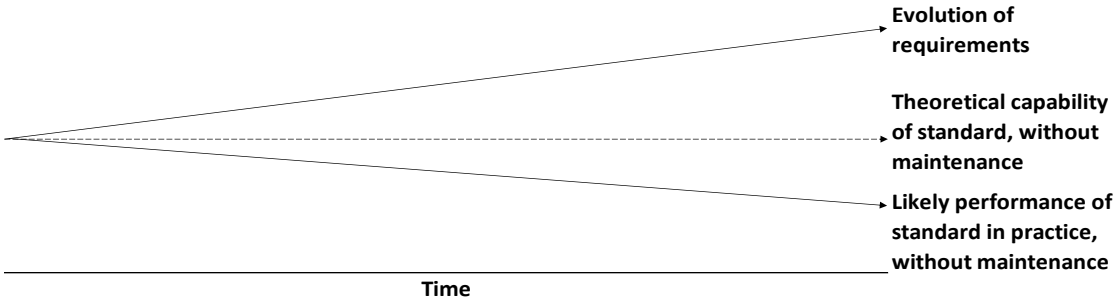


Figure 1 - The performance of standards over time

3. In addition, there are many different kinds of standards that must be used together, for example to manage health data's complexity. A case study illustrates this.

Case study – The TermInfo problem[3]

Information models, such as those underpinning HL7, tend to express generic concepts such as roles, actions, observations and their inter-relationships. Terminology models provide specific descriptions of the higher-order constructs.

While there have always been varying degrees and forms of interchange and collaboration between the developers of clinical information models and clinical terminologies, these have nonetheless been largely developed by distinct and separate standards communities, often dominated by contributors with different expertise such as software engineers, modelers and terminologists. The respective bodies of knowledge and IP reside and are vested in different entities and artefacts. As a result, the combination of these different models and approaches can show gaps and overlaps.

Information models based on the HL7 Reference Information Model (RIM) reflect sets of entities that relate back to the basics of parties and acts. Clinical acts may include things like diagnoses, procedures and observations, but the RIM does not include the detail of which specific diagnoses, procedures and observations. For these, defined terminologies and vocabularies such as SNOMED CT are "called in". Since a system cannot be

[3] Sourced from Rowlands, 2017, Chapter 39.

implemented without specifying in detail the applicable terminologies / vocabularies, these "terminology bindings" are explicitly specified.

Both the HL7 RIM and SNOMED CT provide capability to span the whole health system and are designed to be extremely flexible and to support a very wide range of uses. As a result, there is often more than one way to represent concepts – i.e. more than one possible terminology binding. Kalra and James (2012) provide an example:

> *Negation is an important expression in healthcare – for example "ankle reflexes absent" is a clinical finding that is "rare enough to be a definite clinical sign, irrespective of age". However, negation can be expressed either in the information model or the terminology.*

If the information model (record structure) and terminology both indicate negation, it is particularly difficult to know what was truly meant and therefore what the action for that should be – should the double negation be taken to be emphasis, or should it be taken to mean the positive assertion? Or is it expected that the negative statement has been made using both alternatives (information attribute and terminology) and either one should be used but not both to give the negative information? Due to this ambiguity, some systems might decide to disregard this sort of data altogether, which can also be a problem.

Substantial work has been done to analyse and compile guidance on issues such as these, and guidelines for dealing with them while implementing standards have been published.

However, the case study illustrates the point that standards themselves must be engineered to work together and this cannot simply be assumed. Further, as already established, each standard has a lifecycle. This ability for standards to work together must also be maintained – a change in one may require change in others. Accordingly, *high-quality* standardisation must acknowledge both the need for disparate standards to work together and risks such as inherent or evolving lack of standards interoperability.

Having elaborated these key issues GDHP's final sentence is re-stated and adopted as a mantra in this report:

Interoperability is impossible without high quality standards
that are maintained across their lifecycles
and are continuously (re-) engineered for co-existence.

2.3 Other benefits of standards

The standards literature is replete with additional benefits that may be associated with standards, including those supporting health interoperability.

2.3.1 Safety

Just as a door that demonstrates compliance with a standardised fire rating provides assurance that fire will not breach it for at least a specified period, a standardised exchange of information between two health information systems that both demonstrate compliance with the standard provides assurance of meaningful interchange.

Example - Safety Issues at Transitions of Care (ACSQHC, 2017)

The Australian Commission on Safety and Quality in Health Care (ACSQHC) consulted widely on safety issues at transitions of care, at the request of the then National Health Chief Information Officer Forum.

Limited access to complete and current health and social information was one of six safety issues identified as priorities needing to be addressed. Current information gaps identified included variable data quality, "probably due to poor interoperability of information systems" (p.8), and "issues with the interoperability of systems" causing information transmission and integration deficits (p.8).

Limited opportunities for medication reconciliation was another of the six safety priorities, and the ability to safely access patient data across different clinical information systems was identified as a required improvement.

Addressing safety issues such as these is impossible without high quality standards. Examples of standards directly implicated include (but are not necessarily limited to):

- Data content standards. For example, data that general practitioners (GPs) have identified that they need in a discharge summary in order to provide high quality primary care is likely to be missing unless the content of discharge summaries hospitals is standardised. The provision of data essential to a receiver group of clinicians should not be left to the discretion of a wide range of sender groups.
- Data concept representation standards. Data made accessible during transitions of care are simply unsafe unless the communicating parties – including clinical information systems – are completely aligned in their interpretation of this data.
- Data access and exchange standards. Whether obtained via application program interfaces (APIs) or via messages between information systems, clinical data safety requires the right information to be accessed and delivered, any data transformations undertaken to be transparent,

repeatable, auditable, etc., and any encryption/decryption to be possible without misconstruction, etc.

It does not require much imagination to envisage a myriad of other case studies in which clinical safety is enhanced through standardised interoperability.

2.3.2 Comparability

Standards also enable comparability in a range of different contexts:

- They provide the basis on which systems, products, applications etc. can be compared and contrasted in terms of functionality, performance, value for money, user preferences, etc. As such, they promote consumer choice and empowerment, procurement and market accountability.
- They enable actual performance to be feasibly compared with claimed performance, safeguarding purchasers and investors. It is simply not feasible to undertake different tests of performance for every different product.
- They enable data to be safely and meaningfully compared, assimilated, aggregated, analysed and interpreted. The less data must be transformed for assimilation, the more rapidly it can be applied for clinical and other decision-making.

The first two points are crucially important to procurement of health information systems, in an Asia-Pacific market estimated to be valued at around AUD 28 billion (148 billion globally) by 2020 (Grand View Research, 2015).

The latter point is of exponentially increasing importance in health care, in an era in which increasing amounts of data are coming from outside the sphere of control of health CIOs, and in which the potential for big data analytics in health care is widely agreed to be enormous.

The volume of health data is estimated to be growing at nearly 50% per annum. This is much higher than in other industries (EMC/IDC, 2014). Across all industries, the volume of human- and machine-generated data are growing ten times faster than that of traditional business data, and machine data is growing even more rapidly – at fifty times the growth rate for traditional business data (insideBIGDATA, 2017).

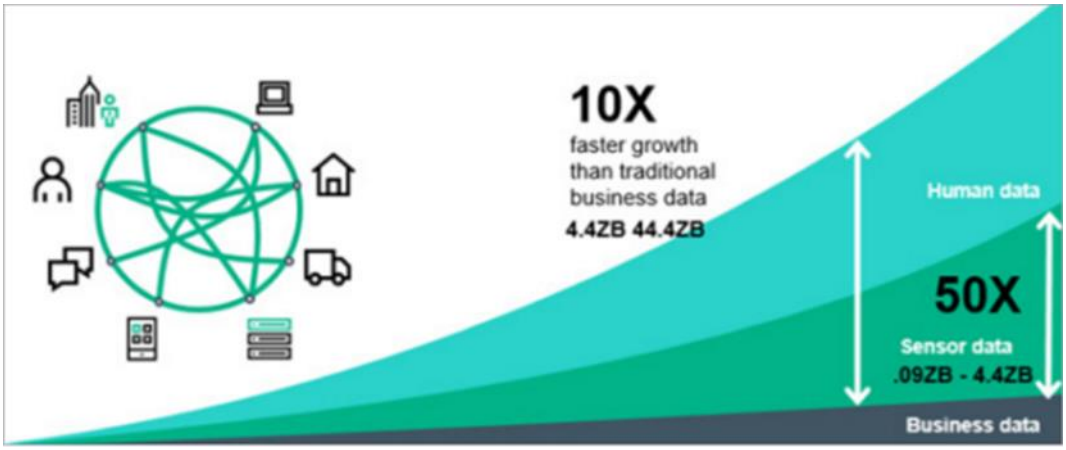


Figure 2 - Growth of data from non-traditional sources (insideBIGDATA, 2017)

Contributors to this enormous growth in the volume of healthcare data include the inherent richness and data density of genomic and imaging data and their growing use, as well as the accelerating proliferation of wearable, implantable and environmental sensors, connected by the Internet of Things (IoT). In 2011, the American Medical Informatics Association (AMIA) Annual Symposium was told that "within 5 years, the majority of clinically relevant data … will be collected outside of clinical settings" (Shapiro et al., 2012). While the accuracy of this prediction remains untested, the direction of travel is clear. An increasing amount of the data used for health care is being sourced outside the system, and outside the sphere of control of health CIOs.

One of the primary ways that these external data can be reliably and safely compared to and assimilated with data generated within health systems is to ensure they embody the same standards. Put the other way around – failure to embrace standards will endanger, slow the timeliness of and/or increase the cost of big data analytics in health care. Health may therefore be miss out on opportunities such as those described in the figure below.

Figure 3 - Applications for big data in health care (NEJM Catalyst, 2018)

2.3.3 Preventing information blocking

Information blocking "occurs when a person or entity – typically a health care provider, IT developer, or EHR vendor – knowingly and unreasonably interferes with the exchange and use of electronic health information" (ONCHIT, 2019). Information blocking may be used to:

- Lock health care providers or patients into specific technologies or health care networks because their data is not readily portable. This can stifle competition and innovation, reduce user satisfaction with health information systems, and increase health care costs.
- Inhibit the exchange of information, e.g. to avoid regulatory compliance or justify fees for access to data. This can also create patient safety risks when critical clinical information is not available when needed.

The USA has recently moved to strengthen regulation designed to encourage interoperability and reduce unwarranted information blocking, including via the use of civil penalties and other disincentives (Anthony & Lipinski, 2019).

Standards are fundamental to dealing with information blocking, since they enable information to be accessed, exchanged or migrated without undue hardship.

2.3.4 Improving economic productivity

Numerous studies from around the world and over time demonstrate clear linkages between the production of standards and economic growth – a collection of these is available via the British Standards Institution website (BSI, n.d.).

Australian macroeconomic research yields comparable results to that undertaken on other countries, and indicates that a 1% increase in the production of standards is associated with a 0.17% increase in GDP (approximately $2.78 billion in 2009) (Standards Australia, 2013). Analyses such as these are not available at the sectoral (e.g. health) or individual standard level, but the National Digital Health strategy's focus on effectiveness and costs suggests belief that there will be positive sectoral benefits.

2.3.5 Simplifying and accelerating product development

Standards can simplify product development in a range of ways, including by:

- Codifying some of the required knowledge, making it more accessible to product developers, and reducing the risks associated with its use. If published by an independent and credible authority, this codified knowledge can typically be relied upon as fit for purpose.
- Ensuring access to complementary products – e.g. a computer built to industry standards should be able to plug-and-play with a printer or other peripherals also built to industry standards.
- Enabling access to positive network externalities – e.g. a new mobile phone built to industry standards should be able to interoperate with global telecommunication networks without the product developer needing to work out for themselves how to do this.

2.3.6 Improving health literacy

Nennen wir einen Spaten einen Spaten.

Unless you are literate in German, you are likely to struggle to understand the above, or at least lack full confidence that your understanding is correct.

Breakdowns in the transfer of information are one of the most important factors in serious adverse events and a major preventable cause of patient harm (ACSQHC, n.d.). This applies both between clinicians and between clinicians, patients and carers. Effectively speaking different languages is an obvious safety risk in the transfer of communication.

However, there is more than safety at stake here. Investments in health advice are likely to be ineffective if the advice is not understood. Low health literacy "has been linked to poor health outcomes such as higher rates of hospitalisation and less frequent use of preventive services.

Both outcomes are associated with higher healthcare costs" (Office of Disease Prevention and Health Promotion, n.d.).

This is an issue for Australia. In 2006, "only 41% of adult Australians had a level of health literacy that would allow them to meet the complex demands of everyday life" (AIHW, 2018, Chapter 4.3, p.1).

What does this have to do with standards?

Quite simply, one of the benefits of standards is that they provide common language for technical concepts, whether in the design and development of clinical information systems, the interoperability of systems and information, or in communication between wide array of stakeholders in health care.

Example -Myocardial infarction (National Center for Biomedical Ontology, 2018)

A myocardial infarction is the same thing as a myocardial infarct and has the following alternate labels: Cardiac infarction, heart attack, infarction of heart, MI, myocardial infarction (disorder).

This knowledge, which may be very important to a patient trying to understand their condition, health risks or behaviours is codified in the SNOMED CT standard and thus can be embedded in an array of systems and applications accessed by clinicians, patients and carers.

Investments in health promotion, underpinned by efforts to improve health literacy, can either be enhanced by using commonly understood language at all points in the health care and wellness systems – or undercut by not doing so. Standards, particularly clinical terminologies and their various interface languages, supports enhancing common understanding.

2.3.7 Facilitating international trade

A great deal of work has been done globally on the complex relationships between standards and international trade, and the World Trade Organization, of which Australia is a member, has clear guidelines on the use of standards as technical barriers to trade (WTO, n.d.). Although there are widely varying nuances and specific circumstances, it would be fair to say that standards are typically viewed by economists as enabling of trade.

Swann (2010) concluded that:

- "In most [econometric] studies, when exporting countries use international standards, this has in most cases a positive (or at least neutral) effect on their export performance.
- "When exporting countries use national standards (i.e. standards specific to country x), that may lead to superior export performance by x.
- "When the importing countries also adopt international standards, the most common effect is also to increase imports. The exceptions can in part be explained.

- "When the importing country uses national standards, the results are more diffuse. For studies that relate exclusively to voluntary standards, the effects are distributed quite evenly. For studies that relate to regulations (i.e. mandatory standards), the effects on imports tend to be negative".

Again, studies focusing specifically on interoperability standards in health care do not appear to exist. However, the anecdotal evidence is nonetheless clear:

- Cerner, Epic, Allscripts and many other multinational health software developers would not be operating in Australia if Australia had not embraced a raft of international standards such as HL7.
- Australian software developers are likely to be forever constrained to the Australian market if they do not adopt and use international standards that bring them at least close to meeting other countries' requirements (systems are still likely to require customization to local contexts).

2.3.8 Standards and innovation

Evidence concerning the relationships between standards and innovation is more nuanced. Standards may both enable and constrain innovation. Even single standards may have several different purposes, ranging from knowledge translation (an innovation promoter) to safety assurance (a possible innovation constrainer).

Qualitative studies of expert opinion suggest that ICT standards have a positive impact on innovation, especially on product variety and the degree and speed of adoption of new products and services, but in general even where positive correlations are demonstrated between standards and innovation, causality is not.

3 The nature of standards and standardisation

Standardisation is a complex and often poorly understood process in any domain. Development of an appropriate, effective and efficient standards model for health care requires understanding of the nature of standards and of standardisation, and some key issues arising.

3.1 What are standards?

There are various definitions in common use, including:

- Standards Australia: Standards are "voluntary documents that set out specifications, procedures and guidelines that aim to ensure products, services, and systems are safe, consistent, and reliable" (n.d.).
- ISO/IEC: Standards are "documents established by consensus and approved by a recognized body, that provide, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context" (n.d.)
- Webopedia: Standards are "definitions or formats that have been approved by a recognized standards organization or accepted as de facto standards by the industry" (n.d.).
- Cambridge Dictionary: A standard is "something that others of a similar type are compared to or measured by, or the expected level of quality" (n.d.).

Standards are agreed ways of doing something. However, definitions that specify "documentation" may now be misleading for the purposes of interoperability standards, which can also include implementable artefacts. While this may be a technical point, it is nonetheless important to achieve a common understanding across the domain of interest. "Established by consensus" is another moot point, which is recognised by Webopedia. Some standards may be established by a market leader but adopted widely by a market – e.g. Adobe's PDF format before it became an ISO standard in 2005.

Hence, for the purposes of this report, which seeks to be very explicit about standards for health system interoperability:

Standards are defined as codified knowledge that provide,
for widespread and repeated use,
rules, guidelines or characteristics for activities or their results,
aimed at ensuring fitness for defined purposes.

Standards can be categorised in various ways, including by:

- Jurisdiction. Standards can be international, regional (e.g. European or joint Australian/New Zealand standards), national or sub-national in their applicability.
- Product type. "Standards" may embody varying degrees of consensus and transparency. For example, Standards Australia publishes Interim Standards,

Technical Specifications and other products as well as Australian Standards – see Appendix B.

- Origin. A de jure standard is a standard that is endorsed by a recognised standards organisation, such as Standards Australia, the International Organization for Standardization (ISO) or the American National Standards Institute (ANSI). De jure standards may also be called "official" or "open" standards.

  A de facto standard is one that originates outside a recognised standards organisation but has become a standard through wide adoption. An example is the QWERTY keyboard.

  A proprietary standard is a form of de facto standard that is controlled by a single organisation and is adopted or emulated by others as a result of the organisation's market power. An example is DOC files (Microsoft Word Document file format). This became a de facto standard used in most word-processing software. Proprietary standards may also be called "closed" standards.

  An open standard may be de jure but may also be produced by a consortium such as the Internet Engineering Task Force (IETF) or the World Wide Web Consortium (W3C).

- Function. For example, product and design standards specify characteristics, design, construction, composition etc. of products or services to ensure fitness for purpose (e.g. standards for plumbing products specify things like the physical dimensions, material characteristics, etc.) whereas performance-based standards are expressed in terms of the outcomes to be achieved (e.g. bushfire standards specify the minimum time it will take for a fire of specified heat to burn through a product such as a fire door – irrespective of what it is made of), and test methods articulate the steps to be followed to establish conformity with product or performance-based specifications.

- Product status. For example, standards may be draft for trial use, current, superseded or withdrawn.

- Maturity level. For example, the US ONCHIT publishes 3 variants of maturity relevant to interoperability standards – Standards Process Maturity, Implementation Maturity and Adoption Level. These are described in Appendix C.

This last categorisation serves as a reminder – standards are products. They have lifecycles, exhibit maturity and may ultimately become obsolete.

3.2 What are interoperability standards?

There are essentially four sub-domains in which standards are required to enable *interoperability*, which is italicised here to draw the distinction between interoperability and interconnectivity. The scope of this report is the application layer of the Open Systems Interconnection (OSI) model. The application layer is an abstraction layer that specifies the shared communications protocols and interface methods used by hosts in a communications network.

These four sub-domains are:

(i) Data content – describing which data are required for various use cases, their associated metadata and the relationships between them.

(ii) Concept representation standards – describing how content will be expressed in ways that are unambiguously understood by disparate parties (human or machine) and meaning is preserved over time, space, context and reuse.

(iii) Data exchange standards – describing the data structures and formats via which data can be accessed within an information system (e.g. via an API) or otherwise exchanged.

(iv) Data integrity standards – describing the rules that implement privacy, security and identity management.

Standards from all these sub-domains typically must work together (integrate) to enable interoperability.

3.3 What is standardisation?

Standards Australia tends to refer to standardisation as the processes for the development of standards and other technical documents. However, this is because its ambit extends only that far. For the purposes of this report, standardisation is defined as:

> **The processes via which specified domains (e.g. the public and private health sectors) achieve a targeted level of consistent implementation of specific standards, to achieve a defined purpose.**

I.e. standardisation is achieved in terms adoption and use of standards, not just their existence, and by achievement of the purpose for which the standard was designed. The latter is important because if any given standard is implemented in inconsistent ways in different systems then the aim (e.g. interoperability) may still not be achieved. For the purposes of this report, standardisation requires rigorous implementation to achieve the desired aims. Standards development in itself may deliver some benefit – the collaborative generation or assimilation of knowledge – but it is standardisation that delivers the primary outcomes sought.

As previously highlighted, standards are products that have lifecycles – and they require ongoing management across their entire lifecycles. Figure 4 below depicts a highly elaborated standards lifecycle. It is highly elaborated in order to elicit maximum understanding of the different dimensions of standardisation. It is also depicted as a circular cycle. However, the dimensions shown are increasingly likely to be bundled and iteratively undertaken in agile methodologies as appropriate for the specific purposes and contexts at hand. The cyclical nature of the diagram is not intended to imply linearity – merely completeness.

The dimensions depicted in Figure 4 are elaborated as follows:

- Inclusion – Refers to recognition of the need for particular (sets of) standards. In the context of interoperability, inclusion is required when a proliferation or absence of standards prevents progress towards a national goal rather than enables it.

- Requirement analysis – Refers to articulation of the uses to which the standard(s) will be put and the functionality required. This should cover the business, informational and technical levels, and include analysis of the feasibility of change. A set of standards is likely to be required to work together to provide an interoperability solution, rather than any single standard in isolation.
- Option analysis – Refers to identification of existing standards or standards under development that can meet the identified requirements, together with a guided assessment of the strengths, weaknesses, opportunities and threats associated with them in the identified context.
- Standards strategy selection – Refers to agreement to adopt or adapt an existing standard or develop a new one.
- Acquisition, adaptation or development – This may include a more detailed round of requirement specification.
- Testing – The resulting standards should be tested for fitness for purpose prior to their deployment. This may involve multiple strategies, including piloting.
- Implementation/migration planning – Refers to identification of the strategies and timeframes for implementation at each critical site and other potential sites.
- Change management, education and training and ongoing support – Depending on the standard selected, awareness raising, education and training strategies will need to be considered, and if appropriate developed, for all relevant organisations and personnel. Implementation support networks may need to be established to assure consistent usage.
- Implementation and implementation testing – Refers to deployment of the proposed standard(s) in live settings. The capture of implementation feedback is also important as input for continuous improvement.
- Compliance, conformance, certification and/or accreditation – Refers to ensuring that products and services embody the standards correctly, potentially before they are able to be deployed.
- Maintenance – Standards require ongoing maintenance to ensure their continuing effectiveness in view of changes to requirements, supporting technologies, market conditions, etc. Different maintenance strategies may need to be defined for specific standards.
- Periodic evaluation/review – A standards review cycle should look to assess the contributions made by the standard(s) to business value, as well as more operational aspects such as performance.
- Deprecation – Refers to the decision to end the lifecycle of a standard.

Figure 4 - Standardisation lifecycle (Rowlands, 2011)

3.4 The nature of standards and standardisation for health sector interoperability

There are many important nuances and challenges relating to standards and standardisation in health care that should be taken into account in the design of a standards development model.

3.4.1 Market failures

Three important economic issues are important in relation to standardisation, and typically lead to market interventions such as public funding and regulation: Network effects, the nature of public goods, and distributive effects.

Network effects

The value of a standard to a new user is directly correlated with the number of existing adopters.

A network effect may be defined as a change in the economic benefit that an agent derives from a product or service when the number of other agents consuming the same kind of product or service changes. Network effects may be direct, indirect or bi-lateral, and positive or negative.

Direct network effects are associated with the number of users of the specific product or service concerned. For example, the costs of being the first and only user of a new telephone network are likely to be high and the benefits non-existent. The more users there are, the

greater the likelihood that a targeted agent will be part of the network, and thus the greater the benefit, and the more likely it is that costs will be driven down.

Indirect network effects are associated with complementary products and services. For example, the more peripherals (e.g. printers, monitors) associated with a new computer, or apps available for a new smart phone operating system, the higher the likely benefits associated with adopting that new technology.

Bi-lateral network effects are compounding effects associated with complementary products. For example, the Internet enabled smart phones as a complementary product, but then the proliferation of smart phones further promoted Internet usage.

The above examples highlight positive network effects. However, negative effects are also possible. Traffic congestion is an example – after a point, greater usage can reduce the benefit experienced by any given agent.

The key issue with positive network effects is that there is little benefit for early adopters, and often high cost, but once a critical mass is attained, the net benefits are high. So, inducements may be required to attract early, risk-taking adopters by reducing cost, facilitating benefit, or both.

Network effects are very likely to be associated with interoperability standards. These may be direct (greater benefit to any given agent the more agents are interoperable, because there is more information to source) and indirect (new products and services likely to spawn), and have the potential to be negative (e.g. flooding the NBN with a tsunami of digital health information), as well as positive.

Public goods

In economics, public goods exhibit two properties. These are:

- Non-excludability – those who don't pay for them cannot be prevented from accessing them
- Non-rivalry – their consumption by one user does not prevent simultaneous consumption by other users.

Interoperability standards are likely to be impure public goods, showing some of the characteristics of public goods, but not necessarily being completely non-excludable or non-rivalrous. For example:

- SNOMED CT-AU standards, HL7/FHIR standards and Australian Standards for health informatics are available free-of-charge to users – the latter as a result of government subsidy. The standards themselves are virtually non-excludable and non-rivalrous.
- However, the resources required to implement them as intended and consistently, as required for interoperability, are both excludable and rivalrous. Their implementation within information systems can be costly, and the requisite expertise is limited.
- There are externalities associated with their use – societal benefits (e.g. consumer participation in health care) can arise, even though they are deployed by health

software providers for profit, and societal dis-benefits can also arise (e.g. risks to privacy).

Public goods are often associated with market failure. Non-excludability gives users incentives for "free-riding" and understatement of their willingness to pay. Economic theory demonstrates that free markets cannot produce optimal results for public goods. Correction of these market failures typically requires market intervention.

In Australia, such market intervention is already provided in some instances – SNOMED CT-AU and AMT and data content standards developed via the AIHW are publicly funded (though whether this is to the extent required for interoperability purposes is as yet a moot point). But the standards required to move these data elements around are not nearly so well supported, despite being equally essential to interoperability.

Distributive effects

Standardisation (as defined above), like many other policy and strategy processes, have (re-) distributive effects. This follows from the network effects and public good theorem, both of which can produce market failures.

For example, the costs of and clinical workflow changes associated with implementing standardised digital hospital discharge summaries fall primarily to hospitals, whereas the productivity benefits primarily accrue to the primary care sector. Similarly, the production of good quality referrals by GPs to hospitals primarily benefits the hospital. Safety and quality benefits of course accrue to the patient – the common agent.

Misalignment between costs and benefits and inability to privatise benefits can be disincentives to standardisation.

3.4.2 Development timeframes

The timeframes associated with standards development are often cited as being problematic.

Standards Australia notes that depending on their complexity, the time frames for standards development projects may vary from eight months for simple projects to four years for the most complex projects (Standards Australia, 2019).

The localisation of base standards is generally towards the simple end technically, requiring standards to be profiled or occasionally extended to meet local needs. For example, it took around seven years for the FHIR standard to reach normative status, but it may take merely hours to use it to meet a particular need.

However, the key issues for localising base standards for the purpose of widespread interoperability are not necessarily technical. Rather, they concern the achievement of consensus. As for any policy development process, building consensus on an issue for which there are multiple possible approaches, diverse and strongly held views, disparate interests ranging from commercial to societal takes time and evokes passion when there are high existing investments in the status quo (large installed bases) and competing demands for the resources required to make changes etc.

Another issue is the timing at which standards selection is undertaken. One stakeholder consulted during this project said that information system rollout schedules were short and

that there was no time to await the localisation of standards, so proprietary approaches were taken – i.e. interoperability could not be considered. But the time to think about this is not when a system is being rolled out. It is before procurement, so vendors know in advance what they will be required to deliver. Initial planning for the system in question commenced a decade ago – plenty of time to consider standards. The issue in such cases is not that standards development takes too long, but that it is not in the correct place in the project plan.

3.5 Characteristics of high-quality standards

The quality (fitness for purpose) of a standard is critical to its usefulness. Characteristics of high-quality standards include (Beale, September 2009; Jawad & Greulich, 2014; PanaEk, 2014):

- Clear and well-defined scope. It should be extremely clear which problem(s) the standard is addressing and in which contexts it is appropriate – or not.
- Fitness for purpose. A standard should, when implemented, meet the requirements specified and/or generate the outcomes required of the product or service incorporating it.
- Practicality. Standards should meet some clear business vision or need – recognising that organisations have both future orientations and current pressures. Clear expression of the business outcome(s) sought and the nature of the problem not only targets and scopes standards development but is critical to adoption engagement.

  Users of standards will also bend them to their pragmatic needs (e.g. clinical workflow, customer preferences) if they are overly elaborate, or extend them differentially if they are not well enough elaborated. Developing standards to the most appropriate level requires sound understanding of the outcomes sought and the issues experienced.
- Clarity and understanding. Interoperability standards are technical in nature. While not everyone may be able to fully understand the content of a technical document, a standard should be written such that:
  - A technically competent user can understand it.
  - A less technically competent but nonetheless interested party can, with reasonable effort, comprehend its importance, applicability, its general concepts and its requirements.
  - Multiple parties (including independent certifiers) can measure the degree of conformance to the standard.

  Use of specialised or highly contextualised terminology should be clarified – the standard should be able to stand alone in this respect.

  The use of normative language (e.g. shall/should, must/may, etc.) should be clearly defined, assiduously used and preferably be consistent across different but interacting standards.

  Similarly, whatever structure and organisation is used in the writing of a standard, this should be both logical and consistent. A user, once familiar with the standard,

should be able to find the information they are seeking in other comparable standards.

- References to other standards. Interoperability standards (e.g. data element standards, concept representation standards, data access/exchange standards) are typically designed to be used together. When other, complementary standards already exist, their use rather than re-invention avoids redundancy and potential inconsistency and saves development time.

- Consistency. The large, international standards organisations involved in interoperability cover such breadth and complexity[4] that even for one standards development organisation (SDO), inconsistent standards are a substantive risk. Add in the fact that these standards organisations have different rules, skill sets and cultures, and can act competitively, and this risk escalates.

  The Joint Initiative Council (JIC)[5] aims to address and resolve gaps, overlaps and counterproductive efforts, but this does not necessarily eliminate them, and this function is not formally reproduced in Australia.

- Quality control. Technical standards may be used by inexperienced practitioners as well as experienced ones. What is clearly a typo to the latter may result in lack of interoperability from the former.

- Supplementation. Standards codify some knowledge, not all that is required. Supplementary resources may be required to provider further direction and guidance or to provide a platform for ongoing maintenance.

- Maintenance. As highlighted earlier, standards are products that require maintenance (repair, exception handling, refreshment, evolution) across their entire lifecycles. Otherwise, they are simply reminders of past consensus (and resource usage).

- Where possible, computable dissemination is also desirable to avoid idiosyncratic interpretation of specifications.

- Maturity. The maturity of any given standard should be understood by its users at any point in time. As highlighted earlier, the US ONCHIT publishes three variants of maturity relevant to interoperability standards – Standards Process Maturity, Implementation Maturity and Adoption Level (see Appendix C).

  Many of the e-health standards developed over the last 10 – 15 years have in fact been published with quite limited testing, whereas prior testing, multiple interoperable implementations with substantial operational experience are highly desirable.

[4] As a reminder, there are over 400,000 concepts in SNOMED-CT AU and over a million relationships between the; and HL7 International has over 50 active working groups (HL7 International, n.d.).

[5] Comprising ISO TC/215 (Health Informatics), HL7 International, CEN, CDISC, and GS1.

Case study – HL7 version 3

Amidst the early steps in the journey towards FHIR, Grahame Grieve declared that "HL7 v3 has failed" (2011) – by which he meant failure to achieve HL7's overall ambitions for interoperability. In fact, FHIR draws upon V3's heritage.

The development of HL7 V3 was a massive undertaking, with the first normative edition being published in 2005 after a decade of development. As it moved away from the inherent customization allowed in V2 and aimed to provide consistent data modelling that would support broader interoperability, it was seen as one of the key standards for the future, particularly by the UK National Health Service (NHS), probably the most important early adopter.

In terms of the ONCHIT's standards process maturity, it would have been categorized as "final" in 2005 – it was considered normative by the organization that maintained it.

But in terms of implementation maturity, it would have been considered only "pilot", despite the large scale of the NHS pilots. Its adoption in terms of discrete organisations was low.

Implementation and market experience were substantially lacking when organisations like the NHS made major investments in this "standard for the future".

In addition, the World Trade Organization (WTO) Committee on Technical Barriers to Trade highlights that globally relevant standards, which should be Australia's preferred position, should (ANSI, 2011):

- Respond effectively to regulatory and market needs
- Respond to scientific and technical developments
- Not distort markets
- Not adversely affects fair competition
- Not stifle innovation and technological development
- Be performance based, as far as possible, as opposed to design prescriptive.

3.6 Requirements for appropriate, effective and efficient standards development

The following set of requirements for appropriate, effective and efficient standards development are assimilated from various documentary sources (ANSI, 2019; IEEE, 2016; ISO, n.d.; ISO/IEC, 2004; Open Data Institute, 2018; OpenStand, n.d.; Standards Australia, 21 January 2016, 2019; The Open Group, 2018) and stakeholder consultation.

A set of principles embodying good standards development practice is articulated, followed by articulation of the different roles and functions required. Finally, some trends affecting health interoperability standards development are identified.

3.6.1 Principles

Principles guiding good practice in standards development include the following:

Principle 1:	**Openness**
Description:	Standards development processes are open to any interested party on a non-discriminatory basis.
Rationale:	Standards development affects a diverse range of stakeholders, benefits from diverse input and strives to build consensus. Poorly designed consultation and governance can lead to lack of consideration of some issues or viewpoints, and subsequent non-adoption.
Implications	Discrimination can be inadvertent as well as intentional. Standards development processes should include a variety of inclusion measures and pathways. It should proactively seek diversity and include explicit stakeholder engagement, input, monitoring and assessment. There should be no undue financial barriers to participation and voting membership on the consensus body should not be conditional upon membership in any organisation, nor unreasonably restricted based on technical qualifications or other such requirements.

Principle 2:	**Transparency**
Description:	Information on current work programs, proposals and how to participate is available to all interested parties.
Rationale:	Transparency enables openness, including to individuals and organisations that may be unsure whether or not they have an interest in the standard(s) concerned and are therefore not actively participating.
Implications	Information on current work programs, proposals and how to participate should be notified to potential stakeholders (pushed) as well as made accessible (pulled). This should include plain language descriptors that do not preclude non-experts. Written procedures should govern the methods used for standards development and these should be available to any interested person.

Principle 3:	**Representation**
Description:	There is balanced participation in the standards development process by interests that will be significantly affected by a resulting standard.
Rationale:	The balance of interests in a standard should be determined through explicit consideration of the objectives, issues, implications, etc., not simply by who participated.
Implications	Transparency and openness enable but do not assure balanced participation – this must be proactively sought. Criteria for balance should be incorporated in written procedures. "The interest categories appropriate to the development of consensus in any given standards activity are a function of the nature of the standards being developed. Interest categories shall be discretely defined, cover all materially affected parties and differentiate each category from the other categories. Such definitions shall be available upon request. In defining the interest categories appropriate to a standards activity, consideration shall be given to at least the following: "a) producer; "b) user; "c) general interest" (ANSI, 2019).

Principle 4:	**Impartiality**
Description:	Standards development processes do not give privilege to or favour the interests of any particular party.
Rationale:	Adoption of standards can have substantive impacts on individuals, organisations, societies and economies. Fairness and equity must be ensured during their development not only to encourage adoption, but to assure fair and equitable outcomes through adoption.
Implications	Standards development processes should not be dominated by any single interest category, individual or organisation. "Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints" (ANSI, 2019). Written views and objections from any participant should be given prompt consideration. Written procedures should contain identifiable, realistic and readily available appeals mechanisms for the impartial handling of procedural objections.

Principle 5:	**Consensus**
Description:	There should be general agreement to the publication of a standard, characterised by (ISO/IEC, 2004): (i) the absence of sustained opposition to substantial issues by any important part of the concerned interests, and (ii) a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments. Note: consensus need not imply unanimity.
Rationale:	There are few de facto standards directly associated with health interoperability, since there is little health software market dominance globally. Most standards concerned are de jure, and these typically require consensus.
Implications	Written procedures should include explicit definition of consensus and describe how this is achieved in practice. Evidence of consensus in accordance with these written procedures should be documented for every standard published.

Principle 6:	**Market need and net benefit**
Description:	A new or significantly revised standard should only be generated when a market need has been clearly defined and net benefit to the Australian community can be reasonably demonstrated.
Rationale:	The potential impacts of a proposed Standard should be understood, including the costs and benefits of its implementation.
Implications	Net benefit means that "a value or benefit to the Australian community that exceeds the costs likely to be imposed on suppliers, users and other parties in the community as a result of its development and implementation" (Standards Australia, 21 January 2016). Net benefit appraisals should be available to stakeholders.

Principle 7:	**Timeliness**
Description:	The degree of urgency with which a standard is required should be considered but should not override other principles.
Rationale:	While a market need might include a high degree of urgency, there are limits to the timeframes for development of appropriate, effective and efficient standards that are likely to achieve the widespread adoption required for health sector interoperability.
Implications	Urgency of need should be considered in terms of the type of product generated (e.g. interim standard, technical specification, draft for trial use), its applicability and maturity (see Appendix C).

This principle also implies that the need for new or significantly modified standards should be taken into account early in interoperability projects, not left until project deadlines may preclude appropriate, effective and efficient standards development.

Principle 8:	**Internationality**
Description:	International standards pertaining to health interoperability should be used in preference to national and sub-national standards.
Rationale:	The Australian Government has committed to using trusted international standards first, where appropriate. This aligns with Australia's obligations under the World Trade Organization's Technical Barriers to Trade Agreement (DIIS, 2019).
Implications	Australian requirements should be incorporated into international standards as far as possible, which requires a proactive program of participation in relevant international standards development processes and fora. Intention to deviate from international standards pertaining to health interoperability should be justified on the basis of net benefit to the Australian community, and aligned with Australia's obligations under the World Trade Organization's Technical Barriers to Trade Agreement.

Principle 9:	**Compliance**
Description:	Standards are developed for compliance with relevant regulation, including competition law.
Rationale:	Standards must not require, in their adoption, the contravention of Australian law.
Implications	Relevant regulations must be identified during standards development processes, their impacts considered, and legal advice sought as appropriate.

Principle 10:	**Coherence**
Description:	Interoperability standards are developed for coherence with other health sector and digital health standards and industry developments as appropriate.
Rationale:	Different standards are typically integrated to achieve interoperability and should be developed with this in mind. Standards development should also take account of emerging needs, as well as current ones.

Implications	Other relevant standards should be identified as early as possible in the standards development process and the potential implications of interaction considered. Standards development processes should explicitly consider both current and likely future needs.

Principle 11:	**Availability**
Description:	Standards for health sector interoperability should be freely available.
Rationale:	Costs of determination whether or not a standard should be used, and of adoption and use should be minimised. Acquisition of all the standards needing to be integrated to achieve interoperability can be quite costly, particularly to small businesses.
Implications	Open-source standards may be preferable where there are competing standards with similar fitness for purpose.

Principle 12:	**Support**
Description:	Approaches to disseminating supplementary knowledge associated with a standard should be considered during its development.
Rationale:	The knowledge codified in a standard may not be all that is required for consistent interpretation and implementation, especially where integration with other standards is required.
Implications	Standards developers should consider the production of supplementary documentation and other means of knowledge translation and dissemination.

3.6.2 Roles and functions

Stakeholder consultation indicates that the following roles and functions are all required for effective standards development, maintenance and management.

Table 1 - Roles, functions and capabilities required for standards development, maintenance and management

Role	Functions	Required characteristics
Funding	• Ensuring sufficient funds and other resources flow from all sources, public and private	• Representativeness, impartiality, transparency
Orchestration of a complex, adaptive	• System-wide oversight of the interoperability standards ecosystem	• Credibility, trust, impartiality • Legitimacy, longevity • Competencies:

Role	Functions	Required characteristics
standards ecosystem	• Development and communication of agreed architecture and roadmap to underpin standards development • Source of truth regarding standards requirements for various purposes (see ONCHIT example at Appendix D) • Ongoing governance of the national Standards Development Model • Development of standardisation policies • Sourcing of resources for sustainable standards development capabilities Liaison and advocacy with other key players to ensure overall architectural coherence • Evaluation of the value realised through the development and adoption of health interoperability standards.	▪ System governance ▪ Engagement, partnership and collaboration ▪ Strategic and tactical planning ▪ Liaison, negotiation, advocacy ▪ Standardisation expertise (strategic, technical) ▪ Health sector knowledge (policy, structures & frameworks) ▪ Digital health industry knowledge (markets) ▪ Enterprise architecture expertise ▪ Policy development and implementation • Capacities: ▪ Effective processes ▪ Accessible infrastructure
Commissioning	• Articulation of the cases for and requirements of new standards development nationally • Articulation of purchaser-required standards development protocols (e.g. process requirements) • Sourcing of resources for new standards development • Assurance that developed standards are fit for purpose	• Credibility, trust, impartiality • Competencies: ▪ Procurement and commissioning expertise ▪ Strong standardisation expertise (technical) ▪ Strong health sector knowledge (workflows, data) ▪ Digital health industry knowledge (standards used and standardisation capabilities) • Capacities: ▪ Effective processes

Role	Functions	Required characteristics
Standards development	• Development of specific, fit-for purpose standards and associated artefacts, sourced both internationally and locally • Whole-of-lifecycle maintenance and product management	• Credibility, trust, representativeness, impartiality, openness, transparency • Competencies: ▪ Standards development expertise ▪ Standards implementation expertise ▪ Awareness of other relevant standards and endeavours ▪ Health sector knowledge (workflows, data) ▪ Digital health industry knowledge (standards used and standardisation capabilities) ▪ Product management expertise ▪ Negotiation skills • Capacities: ▪ Effective, inclusive processes • Accessible infrastructure
SDO accreditation or endorsement	• Independent assurance that SDOs meet international and national requirements for standards development	• Credibility, trust, impartiality, transparency • Legitimacy, longevity • Competencies: ▪ Accreditation expertise ▪ Standards development expertise • Capacities: ▪ Effective, inclusive processes ▪ Accessible infrastructure
Support for standardisation	• Marketing • Consistent and coherent education and training	• Dependent on the kind of support concerned

Role	Functions	Required characteristics
	• Authoritative technical support • Support for networking amongst developers and implementers • Sandpits, reference sites, etc. • Knowledge translation and preservation • Community-building	
Conformance assessment and certification	• Assurance that specific products are standards-compliant	• Credibility, trust, impartiality, transparency • Legitimacy, longevity • Competencies: ▪ Conformance assessment and certification expertise ▪ Strong standardisation expertise (technical) • Capacities: ▪ Effective, inclusive processes ▪ Accessible infrastructure
Research and development	• Ongoing investigation into how standardisation can be best directed to achieve interoperability in a context of exponential growth of the Internet of Things and a data tsunami	• Credibility, trust, impartiality, transparency • Competencies: • Research and development expertise

3.6.3 Trends in standards development

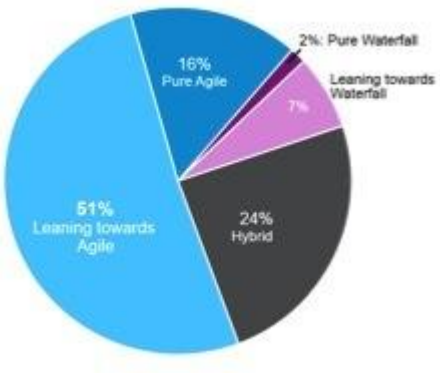
Trends in standards development for health sector interoperability have originated from at least three inter-related sources: trends in technology, changes in commercial orientation within some SDOs, and the increasing importance of standards profiling:

Trends in technology

Significant changes in technology and the way technology projects are increasingly undertaken have impacted both the form that standards take and the way they are developed over the last 15 years or so.

These changes include:

- The growth of agile software development and its maturity into an enterprise-based approach. Although rapid application development methodologies have been around for a long time, agile methods have come to dominate more recently. A recent HP survey of IT professionals illustrates this (Jeremiah, 2015):



The vast majority (>90%) of organisations surveyed reported that they primarily use agile methods, either entirely or infused into other methods.

Of those who have adopted agile methods, the majority have done so since 2009-10.

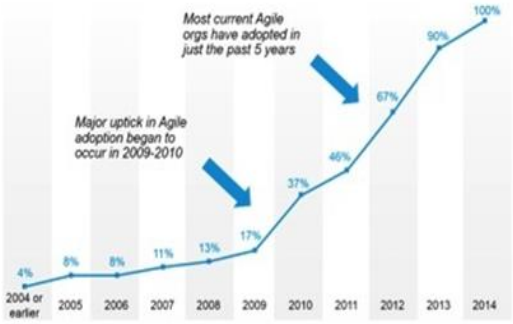


Figure 5 – Use of Agile (Jeremiah, 2015)

This has been driven by a shift in focus from large, standalone applications to smaller, agile-based platforms designed for connectivity, in turn driven by cost and time-to-market pressures. Enterprise-agile has also now taken hold. While agile used to be about small teams, it is increasingly about agile frameworks that coordinate work and releases across multiple teams (Balbes, 2017). DevOps is a natural evolution, focusing on rapid IT service delivery through the adoption of agile, lean practices in the context of a system-oriented approach, and (as the name suggests) seeking to improve collaboration between development and operations teams.

- The growth of the app economy (from a $20 billion industry in 2012 (narrowly-defined) to $143 billion in 2017 (Scarpelli, Miller & Stephens, 2017) and a parallel move to a more data-driven world in which: a) data needs to extracted and assimilated, at large-scale, from a myriad of source systems via automated means; and b) data-driven apps are developed quickly to find out about how well they add value to customers before learning and iterating from the results.
- The widespread connection of legacy systems to the Web as well as the growth of new Web and Cloud-based systems, and in the last few years, the explosive growth of the IoT.
- The corresponding growth of the API economy, enabling connection. An application program interface is a set of routines, protocols, tools and standards that specify how

software components should interact with each other. APIs are based on web service data exchange standards.

All of these and other changes have impacted the form that standards take. In a slower-paced, less connected and less agile world, the traditional form of standards – paper/PDFs – worked well. Knowledge was codified into documents such as the standard itself and possibly accompanying implementation support or contextual documents, and software developers worked from these to develop systems and interfaces between systems. Standards were essentially developed, then handed over to implementers – the corollary of the waterfall approach.

Corollary to the changes in software development paradigms, the newer world requires:

- Greater agility in standards development – to meet accelerated time frames, reduce cost and to build greater fusion between development and operations.
- A move away from document-based paradigms, such as HL7's Clinical Document Architecture (CDA) – the staple of NEHTA's clinical informatics work – and monolithic architectures such as HL7 V3 RIM-based messaging towards standardised API-based paradigms – to meet the needs of apps that access different systems and assimilate data for the user rather than the user having to query these different systems, reconcile the data and assimilate them. API-based approaches allow information to be pulled directly into workflows as needed, rather than be pushed when the source is ready.
- Standards that are released more rapidly, tested iteratively and have a more continuous link between development and operations.

Example – FHIR

FHIR stands for Fast Healthcare Interoperability Resources and the FHIR standard is published by HL7. It defines sets of data formats and elements ("resources") and uses contemporary, web-based API technologies to retrieve and manipulate data. The data stays in the application that is source of truth and the FHIR API retrieves this authoritative data as and when required.

FHIR supports four interoperability paradigms:

- REST – a software architectural style used by many contemporary, large-scale services such as Amazon and Twitter that allows requesting systems to access and manipulate representations of Web resources
- Documents – including CDA documents
- Messages – request/response events including HL7 V2 and V3
- Services – other SOA-based interfaces.

The content of the FHIR resources stays the same irrespective of the interoperability paradigm – introducing both flexibility and rigour at the same time.

FHIR is designed for pragmatism and health-enterprise wide agility. It focuses on implementers, supports multiple paradigms and architectures, targets support for

common scenarios, leverages cross-industry web technologies, and requires human readability as base level of interoperability. However, it also demands strong governance – to ensure it remains standardised.

FHIR resources carry levels of maturity, to give degrees of certainty to the market (HL7, 2018):

- FMM0 – a draft artefact is published
- FMM1 – the artefact produces no build warnings during the build process; the responsible working group considers the artefact substantially complete and ready for implementation
- FMM2 – the artefact has been tested and successfully supports interoperability among at least three independently developed systems, e.g. at an approved Connectathon; the interoperability results have been accepted by the FHIR Management Group
- FMM3 – the artefact has been verified by the relevant working group as meeting conformance resource quality guidelines; and has been subject to a round of formal balloting and comment
- FMM4 – the artefact has been tested across its scope, published in a formal publication and implemented in multiple prototype projects
- FMM5 – the artefact has been published in two formal publication release cycles and been implemented in at least 5 independent production systems in more than one country
- FMM6 – the responsible working group and the FHIR Management Group agree the material is ready to lock down; the artefact has passed HL7 normative ballot.

Accordingly, FHIR has relatively low overhead compared to HL7 V3 and its deployment can be agile but enterprise-rigorous. It is flexible in terms of paradigm applicability, and cycles through development and operation iteratively while allowing implementers to understand their risk (via the maturity model).

Example – SNOMED CT AU

SNOMED CT is both enormous and enormously complex. It contains over 400,000 unique concepts, over a million polyhierarchical relationships between them, and undergoes significant ongoing change – including because our knowledge of human biology continues to grow, requiring our representations of it to evolve.

SNOMED CT is far too large and complex to deliver in traditional document form. It is therefore released electronically, and in association with tooling that facilitates its adoption and ongoing use. Commercial operators, including the CSIRO in Australia, have produced a variety of value-adding tools for use with SNOMED CT and education and training providers have stepped in to upskill potential and existing users – examples of industry collaboration based on viable implementation support business models.

Changes in commercial orientation

Traditionally, interoperability standards development was undertaken by organisations whose business models featured the sale/licensing of standards, in some cases combined with membership revenues.

In 2007, nine countries including Australia collaborated to acquire the rights to SNOMED CT from the College of American Pathologists, which had maintained the clinical terminology on a traditional basis. The International Health Terminologies Standards Development Organization (IHTSDO) saw a change from an organizational licensing model to a national and organisational membership model. As implemented in Australia through NEHTA and now ADHA, the business model is that SNOMED CT is fully funded by government(s) and freely available to users.

In 2013, HL7 International changed its business model to license its standards and related products (e.g. implementation guides, profiles and domain models) at no cost. Its primary revenue source is now membership fees and training and certification fees. HL7 Australia is responsible for (and owns the rights to) localising HL7 standards, and its revenue model is also heavily based on membership. However, in the relatively small Australian market, this pragmatically imposes revenue limitations – and thereby capability constraints. The business model is also arguably skewed towards larger stakeholders and their interests.

Increasingly, both SNOMED and HL7 International standards have been accompanied by tools that facilitate their use and have spawned commercial tool provision. For example, CSIRO provides toolsets for managing the use of CNOMED CT AU through the Australian e-Health Research Centre – also supported substantially by funding though the Queensland and Australian Governments.

Standards profiling and integration

Profiling of standards refers to constraining the optionality inherent within most standards (to ensure they are suitable in many contexts), allowing implementers to document an agreed

subset of the standard and deliver a shared interpretation. It is often a layered or iterative process.

Integration refers to combining more than one standard or profile, none of which is sufficient to meet all requirements by itself, into an *integration profile* that collectively meets the requirement. A metaphor would be that the standards for both fire doors and windows and for wall materials required to build a structure in a bushfire-prone area, must all be profiled (the appropriate flame-resistance rating selected) so that no component provides a point of weakness.

Increasingly, in particular as health information exchanges have proliferated, the development of standardised integration profiles that can be deployed across wide ranges of systems has become important.

Generic steps describing this approach to standards profiling and integration include (van Pelt, 2017):

- Identifying use cases from an end-user perspective, including scenario, actors, privacy requirements and variations.
- Selecting profiles and standards that support the use case (e.g. by selecting a realisation scenario).
- Refining data content, including document templates, metadata and terminology.
- Writing interoperability specifications (implementation guides) that describe the standards/profiles selected, the refined data content, and other project specific local needs. This specification enables implementation of the use case across the various IT systems and devices.
- Organising testing by preparing test cases and a test environment for implementers to demonstrate component interoperability and by organising cross-implementer connectivity testing.

Education, support and standards community participation are additional important elements.

The above is incorporated into the approach that FIHR takes. It is also the approach taken by IHE (Integrating the Healthcare Enterprise) internationally. The Global Digital Health Partnership (GDHP, n.d.)[6], which was initiated by ADHA in 2018 and for which ADHA currently provides the Secretariat, notes that "standards profiling organizations, such as IHE and PCHA/Continua as well as "Gemini" the Joint Initiative between HL7 and IHE focused FHIR, can help drive global harmonization forward by composing international standards according to best-practice" (GDHP, n.d., p.59).

[6] The Global Digital Health Partnership (GDHP) is a collaboration of governments and territories, government agencies and the World Health Organization, formed to support the effective implementation of digital health services. It is currently focused on five work streams: Interoperability, cyber security, evidence and evaluation, policy environments, and clinical and consumer engagement.

3.7 A complex adaptive ecosystem

A business ecosystem is the network of organizations – including suppliers, distributors, customers, competitors, government agencies, and so on – involved in the delivery of a specific product or service through both competition and cooperation. The idea is that each entity in the ecosystem affects and is affected by the others, creating a constantly evolving relationship in which each entity must be flexible and adaptable in order to survive, as in a biological ecosystem. (Investopedia, 2019).

3.7.1 Complex adaptive systems

Complex adaptive systems, both in nature and in socio-technical environments, are defined by a set of common characteristics (Collins, n.d.; Lipsitz, 2012; Rouse, 2008):

- They comprise many independent agents whose behaviours are based on a variety of drivers than may be disinterested, competing or collaborative. These agents do not act in unison or in coordinated ways.

  A large number of independent actors in health care standardisation act independently – for profit, for improved quality and safety, for differentiation, for compliance; to sell products and/or services, to govern, regulate or provide health care; to follow, to lead; to thrive, to survive; and in many other different ways and for many different reasons – but their *collective* actions determine whether or not standardisation that genuinely supports interoperability takes place or not.

- These agents tend to adapt to each other's behaviours, but the overall system behaviours generated are non-linear and dynamic – they may in fact appear to be random or chaotic.

- Agents are intelligent. As they experiment, gain experience, learn and evolve, their individual behaviours change and as a result, overall system behaviours inherently change over time.

- This adaptation and learning results in self-organisation. Behaviour patterns are emergent rather than designed. "The nature of emergent behaviours may range from valuable innovations to unfortunate accidents" (Rouse, 2008).

- Intelligence resides in the whole system. Different individuals may hold specific knowledge or differing interpretations of a common reality, diversity is rich, and no individual possesses all the knowledge required to orchestrate a desired result.

  For example, there are "people who have knowledge of one part of the ecosystem (say terminology) but not another (say software development). It is very easy for such people to come up with brilliant solutions in their own area but also to propose things that software people know just won't work (e.g. because of querying performance)" (Beale, October 2009).

- Accordingly, there is no single point of control. System behaviours are often unpredictable and uncontrollable, and no one is "in charge." Complex adaptive system behaviours are usually more easily influenced than controlled. In a complex adaptive ecosystem, achieving mutual objectives requires first establishing the degree of mutuality, then encouraging effective interactions among the agents.

The table below highlights the kind of characteristics typically used to build convergence towards a desired outcome in a complex adaptive system, juxtaposed against those in a more linear form of traditional organisation. These are the characteristics that are needed for the health interoperability standardisation ecosystem.

Table 2 - Shaping complex adaptive systems compared to traditional systems

	Traditional System	Complex Adaptive System
Roles	Management	Leadership
Methods	Command and Control	Incentives and inhibitions
Measurement	Activities	Outcomes
Focus	Efficiency	Agility
Relationships	Contractual	Personal commitments
Network	Hierarchy	Heterarchy*
Design	Organizational design	Self-organization
Authority	Taken	Given

* A heterarchy possesses a flexible structure made up of interdependent units, with relationships between them characterised by multiple intricate linkages that create networked paths rather than hierarchical ones. Authority within a heterarchy is distributed.

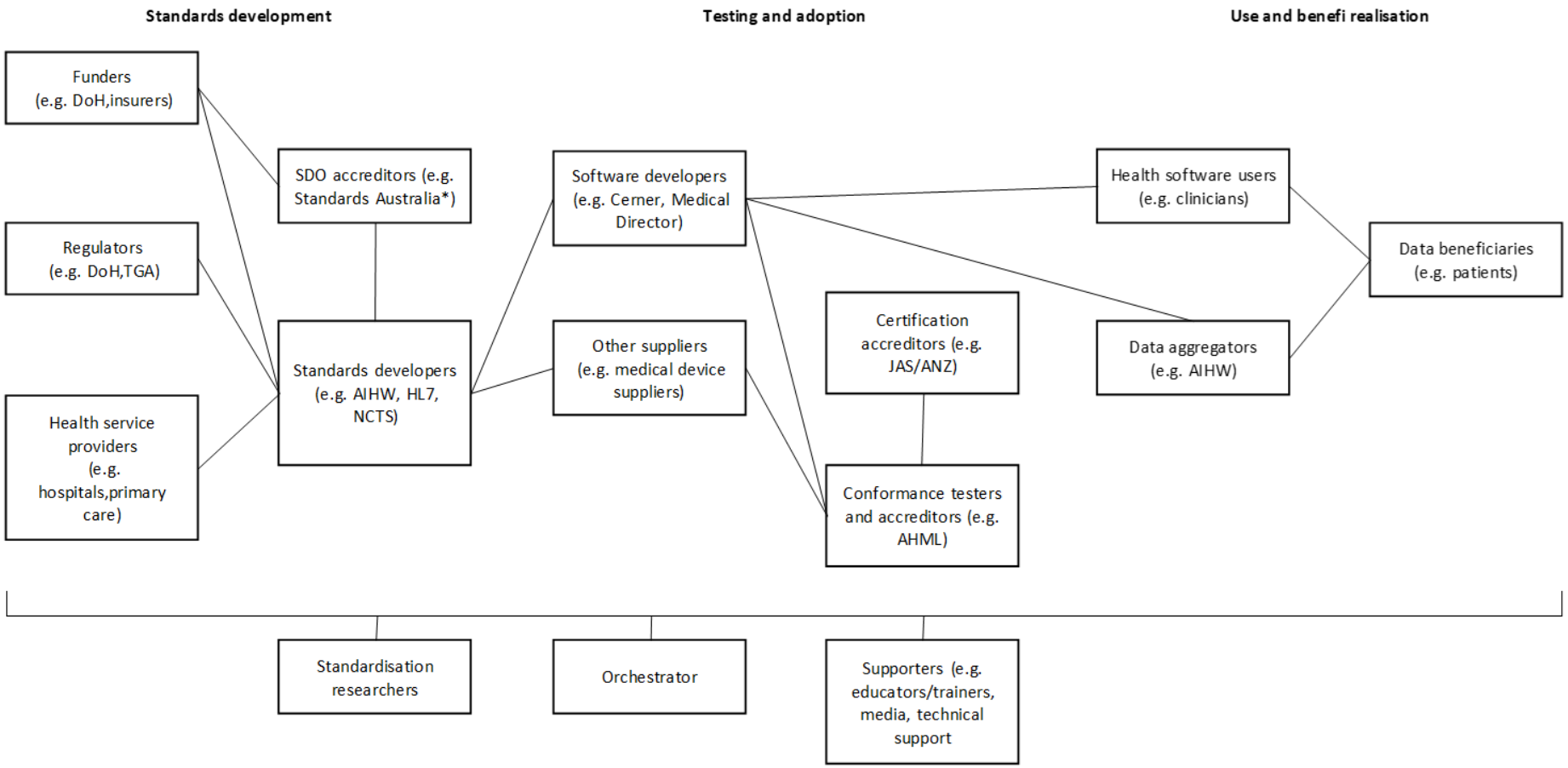
Some additional pointers emerge from the literature on design within complex, socio-technical environments. Socio-technical approaches to design include (Baxter and Sommerville, 2010; Greenhalgh et al, 2010; Petrakaki et al, 2010; Whitworth and Ahmad, 2013):

- Participatory co-design – recognising that software developers (engineers) must be as much part of the solution-building as users (clinicians) and all other stakeholders.
- Computer-supported cooperative work – finding ways to engage different viewpoints meaning fully and efficiently.
- Recognition of the situated nature of actions (e.g. the pressures and motivations for a software developer are not the same as those of a health service provider).
- Agile methods and soft systems methodologies (tools for investigating less structured problems, questioning what the standard/system should do, why and in what context before proceeding to how it should be done).

3.7.2 The ecosystem

The health interoperability standards ecosystem includes a large and diverse range of actors. These are depicted in groups in Figure 6, which also suggests a flow of standardisation activities from left to right. For the sake of readability, only major linkages have been depicted and all are bi-directional.

The ecosystem comprises more than the standards *development* roles and functions described in section 3.6.2, because it includes implementers, users, beneficiaries, et al. – i.e. it extends to the whole standardisation lifecycle. The aim of Figure 6 is to contextualise the standards development roles, illustrating that they exist within rather than entirely comprising, the standards ecosystem.



* Standards Australia accredits other organisations to develop Australian Standards - but only Australian Standards

Figure 6 - A standards ecosystem

4 Lessons learnt

"The noisiest of those competitive battles (between suppliers) will be about standards. The eyes of most sane people tend to glaze over at the very mention of technical standards. But in the computer industry, new standards can be the source of enormous wealth, or the death of corporate empires. With so much at stake, standards arouse violent passions."

(The Economist, February 23, 1993, as cited by Cargill, 2011)

There is a great deal that can be distilled from experience of both successful and not so successful standardisation programs from our own past, from other places and from literature. The quote above is a reminder of one that seems easily forgotten – the content of standards, especially technical ones, may not be terribly interesting to most people, but they do arouse strong reactions because their implementation can have very major consequences.

4.1 Lessons from our past

"Those who cannot remember the past are condemned to repeat it."
(George Santayana, as quoted in Goodreads, n.d.b)

A clear view that standards were crucial to e-health, and interoperability in particular, was expressed in Australia following the release of the National Electronic Records Taskforce in July 2000 (NEHRT, 2000). The then Department of Health and Ageing established a National InfoStructure Development unit to orchestrate standards activity and assess national information infrastructure requirements (such as health identifiers) in collaboration with States, Territories, SDOs and industry. This set of activities was greatly expanded to form NEHTA's initial work program in 2004-05, with the realisation that the foundations for e-health must be addressed prior to a national electronic health record being built.

It took NEHTA some time to establish itself and build its own infrastructure and relationships, etc., but standards development and maintenance looked promising in Australia until 2010-11. It was reasonably well-coordinated, with collaboration and cross-representation between SDOs, NEHTA, industry, jurisdictions and central agencies. There was consistent funding and other resourcing support for standardisation *capabilities* as well as for the acceleration of some specific standards development. NEHTA was also considering building conformance and accreditation capabilities, and there was some support for standards profiling and integration through IHE Australia.

There were weak points:

- There were few market drivers for widespread implementation. The standards well implemented tended to be those that supported the current business models such as point-to-point messaging and within organisation interfacing, while those aiming for more systemic interoperability were largely seen by industry as costs dissociated from benefits.

- Some very mixed signals were also shown to the sector. This is perhaps best demonstrated by a case study.

Case Study – Managed Health Network Grants

The Managed Health Network Grants program provided funding for Divisions of General Practice to implement secure electronic messaging between December 2005 and June 2008. It resulted in an array of different electronic messaging solutions being deployed across the Australian primary care sector – solutions that did not incorporate common standards and thereby did not interoperate systemically.

While some benefits were undoubtedly achieved within Divisions, the program also systematically laid out today's legacy. Large expenditures have been made ever since on secure messaging (quite possibly larger than the original program cost) to try to reverse-engineer this large-scale legacy. ADHA's SMD project today aims to do exactly that. Not coincidentally, this secure messaging work commenced in 2009.

This is not wisdom in hindsight. Many stakeholders at the time argued that an alternate approach could have been to make the program funding available subject to messaging providers demonstrating they could effectively interoperate without special effort – i.e. introduce a market incentive to messaging providers to do then what we have been trying to reverse-engineer ever since. Evaluation of the program in 2009 identified the issue: "the future of eHealth in Australia will rely upon the development of national standards for interoperability, patient and provider identifiers and the establishment of other national foundations for eHealth" (Communio, 2009, p.10). National standards for interoperability, patient and provider identifiers and other national foundations for eHealth were already under development.

Yes, some local benefits were undoubtedly achieved. But a policy decision was also taken to deploy large-scale lack of standardisation, and the overall, whole-of-lifecycle cost-effectiveness of the Managed Health Network Grants program should be understood in this light.

Nationally, we were talking about the deployment of standards and doing the opposite.

[Note: Examples such as these are not included to sleight the decision-makers of the day. Rather, they are included because we should learn from our past, and this example illustrates the costs of lack of orchestration. It is not an isolated example.]

4.1.1 2010-11 to 2016

The 2010-11 Federal Budget allocated $466.7 million for the creation of the Personally-Controlled Electronic Health Record (PCEHR) which NEHTA was required to implement from 1 July 2012.

The PCEHR was envisaged at that time as a driver of broader interoperability through standardisation, not just as a medical record repository (NEHTA, 2011):

- "The PCEHR System will provide the necessary national infrastructure, standards and specifications to enable secure access to an individual's health information drawn from multiple sources. Suppliers of eHealth systems will be able to enhance their products and services to become conformant with the relevant standards and specifications and support healthcare organisations in accessing the PCEHR System" (p.2).
- "Beyond July 2012, the policy directions for eHealth are clear. The Government's complementary investment in tele-health coupled with the rollout of the National Broadband Network align with the National E-Health Strategy trajectory endorsed by the Australian Health Ministers' Conference in 2008" (p.15)

  [That Strategy premised that eHealth systems and services such as the PCEHR must sit on top of information infrastructure foundations (standards, rules and protocols) analogous to an "information highway" (Deloitte, 2008).]
- Accordingly, the PCEHR was designed to "use a standards-based approach and … leverage existing Australian and International Standards and technical specifications" (NEHTA, 2011, p.65)

However, the PCEHR roll-out required the development of standards at a pace inconsistent with a key success factor for successful standardisation – the need for consensus amongst diverse interests in the absence of existing, market-proven standards.

The PCEHR-related specifications were largely developed by NEHTA staff and subsequently put to Standards Australia, for ratification. They were quickly embedded into PCEHR developments, and subsequent changes would have meant changes to the PCEHR system – i.e. once implemented, the costs of change became high.

When its fast-tracked specifications were put to Standards Australia for ratification, many in the IT-014 (Health Informatics Technical Committee) community:

- Expressed doubts about clinical safety aspects.
- Argued that Standards Australia's rules about openness, transparency and consensus had not been followed.
- Felt that changes were required to fit the purposes of wider interoperability.
- Felt that resistance was high to making changes that would require PCEHR re-work, so evolution of the fast-tracked standards was unlikely to be implemented anyway.

Standards Australia was caught in the crossfire between NEHTA – a potentially significant funder – and its own community of technical experts, many of whom had

become increasingly disillusioned. Standards Australia's ability to input more broadly to satisfying PCEHR requirements was decimated by the withdrawal of funding:

> "Standards Australia was forced to discontinue work on 60 technical standards for the PCEHR in July 2011 because further funding had not been forthcoming from the Government" (Jolly, 2011).

NEHTA's specifications were used for the PCEHR, but their use more broadly was very limited at best. NEHTA could not simultaneously support effective *standards* production and be a major consumer of standards.

The 18 months to July 2012 were a blur of frenetic activity – decisions were made and actions taken in fast-motion. The unintended consequences included:

- An end to the close working relationship between NEHTA and Standards Australia.
- An end to the working relationship between HL7 Australia and Standards Australia via which HL7 localisations had been developed and maintained under the IT-014 ambit. HL7 Australia lost faith in Standards Australia's independence.
- Significant animosity between NEHTA and the broader health informatics standards development community and a loss of credibility for the national program in the domain of interoperability standardisation.

Many of the specifications developed during this period had nowhere to go for ongoing lifecycle maintenance and management – while NEHTA had engaged in a vigorous program of standards *development*, it was not set up to perform the ongoing roles associated with standards *product management*. Many of the specifications developed during this period have not been maintained since.

The split between Standards Australia and HL7 Australia had further ramifications. The entire stock of HL7 standards published through Standards Australia was its intellectual property, but it no longer had the rights to create new HL7-related IP. And HL7 Australia could not further maintain those Australian Standards, since Standards Australia's rules involve its ownership of the resulting IP. HL7 International's increasing protection of its IP precluded this, even if HL7 Australia had been willing.

This stock of standards remains in limbo – effectively unmaintained.

The following statements from the Royle review of the PCEHR provide a telling summary (Royle, Hambleton & Walduck, 2013):

> "The Governance processes around the PCEHR did not adequately represent the industry … and did not effectively balance the needs of government and private sector organisations" (p.14).
>
> and
>
> "Development of and compliance with standards are critical for adoption of any federated system or process. Common terms and language, IT protocols and report structures will improve integration and application however standards should be developed with current workflows in mind *and using accepted and tested methods for development*" (p.14).

The Lesson

Before 2010-11, NEHTA's role had primarily been to promote interoperability across the health sector by encouraging coordination of standardisation and development of interoperability infrastructure that was both more economical and safer to provide for the whole sector than for disparate parts of the health system to provide for themselves, such as health identifiers.

There was still some criticism of NEHTA's modus operandi, which was seen as not sufficiently open and consultative, but the Boston Consulting Group's 2007 evaluation of NEHTA nonetheless praised its eHealth standards role.

NEHTA becoming a mainstream eHealth solution provider in 2010-11, however this introduced a singular focus to its interests. The needs of the PCEHR became all consuming, and the view that draft standards could quickly be developed without substantial contribution from the wide range of stakeholders concerned, then converted to standards later, proved naïve – once implemented in the PCEHR, the costs of change would be preclusively high, and the standards were weighted heavily towards PCEHR needs.

The lesson – coordination of standardisation for interoperability across the health sector is difficult to combine with the delivery of any particular eHealth solution. The UK NHS encountered the same difficulty, and it is noteworthy that the successful coordination role played by the ONCHIT in the US is not similarly sullied by the responsibility to deliver an eHealth application.

4.1.2 From 2016 – ADHA

NEHTA was disbanded and replaced with ADHA partly because of its loss of credibility with the health informatics community. Royle et al (2013) argued that:

- NEHTA did "not have the confidence of the industry or audience that it is attempting to represent. Multiple factors … contributed to this including a significant broadening of the remit of NEHTA since its inception. A reset of this function is critical to ensure the Australian health industry can continue to evolve with a strong set of foundational capability that will enable operating efficiencies for all providers, whilst driving improved patient care benefits" (p.20).
- A reset was required for the policies, standards and frameworks necessary to enable interoperability in a decentralised environment, allowing for

> commercial models that ensure providers can generate an acceptable return on the investments made in shared infrastructure (p.17).

Royle et al also argued for "a regulatory body that monitors and ensures compliance against eHealth standards that are set and maintained by [ADHA]" (p.26).

ADHA has gone some way to retrieving this situation through a strong focus on industry engagement, and recent trends in IT standardisation towards agility and better connection between development and implementation are allowing standards communities globally to better deal with such pressures.

However, standardisation for health interoperability in Australia will not improve substantially until structural issues addressing the delineation of roles and functions are addressed.

4.1.3 Cultural issues

Health care more generally arouses great passions and great commitment. Within standards communities, there is a diversity of agendas, expertise, preferences and perspectives. A plethora of players are involved – small, medium and large businesses; volunteers; newcomers and long-termers; clinicians, software developers, informaticians and managers. Add the personality politics of health to these economic interests and the mix is volatile.

4.2 Lessons from overseas

Standardisation occurs in virtually all industries, markets and nations, but with different drivers and characteristics.

ADHA commissioned a report on Australian and international health informatics standards (EY, 2018), and this section draws from that report as well as additional sources. The EY report also provides wider, complementary reading on a range of international and Australian standards organisations.

4.2.1 The UK, USA and Europe

The UK NHS encountered similar difficulties to Australia, but is now "rising from the ashes", led by two key groups working collaboratively within their own ambits and together. The Professional Records Standards Body (PRSB) develops and helps implement standards for the structure and content of health and social care records[7]; while INTEROPen is a community of individuals, industry, standards organisations and providers who collaborate on identifying, developing and adopting technical standards for interoperability.

In July 2019, NHSX will commence as a new organisation for digital, data and technology operating outside the NHS. NHSX will "articulate clear standards for the use of technology in the NHS, including mandating internationally recognized standards for interoperability such as ICD-10, SNOMED-CT and HTML5" (Mackintosh, 2019).

[7] The PRSB's membership includes clinical and professional disciplines as well as patient groups. It develops national standards for the structure and content of health and social care records such as referral letters, discharge summaries and other handover communications. More information is provided at Appendix E.

Internationally, the US is now a world leader in standardisation for health system interoperability at large scale. Leadership is bipartisan and high profile. The roles described in section 3.6.2 above are well-delineated and delivered collaboratively, and it is noteworthy that the successful orchestration role played by the Office of the National Coordinator of Health Information Technology (ONCHIT) in the US is not similarly compromised by the responsibility to deliver an eHealth application.

In Europe, an eStandards project has been commissioned to generate a shared vision and roadmap for standards-based interoperability, emphasise integrating various base standards, support testing, deployment and feedback from implementation, and support standards communities.

4.2.2 WHO fora on Health Data Standardisation and Interoperability

A 2012 World Health Organization (WHO) global forum on Health Data Standardisation and Interoperability concluded that (EY, 2011, p.25):

- "It is essential to have national policies for eHealth and health information technology standardization.
- "Funding needs to be part of a national eHealth strategy in order to sustain the implementation of standards.
- "Competency-based workforce is essential for successful implementation of standards at national and sub-national levels", and "it is important for national governments to engage academic institutions and health-related non-governmental organisations to formalise specialised training programs for existing heath care professionals on standardisation and eHealth systems".

WHO convened a second such forum in Geneva in February 2014.This second forum included explicit consideration of successful standards adoption, and its conclusions noted that policies for standardisation and interoperability must (WHO, 2014):

- Demonstrate political will.
- Be embedded in a national *health* plan – i.e. be explicitly recognised in discussions of the health system sought, not just the technologies for the health system.
- Be long term, provide continuity, and commit to long-term investment.
- "Be based on mutual trust and understanding and genuine collaboration between all stakeholders from lawmakers to patients, facilitated from the start by a participative approach to policy-making, and encompassing public and private partnerships where necessary" (p.2).
- "Set health data and health IT standards to ensure interoperability at data, device and system levels, in a framework containing a fixed core set of maintained standards allowing for a degree of innovation outside that core set and allowing for development based on the capacity and maturity of eHealth systems and services; and regulate an appropriate degree of adoption in the country context" (p.2).

- Use or adapt existing international standards where possible.
- Build capacity from country and ministry level down to that of frontline health workers.
- Ensure good governance, balancing top-down and bottom-up approaches and based on a shared vision.

4.2.3 Global Digital Health Partnership

The GDHP notes that (n.d.):

- All 15 of its member countries and territories use internationally recognised standards throughout their digital health systems. ICD-10, LOINC®, and SNOMED CT® were in play almost unanimously, while HL7 standards and IHE profiles were mostly used to meet interoperability use cases and FHIR is rapidly emerging as a next-generation interoperability standard.
- There are opportunities for global harmonisation and alignment through standards bodies such as IHE and HL7. Nations should support, foster and cooperate with international standards development organisations, and participate in relevant international standards bodies such as HL7® International (46), SNOMED International (47), IHE International (39), ISO (48) and others as appropriate.
- Countries should work together to present, where appropriate, more unified requirements to health IT vendors, with the aim of driving down cost and decreasing time to market for Health IT solutions, and to better align standards globally.

4.2.4 Lessons from eHealth more broadly

There is now also a significant body of knowledge about good practices in implementing e-health applications and solutions (e.g. KPMG, 2012; Mair et al, 2012; NHS & DHHS, 2016; Stroetmann et al, 2006 and 2011; (US) National E-Health Collaborative, 2011). Synthesis of these and other sources provides the following profile of e-health implementation success factors (Rowlands, 2017), many of which are extremely pertinent to standardisation more specifically:

- Engagement, commitment and involvement of all stakeholders. All phases of e-health development, implementation and deployment must be supported by citizens / patients / clients, health providers, industry, authorities and funders. This requires intensive, early and ongoing efforts to foster a trusting and learning environment.

  The realities of stakeholders concerning both their business and the culture within which it is delivered must be understood and attended to, or utilisation will not occur.
- Clinical leadership and engagement represent perhaps the most critical of success factors. Realisation of clinical value requires change to clinical practices, and this can be daunting. This is facilitated by ensuring that clinical

staff own and drive e-health programs, and also by demonstrating program benefits through evidence based clinical outcome.

- High quality, multi-disciplinary teams are required for all dimensions of the investment, including procurement, project management, training and change management. Team profiles should include understanding of:
  - The potential of ICT for applications in health-service related contexts.
  - When to use external and when internal skills and resources.
  - How to procure and manage services from ICT suppliers and in-house teams.
  - How healthcare functions and how the various process elements need to interact as a healthcare chain or value system.
  - Clinical knowledge of healthcare practices.
  - How to achieve organisational change in complex settings.

  These teams must also have considerable personal credibility with stakeholders.
- Focus should be on core elements that drive the greatest benefits for the largest number of people, then incrementally adding components once the core system has been adopted. Requirements must be well-defined.
- Organisational changes and changes in clinical and working practices are what deliver the benefits. Patience is required in addition to excellent change management – it may take a relatively long time to achieve a critical mass of utilisation leading to realisation of benefits.
- Common barriers to the growth and sustainability of e-health initiatives include:
  - Policy and procedural complexity in the healthcare landscape such as the coherence of funding mechanisms with the objectives being pursued.
  - Sustainable business models including the achievement of critical mass.
  - Insufficient resourcing and incentivisation for ongoing maintenance and technical support, system adjustments, and continual staff training and engagement.
  - Lack of consistent procurement practices articulating standards requirements, and lack of conformance testing.

4.3 Lessons from other industries

EY's findings from its global scan included:

- "Industries and markets that are driven by user demand for compliance of standards have had greater success and [more] rapid adoption" (p.6)

- "The collaboration and involvement of a committed community of practice eager to develop, implement and maintain standards to improve interoperability … is paramount" (p.69)
- "'Perfect' theoretical standards that are produced through lengthy processes [are] seen as a barrier to interoperability in healthcare". Rather, interoperability standards "should be pragmatic, practical, implementable, and involve an agile process of developing and testing to support the growing needs of the industry. Using real case scenarios and testing through Connectathons [undertaken by FHIR and IHE] are seen as practical means to progress" (p.69).

The case study below provides a corollary from IT more generally.

Case study – the Open Systems Interconnection (OSI) standards (Cargill, 2011)

The Open Systems Interconnection standards published by ISO/IEC/ITU was a large body of work that aimed to enable non-proprietary computer interconnectivity. It was developed from the 'mid 70s to the 'mid-80s and its use was mandated by many governments (e.g. via the US Government OSI Protocol [GOSIP]). However, it was rapidly overtaken in the market with the commercialisation of the TCP/IP stack.

The OSI protocol was a technically driven, major change to current practice. It was highly complex and required considerable expertise to implement correctly. Reference implementations and test beds were lacking when the initial deployments were made, which led to initial interconnection failures. Market perceptions were poor.

In contrast, the TCP/IP drew upon a decade of work in the US defence sector, and as a coalition of interests commercialised it they took the approach of "rough consensus, running code, and dual implementations" – testing as they went Ultimately, TCP/IP provided a simpler solution that could be implemented by all vendors.

The OSI effort did, however, develop and proliferate knowledge about the conceptual basis for interconnectivity, and it is still important academically.

Health care is currently seeing a similar phenomenon in the rapid growth of FHIR.

Other reviews of standardisation provide further insights, including:

- "the more an industry depends on interoperability for sales and growth, the more standards will be in evidence" (Cargill, 2011, para. 1)
- "the size of the firms in coalitions supporting a technology and the extent to which they support their position through written contributions are significant determinants of technological choice in the standards decisions studied. The market share of the firms in the coalition was found to be significant only for

the buyers of compatible products, i.e., the monopsony power was significant, not the monopoly power. In addition, the technologies whose sponsors weighted market factors more highly than technical factors were more likely to be adopted in the standards decision studied. The proponents of both the adopted and non-adopted technologies were found to have equal belief in the overall technical superiority of their technical alternative, even after the decision. The installed base of a technology and process skills were not found to be significant predictors of the committee outcome" (Weiss & Sirbu, 1990, as cited by Cargill, 2011).

The outcomes of this study, which examined success factors influencing technological standardisation, are worth restating in plainer language – market considerations were found to be more important than technological excellence; and the market power (degree of monopsony) of buyers was more important than the market power (degree of monopoly) of sellers.

- "From our research, the advantages of Interoperability are quite clear from a purely technical perspective [but] considerations of all the variables and constraints a business operates under must be accurately evaluated to determine the benefits offered" (Berryman et al, 2013). For example, the greater the interoperability, the greater also the need for (and cost of) security. So, security standards become a part of the suite required, and the costs of maintaining security become part of the interoperability cost-effectiveness conundrum.

Standardisation has, perhaps, advanced more quickly in some other industries. However, great care must be taken in comparing and contrasting with interoperability for health. For example, reference is often made to the performance of the finance industry, but some important caveats are required:

- Firstly, there is enormous business motivation for the adoption of globally consistent financial transaction standards – namely, access to highly profitable markets. Even so, some core data is not fully standardised – e.g. Australian BSBs, international SWIFT numbers and IBANs and US Routing Numbers are all structured differently and are mapped instead of standardised.
- There is also a vast difference in complexity of the data being exchanged. All industries including finance and health must deal with addressing, demographic and other contextual data, but the core transactional data exchanged in finance is debits and credits – simple binary concepts that are used across all dimensions of finance and have been unchanged for over 700 years. In contrast, the transactional data in health comprises representations of human biology and other domains – 400,000+ concepts in SNOMET CT-AU with over a million, polyhierarchical relationships between them – and different representations for different purposes and industry sub-sectors. In additional, health concept representations change continuously as our knowledge of human biology evolves.

The airline industry is also often cited as an exemplar and does have some similarity in terms of its safety focus. However, travel booking systems came out of single applications that were increasingly made available to other parties, and thus cemented

as de-facto standards, while the IATA Operational Safety Audit (IOSA) standards – the industry's core safety standards – came about for market-based reasons. The IOSA program was developed between 2001 and 2003 through collaboration between disparate aviation industry stakeholders. It was initiated by the industry in response to an exponential increase in the number and cost of safety audits. In 2001, there were over 70,000 audits in use, costing in excess of $3 billion worldwide, with audits known to overlap in areas of content and intent (EY, 2018).

The Internet Engineering Task Force (IETF) commenced with the strong public investment by the US Government, but with the growth in importance of the Internet has developed into a self-sustaining initiative, based on widespread collaboration and adherence to principles of open standards development. The drivers are clear – to participate, adopt.

There are also potentially lessons arising from the National Construction Code (NCC) in Australia about the orderly implementation of standards, recognition that it takes time for industry to prepare for this, and the calling of standards into regulation. The NCC provides minimum requirements for safety, amenity and other characteristics in the design, construction, performance and liveability of new buildings and new building work. Its use is mandated through regulation in each State and Territory. It allows for variations in climate and other conditions. The NCC is a Council of Australian Governments (COAG) initiative developed to incorporate all on-site construction requirements into a single code. Changes to the NCC have been traditionally applied annually but have recently moved to a three yearly implementation cycle.

4.4 Lessons from management science

As highlighted in section 3.7, the standards ecosystem is a complex adaptive system – it has myriad independent agents whose behaviours are based on a variety of drivers and may be disinterested, competing or collaborative. Management science shows that these agents tend to adapt to each other's behaviours, but the overall system behaviours generated are non-linear and dynamic – they may in fact appear random or chaotic. They are also intelligent. As they experiment, gain experience, learn and evolve, their individual behaviours change and as a result, overall system behaviours inherently change over time. This adaptation and learning results in self-organisation. Behaviour patterns are emergent rather than designed.

Accordingly, there is no single point of control – no one is "in charge." Complex adaptive system behaviours are more easily influenced than controlled. Achieving mutual objectives requires first establishing the degree of mutuality, then encouraging effective interactions among the agents.

4.5 Summary – Key lessons

There is substantial commonality from the lessons arising from our recent past, other countries and industries, and the literature. The key lessons would appear to include:

- There are strong advantages to the separation of the ecosystem orchestration role from the delivery of e-health solutions. Good governance involves balancing top-down and bottom-up approaches, and a shared vision.

- The need for interoperability and standards (jointly) should be identified in a national *health* plan, as a critical enabler of health system improvement – i.e. be explicitly recognised in discussions of the health system sought, *not just the technologies* for the health system.
- In the absence of well-established industry standards, standards development must genuinely recognise the diversity of interests and potential gravity of consequences involved, and ensure openness, transparency, representation, impartiality, consensus, etc.
- Focus should be on core elements that drive the greatest benefits for the largest number of people. Requirements must be well-defined.
- Existing international standards should be used or adapted where possible. Note that this requires substantial work and sufficient capacity within the standards ecosystem.
- The existence of strong market drivers is critical to widespread implementation, and signals to the market must be consistent. Market considerations are more important than technological excellence, and the market power of buyers may be more important than that of sellers.
- The realities of culture must also be understood and attended to.
- Regulation, conformance testing and accreditation have strong roles to play.

PART B: CURRENT STATE ANALYSIS

(HP, n.d.)

"Things work out best for those who make the best of how things work out."

(John Wooden, as quoted by Daskal, n.d.)

5 Demand for interoperability standards is increasing

A wide variety of push and pull factors are dramatically increasing the demand for health sector interoperability and the standards that enable it. While consideration of interoperability more generally is beyond the scope of this report and is currently the subject of ADHA consultation, it is important to understand these demand drivers, depicted below.

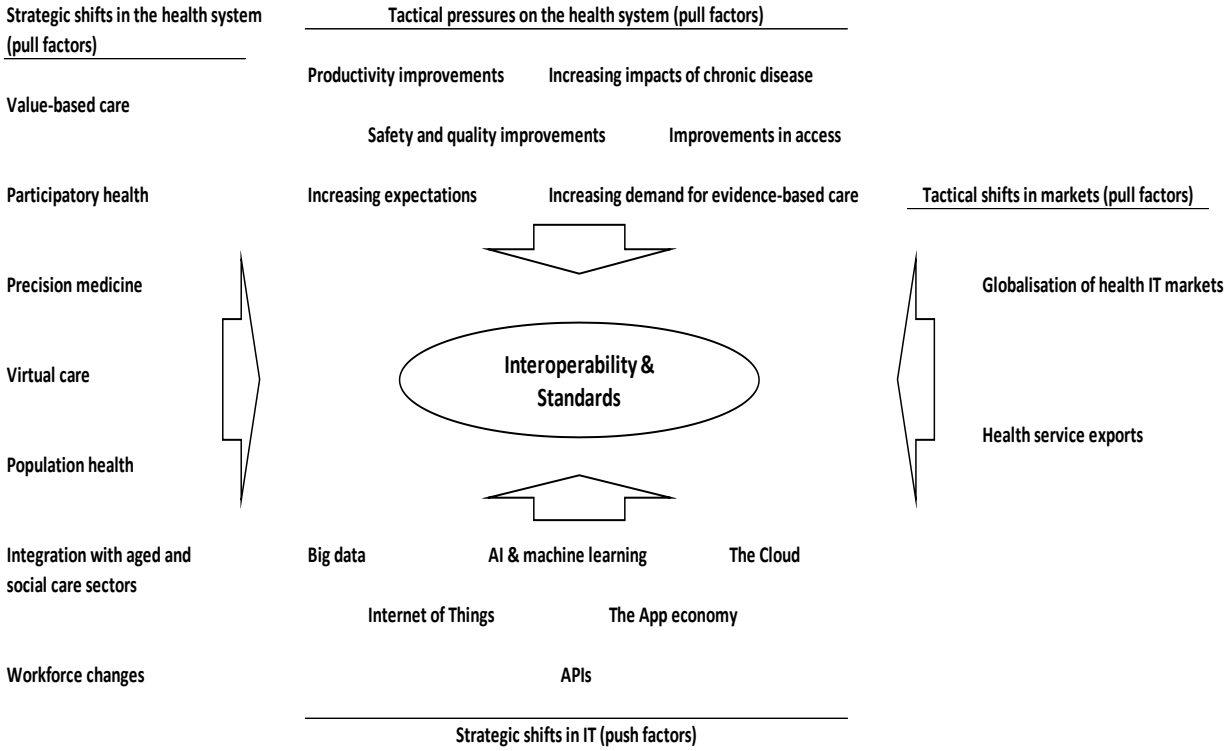


Figure 7 - Demand drivers for interoperability and standards

These demand drivers, many of which are inter-related, are briefly explained below.

5.1 Strategic shifts in the health system

The following factors are strategic shifts in health care – fundamental changes in the context for or paradigms for delivery of health services.

Value-based care

A shift is underway in most developed countries to value-based care – a delivery model in which health service providers are paid based on patient health outcomes rather than fee for service (NEJM Catalyst, 2017). Value is defined as the health outcomes achieved for defined population segments (for example, COPD sufferers in Western Sydney or people at risk of unplanned hospital readmission) for a given cost. The goal is to continuously improve the ratio of outcomes to costs through increasingly targeted, segment-specific clinical interventions (WEF/BCG, 2018).

A range of jurisdictions are committed to this strategic shift (e.g. Koff, 2016; Queensland Health, 2016; Sustainable Health Review, 2019).

Value-based care is highly dependent on high-quality data being available as, where and when needed – i.e. through interoperability. The World Economic Forum (WEF) recognises standards as a fundamental enabler of value-based care and has commenced development of a global roadmap for health informatics standardisation.

Participatory health

Participatory health represents a transformation in the patient-provider relationship where individuals work with their health professional team as an equal and responsible partner. This is critically enabled by interoperability and standards – participatory health becomes possible at scale through equal team (provider and patient) access to clinical data, information and knowledge, curation and navigation, and data assimilation (EY, n.d.).

Precision medicine

Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person (NIH, 2019). Precision medicine is underpinned by the digitisation of individuals' health profiles – the assimilation of data about them from a multitude of health service providers and devices (Aptekar et al, 2019). This is clearly powered by interoperability and standards.

Virtual care

While business issues such as funding and reimbursement remain problematic, virtual care – virtual health services episodes that take place via communications technology – is expanding here just as it is around the world. Globally, the market for virtual care solutions is forecast to grow at a compound annual rate of around 26% from 2018-26, driven by increasing deployment by both traditional health services (hospitals and primary care) and new, online only entrants (Persistence, 2018); and telehealth video consultation sessions are expected to increase from 19.7 million in 2014 to 158.4 million per year by 2020 (BusinessWire, 2015).

An example is the NHS GP at Hand service, launched in November 2017, offered via the Babylon Health app, and available to anyone who lives or works within 40 minutes of five affiliated London clinics, currently serves around 48,000 people (Macaulay, 2019).

However, if virtual care models are to be simply a part of a connected health system rather than a separate, siloed slice, then again, they will require interoperability with the rest of the sector – supported by standards.

Population health

While some population/public health services are already linking to the wider system (e.g. immunisation and screening data uploads to My Health Record), the potential for interoperability standards to drive advances in population health is substantial, including via:

- More routine data linkage to identify individuals at risk, sampling in relation to complex health issues, assimilate patient journey data, etc.

- Enhanced ability to compare, contrast and aggregate data sets, driven by more coherent and consistent data standards.
- Enhanced ability to personalise and situate health promotion initiatives to address behavioural health issues.

In the US, population health management is seen as essential to and a key driver of future innovations in data exchange (Bresnick, 2014; Hobson, 2019).

Integration with the aged and social care sectors

With the ageing of Australia's population, greater integration between the historically segmented aged care and health care sectors is occurring. In some other countries, notably the UK, greater integration between health and social care is also underway.

It is noteworthy that the aged care sector's technology roadmap cites the need for interoperability, open standards and common platforms as its number 1 issue (Flinders University, 2017), and that standardisation is acknowledged as a critical enabler of interoperability. The roadmap calls for the aged care sector to reach agreement on interoperability standards – this should be undertaken in concert with the health sector.

Clinical Trials

Australia has traditionally been competitive in the global market for undertaking high quality clinical trials, being able to deliver these within reasonable timeframes and at reasonable cost. The clinical trials sector is worth around $1 billion per annum to Australia with direct foreign investment of over $450 million per annum (Australian Government, 2011).

To support Australia's ongoing international competitiveness as well as to reap clinical benefit, the Australian Government recommended in 2011 that "NEHTA and state and territory governments make the clinical research system a key consideration when designing, developing and implementing e-health standards, specifications, strategies, frameworks, systems and programs" (p.5). Since then, the US Institute of Medicine (IOM) has cited "compelling justifications for sharing clinical trial data" (ION, 2015, p.1), requiring high quality interoperability – a likely characteristic for future competitiveness.

Workforce changes

Australian health workforce projections forecast significant shortages of doctors and nurses over the next decade (Health Workforce Australia, 2014 a, b).

Responses to these scenarios include many of the initiatives discussed above (e.g. virtual care) and below (e.g. productivity improvements). Workforce shortages are compounding factors, increasing demand for interoperability and standards via these other channels, but nonetheless require noting.

5.2 Tactical pressures

The following factors represent tactical pressures. They are ongoing, irrespective of strategic directions, and must be responded to. They will continue to drive demands for interoperability improvements, and the standards that support them.

Productivity improvements

It is difficult to estimate the quantum of impacts that interoperability could have on health care, though recent estimates from the US are that greater ability to exchange data could save more than $30 billion a year (Whitlatch, 2019).

High quality information on the quantum of benefit is not available in Australia, but it remains very likely that substantial cost savings can be achieved via reducing unnecessary diagnostic testing, more effective medication management, improved care handovers leading to reduced hospital readmissions, streamlined clinical workflows, etc.

Increasing impacts of chronic disease

The chronic disease tsunami is now well and truly upon us. Chronic disease accounted for 87% of all deaths in 2015 and accounted for 61% of the total burden of disease in Australia in 2011 (AIHW, 2018). Consequently, effective data sharing occurs across health settings, services and sectors is one of the strategic priorities articulated in the National Strategic Framework for Chronic Conditions (AHMAC, 2017).

Safety and quality improvements

One of the strategic pillars of the National Digital Health Strategy is to improve the safety and the quality of patient care by ensuring a connected health system that seamlessly shares high-quality data with the right people at the right time. This is a global aim. For example, the ONCHIT cites that better data standards are part of the solution to problems such as data matching, data quality and data integrity loss during data exchanges – all of which are seen as major barriers to patient safety (Health, 2016).

Improvements in access

The National Digital Health Strategy also notes that interoperability can address systemic issues of access to health services, particularly in rural and remote areas.

Increasing expectations

The National Digital Health Strategy cites “optimism and enthusiasm among both health consumers and healthcare providers that digital technology will transform healthcare and improve health outcomes” (ADHA, 2017, p.48).

Australian consumers appear increasingly positive about digital health technologies. They “are increasingly using digital technologies to manage their own health, they are adopting virtual care, and they see the advantages of harnessing the collective power of humans and machines” (Accenture, 2018).

While interoperability tends not to be highlighted per se by consumers, let alone standards, it is clear from studies such as Accenture’s that the benefits they are increasingly seeking are dependent on these.

Increasing demands for evidence-based care

The ongoing quest for evidence-based care, for example to reduce unwarranted variations in clinical care and improve health outcomes generally, is no longer just the

realm of passive knowledge dissemination or clinical decision support within health care organisations. Increasingly, in the context of complex conditions that can be measured across and associated with a wide variety of settings, it will rely on the ability to assimilate data, information and knowledge, enabled by AI and machine learning.

However, the ability to safely associate requisite knowledge with individual patient data is highly dependent on standards.

5.3 Strategic shifts in IT

Increasing demand for health sector interoperability and standards also derives from new and maturing technologies, or at least technologies that remain relatively new to health care. These are cases where technology availability drives new or increasing demand.

Big data

Analysis of big data – the vast quantities of information created by ubiquitous digitisation – has proceeded more slowly to date in health care than in some other industries, but market research suggests that this is changing. Worldwide revenues for big data and business analytics is growing at a compound annual rate of around 12% (Press, 2017). Now, the global market for big data in healthcare is expected to also demonstrate robust growth (Reuters, 2019), driven by the needs to investigate control of health care costs and improve patient outcomes.

The Senate Select Committee on Health recently noted that big data has the potential to create big opportunities for Australian health care (The Senate, 2016), but also that this potential is not currently being realised, and "the lost opportunities will only grow as technology continues to open up new ways to use and analyse data" (p.13). Clearly, there are both market and Australian Government expectations that access to and analysis of big data will increase in Australian health care.

Once again, however, one of the major hurdles is the spread of clinical data across organisations, and the embodiment of inconsistent data standards.

AI and machine learning

The application of artificial intelligence and machine learning (AI/ML) has risen dramatically in recent years, as can be demonstrated by the proxy measure of investment in AI/ML companies specialising in health – See Figure 8 below (Zweig & Tran, n.d.).

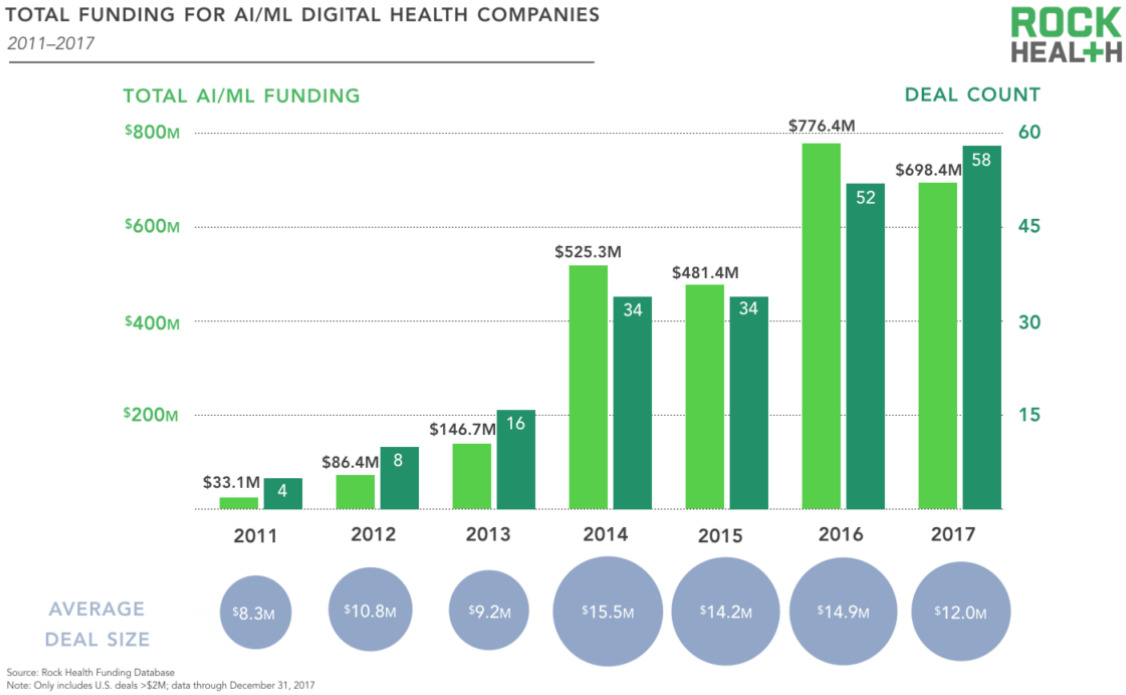


Figure 8 - Total funding for AI/ML digital health companies, 2011-17

As for big data, however, barriers to the use of AI/ML in health care include the quality and consistency of data-and the use of consistent standards across entire patient journeys.

The Cloud

The global health care cloud computing market is estimated to grow at an annual growth rate of around 14% from 2019 to 2026 (Linthicum, 2019), driven by the familiar forces of cost control and better patient outcomes. But the flip side of this coin is that greater use of the Cloud provides on-demand access to clinical IT, encouraging demand for complementary information. Hence this is another case of a technology proliferation driving demand, by introducing the new "art of the possible" to clinicians.

mHealth

The mobile health (mHealth) market is thought to be growing at a compound annual rate of nearly 48 percent (Heath, 2015). Led by the ONCHIT through its nationwide interoperability roadmap, mobile data interoperability is a key front in efforts to improve US health information exchange, and given the dominance of US vendors in this market, this demand is playing out globally. Establishing shared and explicit standards and developing trusted environments for data flow that enables patients to make their health records accessible anywhere they choose to seek care are now strong drivers within mHealth markets (Gruessner, 2015).

Internet of Things (IoT)

Business Insider forecasts that the number of IoT devices globally will increase from about 10 billion in 2018 to more than 64 billion by 2025 (Newman, 2019), with health

care contributing around 30% compound average growth (Medgadget, 2019). The IoT will be one of the major drivers for exponential growth in the volumes of health data within the immediate future.

However, a key feature of the data captured via IoT devices is that the majority will be sourced from outside the health system. Although there is increasing confidence that the data will be of sound quality, as devices are increasingly of medical grade, there is no guarantee that the same data standards will be used, making data assimilation difficult. Larger vendors in particular are increasingly committing to FHIR standards, but localisation will still be required to ensure IoT devices can safely and efficiently communicate and be assimilated with Australian health services and their data.

The App economy

Health care consumers continue to show strong use of digital technologies, and there were over 318,000 health apps available on the top app stores worldwide in 2018 (Liquid State, 2018). The global mHealth app market is projected to rise from USD 28.320 billion in 2018 to 102.35 billion by 2023.

The narrative is the same as for the IoT – if this external, consumer-facing data is to be used by health services, then this will be standards dependent.

APIs

Application programming interfaces (APIs) provide the means for one software program to access the services of another. As for other technologies considered above, the use of APIs is increasing massively (as depicted below), including in health care.

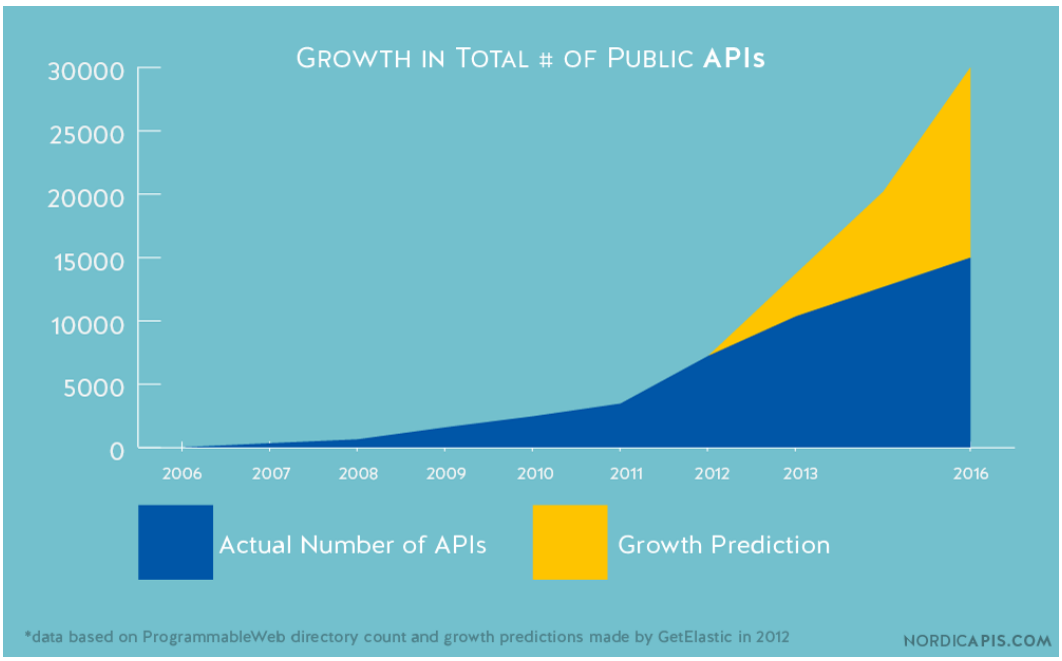


Figure 9 - Growth in the use of APIs, 2006 – 2016 (Anthony, 2016)

Examples of the potential of APIs in health care include easier access to detailed clinical data and opening the health sector to innovators who could create new tools tapping the latent value of health's massive data holdings.

ONCHIT's API Task Force concluded that industry-standard APIs would be beneficial to the API developer community, and that existing standards are adequate to support health APIs broadly (2016). However, as for other base standards, profiling these to Australian usage is still required.

5.4 Tactical shifts in markets

Finally, and briefly, the final set of demand drivers for interoperability standards comprises the global markets for health software, and for health exports.

Globalisation of health IT markets

The global healthcare IT market is thought to be growing at a compound average rate of over 12% (Grand View Research, 2015). In recent years, new EHR vendors have entered the Australian market, and some Australian vendors are refocusing on international opportunities.

Reduction of the costs of customising internationally-sourced software, and of the barriers to global markets facing Australian developers, are both highly standards-related. The GDHP notes that:

> "The consequence of the high degree of participation in international standards development is that a solid platform exists for driving greater collaboration between GDHP countries in addressing interoperability challenges" (n.d., p.58)

and that

> "Greater availability of open, non-proprietary standards can enhance market competition and support new innovative options for consumers" (p.58).

Accordingly, GDHP proposes to investigate how member countries can work together to present, as appropriate, more international requirements to Health IT vendors, with the aim of driving down cost and decreasing time to market for Health IT solutions. This will require greater international collaboration on international standards development, profiling and integration.

It is also noteworthy that Austrade sees Australia's digital health market as strategically important (n.d.):

> "Australia is a compelling destination to test, develop and commercialise digital health solutions. We have embraced digital health to provide new ways of delivering services and to transform current processes, improve outcomes and increase efficiencies. With diverse collaboration and investment opportunities, we are an ideal healthcare partner."

Health service exports

Australia is currently a minor exporter of health services (just $30 million in 2013), in contrast to education which contributed 4.5% of GDP that year (Bartlett, Butler &

Rogan, 2016) and also in contrast to many of our regional neighbours such as India, Malaysia, Singapore and Thailand.

Accordingly, health service exports are mentioned only as a wildcard demand driver in the context of a growing market estimated at 20-24 million cross-border patients worldwide and valued at USD 65-87.5 billion in 2019 (Patients Beyond Borders, n.d.). PWC has noted the opportunity for Australia's healthcare sector to become a major export industry, estimating that Australia could raise, in the near term, annual revenue of as much as $3 billion through medical tourism and $1.9 billion for delivering telemedicine and teleradiology services overseas (Bartlett, Butler & Rogan, 2016).

If Australia were to pursue this opportunity, the ability to ensure the information generated contributes to patients' lifetime health records, standards-based, could be an important adjunct.

5.5 Summary – Demand factors

Development of an economic model of demand for interoperability standards is beyond the scope of this report, and more appropriately lies within the realm of interoperability more broadly, since standards are a necessary but not sufficient element. However, this section aims to demonstrate that the demand drivers for interoperability and the standards that support it are very diverse, strategically and tactically important and growing, as are the needs for standards integration and internationalisation.

6 Supply capability is constrained

Despite agreement that there are areas of excellence, comprehensive stakeholder consultation encountered *no-one* who considered digital health standards development and maintenance capabilities in Australia to be in robust shape overall at present.

Qualitatively assessed, those working within formal standards development communities – the standards producers – tended to view the current state more negatively than standards consumers. On the one hand, this may reflect lingering disillusionment with developments in standardisation in Australia over recent years (see section 4.1). On the other, the consultations suggested that this more likely reflects deep knowledge of the standards work required to support widespread interoperability and pessimism as to whether Australia currently has the capacity, and perhaps the will, to meet these demands.

Some standards consumers indicated that they believe we have all the standards we need for successful, sector-wide interoperability. This is a misinformed view. It is very likely that we currently[8] have all the *base* standards, or standards frameworks, required. However, a great deal of work is still required to profile these base standards for specific use cases, to integrate standards from different sub-domains, and ensure they are fit for purpose – see section 3.6.3. Newer standards such as FHIR can be profiled quite quickly if proprietary interfaces are required. However, achieving the consensus required to support widespread, public and private health sector interoperability, taking into account the diversity of interests and perspectives involved, is a much more elaborate task.

There is also substantial work required to maintain these standards over their lifecycles, which are potentially quite long.

6.1 Suppliers

Australia's interoperability standards suppliers are examined below by sub-domain. Complementary service providers are then considered. Because the standards of interest for this report must support widespread interoperability, no single software supplier has sufficient monopoly power in the Australia market to dictate standards for adoption, and no single consumer of standards has sufficient monopsony power[9], proprietary standards developers/profilers are not considered in this analysis.

It should be noted that, for the purposes of this report, standards suppliers are each allocated to only one sub-domain. For example, HL7 Australia may generate some data

[8] This scenario can change rapidly with the introduction of new technologies or unforeseen changes in health sector priorities. For example, HL7 Version 2 met very well the need for system interfacing within health organisations but struggled when continuity of care between organisations became the new norm.

[9] For example, DHS is a major data repository holder and interacts with both public and provide sectors, but its ambit is too restrictive to be able to dictate overall health sector interoperability standards requirements. This contrasts with an aircraft integrator such as Boeing or Airbus, which have such enormous purchasing power and tight requirements that they can dictate standards to component suppliers globally.

content specifications, but primarily uses existing metadata and is allocated herein to the data exchange sub-domain.

6.1.1 Data content suppliers

The following organisations are major suppliers of the metadata describing the data elements (to be) shared within the health sector:

- **Australian Institute for Health and Welfare (AIHW).** One of the AIHW's functions is developing and maintaining national health data and information standards and related national health information infrastructure (such as METEOR, its Metadata Online Registry).

  AIHW's data and information standards development and maintenance work is undertaken by its staff, supported by the National Health Data and Information Standards Committee (NHDISC). NHDISC oversees the development of, and endorses, National Minimum Data Sets and other, non-mandated data sets.

  NHDISC's membership comprises:

  - All signatories to the National Health Information Agreement, namely all jurisdictions together with the AIHW, Australian Bureau of Statistics, Department of Veterans' Affairs (DVA), Department of Human Services (DHS), Australian Commission on Safety and Quality in Health Care, Independent Hospital Pricing Authority and the National Health Funding Body.
  - Representatives from other organisations/sectors, namely the Australian Digital Health Agency, Private hospitals sector, Productivity Commission, National Health and Medical Research Council and the private health insurance sector (Observer status.)

  AIHW can appoint any other member it determines necessary and invite observers to attend meetings.

  While AIHW's data standards are oriented to the collection of statistical data, they include many clinical data items and should, as far as possible, support multiple uses, including data exchange. For example, an Apgar score at 5 minutes after birth may be of interest: a) to the baby's GP and a visiting child health nurse, despatched from the hospital via a discharge summary; b) for inclusion in the child's longitudinal health record; and c) as an input to the compilation of perinatal statistics.

  Several industry figures consulted expressed dissatisfaction with their exclusion from AIHW's data development activities. While they are typically consulted by their customers (e.g. jurisdictions), they have expressed a desire for more direct input on the basis that their work programs may be significantly affected, and they may be required to meet multiple needs for similar data. Assessment of the validity of such claims is beyond the scope of this report, but the representation principle should perhaps be considered here.

The AIHW is also contributing to the development of the International Classification of Diseases 11th revision (ICD-11), which is approaching finalisation.

- **ADHA (the Agency).** ADHA's Clinical Informatics team also undertakes a substantial amount of data content specification, as did its predecessor at NEHTA. From 2005 – 2010, these specifications were developed in consultation with a wide range of clinical and technical experts to support a wide range of interoperability use cases. From 2010 – 2016, these switched to the narrower focus of the PCEHR/My Health Record. As noted earlier, however, none of these specifications appear to have been maintained. The Agency does not appear to have appropriate product management capability to maintain and manage these specifications over their lifecycles.

  The Clinical Informatics team is currently developing FHIR-based specifications via HL7 Australia's standards community, and these are addressed under the data exchange standard sub-domain below.

- **openEHR.** openEHR comprises open specifications, clinical models and software that can be used to create standards and build information and interoperability solutions for health care. It is supported, and its artefacts created, by an active global community.

  openEHR's Clinical Modelling Program is undertaken by clinicians and health informaticians using a Clinical Knowledge Manager. They build "archetypes" and "templates" – respectively, data content specifications that can be re-used in numerous contexts, and compound sets of archetypes relating to specific use case (e.g. a discharge summary). These archetypes and templates act as international standards for re-usable clinical content. Dr Heather Leslie, a Melbourne-based GP, is one of two global Clinical Modelling Program leads, and Dr Sam Heard, A NT-based GP and ADHA Board member, is one of openEHR's founders, and a member of its Community Interest Company, Foundation Board and Governance Board.

- **CSIRO.** CSIRO's Australian eHealth Research Centre is currently working with AIHW on a GP reference set. While this is CSIRO's first foray into national data set development, it may not be its last.

- **GS1.** While GS1 would not typically be thought of in terms of interoperability, there may be use cases when its standards become in-scope. For example, clinical references to implantable devices might encapsulate the same identifiers used for supply chain purposes.

  GS1 has a formal and well-articulated process for standards development globally. Its standards development manual (GS1, 2018) is accessible at https://www.gs1.org/sites/default/files/docs/gsmp/gsmp_manual.pdf. Like other recognised standards organisations, it acts as a facilitator for standards developers, is a supporter of standards communities pertaining to a variety of sub-domains, and the owner of the IP generated.

Of the primary suppliers AIHW, ADHA and CSIRO are fully publicly funded to undertake this work. To the extent that GS1 is involved in any interoperability standardisation, it is very likely that the standards community members undertaking this work would be either Australian, State or Territory Government employees, and therefore this work would also be publicly funded.

The openEHR community is global and works on a volunteer basis.

6.1.2 Health Concept representation suppliers

The following organisations are major suppliers of the metadata describing the data elements (to be) shared within the health sector:

- **ADHA's National Clinical Terminologies Service (NCTS).** NCTS manages, develops and distributes national clinical terminologies and related tools and services to support Australian digital health requirements. It is the Australian National Release Centre for SNOMED CT on behalf of SNOMED International, and develops, maintains and supplies the Australian Medicines Terminology (AMT).

  NCTS is supported in its role of localising clinical terminologies to Australian needs by the:

  - Australian Clinical Terminology User Group (AuCT-UG), a "self-governing national forum for the terminology community of practice including developers, implementers and users" (ADHA, n.d.), and the
  - Australian Medicines Terminology (AMT) Support Group, an open forum to provide an opportunity for individuals to participate in the ongoing development of the AMT.

  NCTS also participates in international standardisation activities, including through supporting attendance at bi-annual SNOMED International Business Meetings, though the extent of this attendance has declined over recent years. This is of some concern, since the first choice in standardisation should be to negotiate Australian requirements into the international versions of a standard. The greater the distance between international standards and Australian requirements:

  - The more costly it is to customise multinational software to local needs. Multinational vendors will always use the international versions, to minimise their barriers to global markets.
  - The higher the barriers for Australian vendors wanting to participate in global markets.

  International standardisation meetings such as these typically feature some plenary sessions, but most of the negotiation on standards takes place in parallel Advisory Group meetings, making it very difficult for participants to

influence developments in multiple arenas. SNOMED International currently has seven Advisory Groups[10] (SNOMED International, n.d.).

While considerable work also takes place between face-to-face meetings, via teleconferencing and using collaboration tools, regular attendance at the Business meetings is encouraged by SNOMED International in order to minimise repetition of discussions – i.e. to increase efficiency, productivity and timeliness. As for other collaborative/negotiative developments, continuity of attendance also facilitates the building of relationships and influence.

Currently, there would also appear to be little succession planning from the Agency, with a minimal contingent attending the Business Meetings. Again, it takes time and effort to build relationships and influence amongst 38 Member countries, members of the Vendor Liaison Forum and other stakeholders, and there is risk in over-reliance on two individuals.

Other stakeholders can and do attend the Business Meetings, particularly CSIRO employees. However, these attendances are primarily to meet CSIRO's commercial objectives as a tooling supplier and implementation support service, not necessarily to embed Australia's needs into the international standards. There are some barriers to attendance by others, particularly the self-employed or employees of smaller organisations, who face not only costs of travel[11] but also opportunity costs associated with their workplace absence – the people most expert, who can contribute the most to international negotiations, are of course also amongst the most in demand people locally.

- **The Independent Hospital Pricing Authority (IHPA).** IHPA determines some data set specifications (data content specifications) in support of Activity Based Funding, and also manages a range of classifications[12]. While classifications typically support data aggregation rather than patient-level clinical communications, there may nonetheless be some occasions on which patient data includes classifications such as ICD codes. Perhaps more importantly, mappings between classifications and clinical terminologies can reduce the need for parallel data coding and storage. SNOMED International maintains such mappings for SNOMED CT and ICD-10.
- **WHO.** WHO maintains a range of classifications internationally, including ICD-10 and the International Classification of Functioning, Disability and Health (ICF). Again, while these typically support data aggregation, there may

[10] Content Managers Advisory Group, E-Learning Advisory Group, Terminology Release Advisory Group, Modeling Advisory Group, SNOMED CT Editorial Advisory Group, Software Development Advisory Group, Tooling User Advisory Group.

[11] Although SNOMED International meets the basic costs of attendance for those nominated to Advisory Groups by the Agency, this typically does not fully cover costs.

[12] These include AN-DRGs; the AN-SNAP classification for subacute and non-acute care patients; the Tier 2 classification system for non-admitted care; the Australian Mental Health Care Classification (AMHCC); the Emergency Department ICD-10-AM Principal Diagnosis Short List (ED Short List); and, from July 2019, ICD-10-AM.

nonetheless be some occasions on which patient-level data is represented via classifications. Negotiations with WHO regarding its family of classifications is undertaken through AIHW.

As for the data content standards, this sub-domain is mostly undertaken via public funding. The NCTS is funded publicly, as are CSIRO, AIHW and IHPA to the extent that they are involved in concept representation standards development for interoperability purposes.

6.1.3 Data exchange standard suppliers

By far the major supplier of data exchange standards supporting health interoperability both within Australia and globally is HL7.

Health Level Seven International (HL7) is a not-for-profit organisation that provides a family of standards[13] for the exchange, integration, sharing and retrieval of electronic health information. It is accredited by ANSI.

HL7's standards development processes are rigorous and based on the requirements for continued ANSI accreditation (HL7 International, 2018). They are documented at http://www.hl7.org/documentcenter/public_temp_B78051DB-1C23-BA17-0C95F4BB214B64AF/procedures/HL7_Essential_Requirements.pdf.

Standards development and maintenance is primary undertaken within HL7 Work Groups. There are currently 57 Work Groups (listed at http://www.hl7.org/Special/committees/index.cfm) and a number of other projects, FHIR Accelerator Projects and user Groups. HL7 Working Group Meetings are held three times per year at varying locations but primarily in the USA. As for SNOMED's Business meetings, these serve multiple purposes – they provide opportunities for face-to-face coloration and negotiation on standards, enable relationship and influence building, provide educational opportunities and allow participants to network with industry leaders from around the world. A great deal of work also happens between meetings.

HL7's ANSI-approved standards are licensed at no cost, as are its published implementation guides, profiles and domain analysis models (DAM), and current standards for trial use (STU). HL7 members have early access to new HL7 standards as a member-only benefit; these are licensed free-of-charge to non-members after three months. However, strict intellectual property rights are associated with all HL7 material that has passed its balloting processes.

[13] These comprise the HL7 V2 messaging standard; HL7 V3, a suite of specifications based on HL7's Reference Information Model (RIM); CDA, a document markup standard that specifies the structure and semantics of clinical documents for exchange purposes; HL7 FHIR, an interoperability standard intended to facilitate the exchange of healthcare information between organisations; and the Arden Syntax, a formalism for representing procedural clinical knowledge in order to share it.

HL7 has Affiliates in 37 countries excluding the USA where it is based and including Australia. HL7 Affiliates are independent legal entities that:

- Represent their members at HL7 International and within their Territories on HL7 matters.
- Participate in HL7 International's standards development processes.
- Promote the relevance and fitness of the HL7 Protocol Specifications, HL7 Educational Material and Other HL7 Material within their Territories.
- Distribute, translate and localise the HL7 Protocol Specifications as appropriate.
- Administer and proctor HL7 Electronic Certification tests within their Territories as appropriate.
- Promote HL7 standards and educate, inform and support current and potential users within their Territories to promote consistent and widespread usage of the standards.

Importantly, the right to create, reproduce, distribute and control the use of HL7 localisations is exclusively granted to Affiliates such as HL7 Australia – i.e. localisations created by other organisations, including ADHA, cannot be regarded as HL7 localisations. Rather, they are proprietary specifications. Affiliate Localisations of HL7 Protocol Specifications require a successful ballot at the Affiliate level, and are jointly copyrighted by HL7 International and the Affiliate. No local change or additions to the HL7 Protocol Specifications may be made without the written approval of HL7 International, except for the production of Affiliate Localisations.

Affiliates 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.

HL7 International does not grant any third parties the right to distribute or provide access to the HL7 Protocol Specifications within an Affiliate's Territory except as provided by licenses to HL7 Organisational Members.

Affiliates are required to operate according to a set of documented principles including open membership and consensus-based balloting rules, and to protect HL7's intellectual property, copyrights and trademarks. Ownership rights to HL7 International Material or HL7 International Trademarks may not be transferred to any other party.

In other words, Australian localisations of HL7 standards, including FHIR, cannot have any status other than being for proprietary usage without being developed by HL7 Australia, being developed by an agency formally authorised to do so (but still requiring balloting by Affiliate members), or with the express approval of HL7 International (unlikely to be granted as it would undermine HL7 Australia).

HL7 Australia

Like other SDOs, the HL7 Australia organisation itself is minimalist – it acts as a supporter and facilitator for its standards development community, providing

collaboration tools and development processes, managing ballots and managing the lifecycles of the Localisations produced. It provides some complementary services – education, training and implementation support to support consistent adoption and use to enable meaningful interoperability. As indicated above, it is also an owner of the IP generated by the community.

HL7 Australia currently supports four Work Groups covering the sub-domains of Child Health, Orders and Observations, Medications and Patient Administration.

HL7 Australia is on growth pathway. When it withdrew from developing standards within Standards Australia, it had little of the requisite capabilities for community support, and an inadequate business model. Over the past two years it has been building its membership base and has implemented a fee structure that enables it to purchase limited and episodic administrative support, provide basic collaboration tools and offer highly targeted implementation support. For the most part though, its volunteer Board members are also its staff. With two exceptions, these individuals are all self-employed.

This scenario constrains Australian data exchange standards development in three ways:

- HL7 Australia is operating in a relatively small market with many "free riders"[14]. While its recent membership growth is encouraging, there are logical limits to its revenue capacity that are similarly experienced by other Australian health informatics non-profits, including the Health Informatics Society of Australia (HISA).
- While the Board is aware of evident demand for expansion of its activities, these are constrained by lack of further capacity for Board members to devote more time to supporting them.
- There is high risk associated with even current activities. For example, ADHA's clinical informatics team is currently engaged in developing a series of FHIR specifications within the HL7 Australia communities; the Royal College of Pathologists of Australasia (RCPA) has strongly supported the development of the Localisation of HL7 Version 2.4 for Australian Diagnostics and Referral Messaging; a range of parties including jurisdictions are supporting the Child Health localisation work; and the Patient Administration work is substantially undertaken by a single individual.

  However, even where agencies such as ADHA, RCPA and jurisdictions supply labour to initially develop standards, these still require ongoing maintenance and management over their entire lifecycles.

  If these products are to be de jure standards rather than proprietary versions, then they must be developed within the HL7 Australia communities and according to its (and ultimately HL7 International's) rules. But once completed

[14] In Economics, the free rider problem occurs when some individuals/organisations consume more than their fair share or pay less than their fair share of the cost of a shared resource. It is a source of market failure.

> they are entrusted to an organisation with thin infrastructure and low product management capacity that is provided by part-time volunteer Board members.
>
> While this is currently being managed – just – it does not seem sustainable as localisation activities grow. Some technical experts consulted have serious concerns about this risk.
>
> Put bluntly: strategic shifts in and substantial pressures on the Australian health system that require interoperability and standards are being put at risk of bottlenecking within HL7 Australia. While data content and representation standards are well funded from the public purse, their incorporation into data exchange standards is not, and natural constraints to HL7 Australia's business model together with market failures that cause the private sector to underinvest suggest that (greater[15]) public investment is required.

HL7 Australia's ability to influence HL7 international standards development is also dangerously low. As for SNOMED, the inclusion of Australian requirements in the international versions of the standards is a superior solution to excessive Australian localisation. However, despite a great deal of work being done between HL7 International Working Group Meetings, attendance (and continuity of attendance) is extremely beneficial to success. Currently, this is entirely dependent on private sector funding, including by self-employed individuals who experience opportunity costs as well as direct costs.

Australia has a strong track history of successful inclusion of requirements into international HL7 standards, due in no small part to previous DoH funding support for travel, but this funding was terminated and our influence is in decline.

The notable exception here is FHIR, which was largely developed by Australia's Grahame Grieve and is building a strong support base around the world. However, Grahame's exceptional influence and expertise are primarily directed to ongoing development and use of the international, base standards, not Australian needs.

IHE

IHE Profiles organise and leverage the integration capabilities that can be achieved by coordinated implementation of communication standards such as DICOM, HL7, W3C and security standards. They provide precise definitions of how standards can be implemented to meet specific clinical needs. IHE profiles have been developed for a variety of clinical domains including cardiology, eye care, pathology and laboratory medicine, patient care coordination, pharmacy and public health.

IHE Connectathons provide detailed implementation and testing processes to demonstrate that participating systems can really exchange information with corresponding systems in a structured and supervised peer-to-peer testing environment.

[15] Some jurisdictions are HL7 Australia members, and paying membership fees. However, once again, there are obvious limits to the revenue that can be publicly sourced via this model.

FHIR has incorporated Connectathons into its methodology, and globally there are strong relationships between IHE and FHIR. For example, Project Gemini, implements FHIR within IHE interoperability profiles. IHE has a longstanding collaborative relationship with HL7 International.

IHE Australia has a tiny footprint in Australia despite its potential to support vendors and implementers in building healthcare computing systems and interfaces based on and compliant with global standards. While this is at odds with other countries' interests in IHE, it is in part because of Australia's small market – it is largely the same people who are engaged in HL7/FHIR and IHE activities.

Nonetheless, IHE does produce profiles internationally, and existing interoperability profiles that are fit for purpose (or could be with a modicum of localisation) should be preferred to re-inventing them. Accordingly, some support for IHE Australia would be advisable to enable leveraging of this international work.

OMG

The Object Management Group (OMG) healthcare standards were developed in collaboration with HL7 International, and provide for co-existence of traditional healthcare integration strategies and newer interface protocols via a model-based platform. They aim to standardise interfaces for healthcare objects and provide complementary functions (e.g. service directory and common terminology service specifications) designed to bridge disparate systems and solutions.

CDISC

CDISC specialises in data standards for clinical research, with the aim of maximising its impact through making it more accessible, interoperable and reusable.

ADHA

The Agency's Secure Messaging Program works collaboratively with industry and suppliers of secure messaging solutions and clinical software to provide implementable solutions for point-to-point interoperability.

Conclusion

Data exchange standards development is substantially weaker than the other three interoperability sub-domains, though equally necessary. Using a private sector funding model is likely to sustain this structural weakness, since the impure public good nature of health care interoperability standards is always likely to induce underinvestment.

Even though there is some public support provided through jurisdictional memberships and the supply of labour to the HL7 community, there is still excessive risk since the lifecycle maintenance of the resulting standards is underinvested and capacity is still constrained to the community support that can be provided by part-time, volunteer Board members.

To provide the capabilities that the health sector is demanding and will continue to demand for Australian localisations, HL7 Australia needs a small full-time staff and some infrastructure enhancement that the current business model is unlikely to support.

6.1.4 Data integrity standard suppliers

The following standards developers are active within this sub-domain:

- **Standards Australia.** Standards Australia is recognised by the Australian Government as the nation's peak non-government, not-for-profit standards organisation. Its standards development process is summarised at https://www.standards.org.au/standards-development/developing-standards/process and is based on the principles of openness, transparency, balance of representation and consensus.

  Standards Australia and its Health Informatics Technical Committee, IT-014, are now minimally involved in standards supporting health sector interoperability. IT-014's activities now primarily concern mirroring relevant ISO standards and working out what to do with aged Australian Standards.

  There are, however, some ISO and existing Australian standards that could enter the interoperability arena, such as:

  - ISO/IEEE 11073-10207, Personal health device communication. This concerns the definition and structuring of information that is communicated in a distributed system of point-of-care medical devices and medical information technology (IT) systems in which medical data needs to be exchanged.
  - ISO 13606, Electronic health record communication. This concerns the communication of part or all of the electronic health record (EHR) of a single identified subject of care between EHR systems, or between EHR systems and a centralized EHR data repository.
  - ISO 17090, Public key infrastructure. This concerns the procedural requirements for validating an entity credential based on Healthcare PKI defined in the ISO 17090 series used in healthcare information systems including accessing remote systems.
  - ISO 25237, Pseudonymization. This contains principles and requirements for privacy protection using pseudonymization services for the protection of personal health information.
  - ISO 27799, Information security management in health using ISO/IEC 27002. This gives guidelines for organisational information security standards and information security management practices including the selection, implementation and management of controls. It applies to health information in all its aspects including its transmission.
  - ISO 21090, Harmonized data types for information interchange. This provides a set of datatype definitions for representing and exchanging basic concepts that are commonly encountered in information exchange in health care.

  This is not a comprehensive list.

Standards Australia remains committed to supporting the Australian health sector, and as long as the workload relating to interoperability remains limited, is probably able to do so. However, IT-014 has little capacity and little ability to be more active in this domain.

- **ISO.** ISO is not discussed further here. The conduit to ISO is through Standards Australia.
- **Digital Transformation Agency (DTA).** While DTA's ambit is Australian Government agencies, this includes some important health players such as DHS, DVA and the Department of Defence. Among other things, DTA develops policies, standards and platforms for digital service delivery, including digital identities.

This sub-domain is not particularly active, and most work on identity management, security and privacy in connection to health sector interoperability is undertaken by ADHA. As such, it is publicly funded.

6.1.5 Suppliers of complementary services

Complementary services include marketing and advocacy, education and training (both generally about standardisation and specifically about the implementation of particular standards), the provision of relevant tools and conformance testing and accreditation.

The tooling environment is the strongest of these, and is particularly strong in terms of health concept representation tools. NCTS's tools are complemented by CSIRO's investments in tooling. Bothe NCTS and CSIRO are involved in education, training and other implementation support services.

Training in the sub-domain of data exchange is, again, weaker.

Even the best-written standards rarely encompass all the knowledge held about the standard, the motivations for and decisions made during its design and development, learnings accumulated about how it is interpreted by its readers, how it has been implemented most effectively, what happened when it was, and so on. Rather, this crucial knowledge tends to be vested in members, both individually and collectively, of the relevant standards communities.

Knowledge translation is a big deal in standardisation because, as our legacy systems remind us daily, there may be very different instantiations of the same standard in different systems. Standards are necessary but not sufficient for interoperability, and another of the "necessaries" is education, training and support for consistent interpretation and implementation.

Figure 10 below illustrates HL7 Australia's current lack of capacity to support implementation, and IHE Australia has an annual event at HIC, but no real capacity to do anything else. A few management and health informatics consultants are spread relatively thin and tend to work mainly with the larger health providers. Digital Health & HL7 Education Partners has "trained over 500 people in the last two years" (n.d.), but once again their website is instructive – Figure 11 shows no standards training schedule for 2019 as yet.

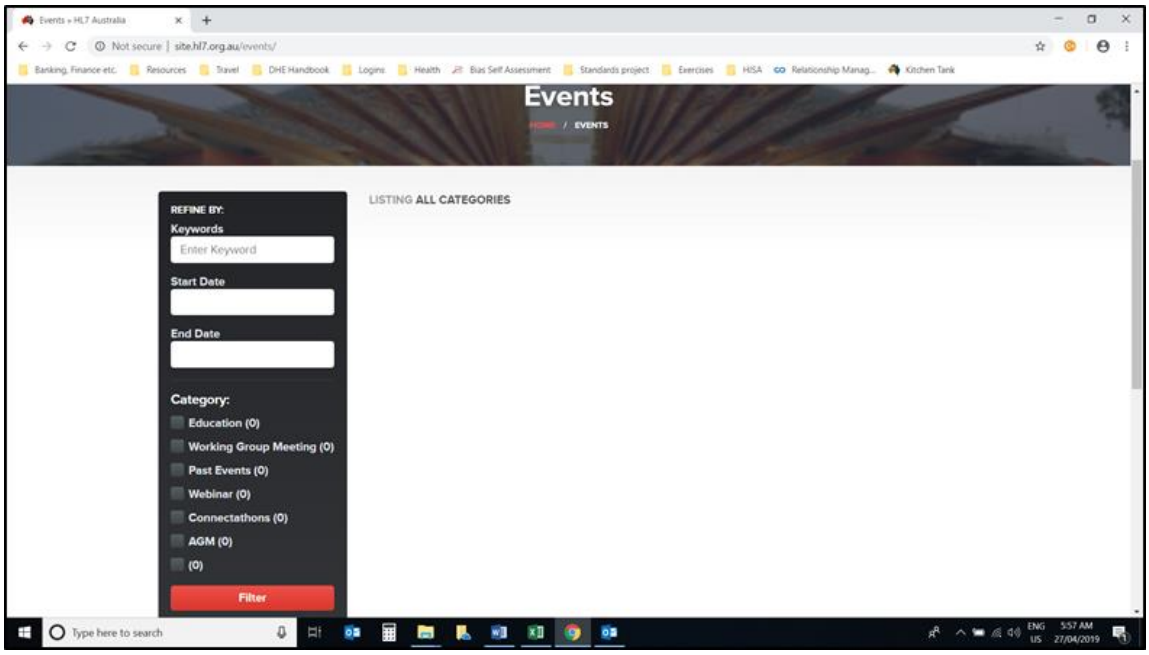


Figure 10 - HL7 Australia education and other events page, 27 April 2019 (HL7 Australia, n.d.)

Figure 11 - Digital Health and HL7 Education Partners training schedule page, 27 April 2019.

This is not symptomatic of a vibrant knowledge translation and implementation support environment. Compare these programs with the (randomly chosen) HL7 New Zealand and UK equivalent webpages (Figure 12 below).

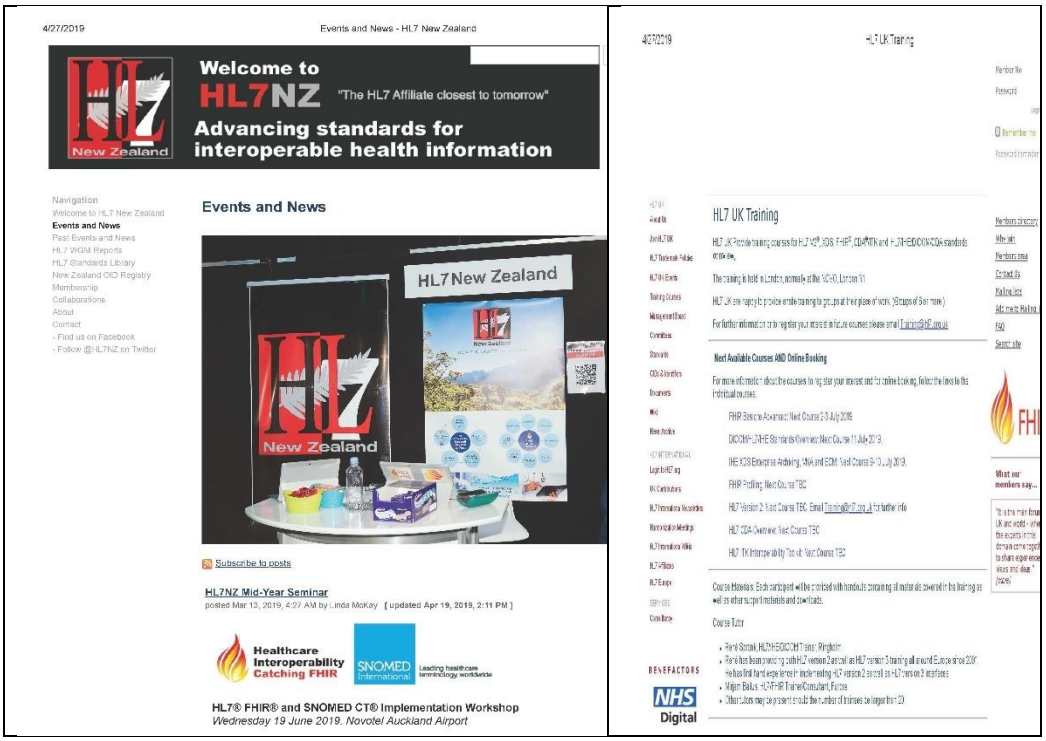


Figure 12 - HL7 NZ and UK training schedule pages, 27 April 2019

Conformance testing and accreditation

Conformance testing and accreditation are outside the domain of standards development and out-of-scope for this project. Nonetheless they are referenced here because of their importance in encouraging adoption and use, as demonstrated internationally and in other industries.

6.2 Standards development orientation

Standards development in Australia is currently very "policy-driven". The bulk of more formal standards development activity is conducted, led or funded by ADHA in support of their national work programs. These are strongly future-focused. They aim to provide capabilities to enable tomorrow's health system, not today's. However, despite the need to have an eye to the future, health service providers and health software developers by and large are concerned with today's issues and requirements, driven by their customers current needs. Hence, when asked to implement some new standards to enable future capability, health software providers are often heard to say: "But my customers aren't asking for this (and therefore won't pay for it), so why should I incur the cost of implementing it?"

Meanwhile, many vendors are busy implementing standards inside theirs systems and for health data exchanges, using messages and APIs, and working case by case in doing so, without overarching guidance as to preferred standards or consistent implementation.

Example – Encryption of secure messaging

"If SMD [the Secure Message Delivery standard developed by NEHTA] were mandated and implemented tomorrow, messaging as we know it would just stop happening" (MacIsaac, 2019).

This is in large part because the SMD incorporates enhanced encryption of messages preventing intermediaries from intercepting and transforming the messages in any way. This is a noble and sensible aim for a future health sector.

However, in today's health sector, there is a whole industry category built around doing just that – intercepting and transforming the messages. The sending and end-destination systems used in health care typically either do not comply with Australian messaging and/or vocabulary standards, or "comply" with them in different ways. Intermediaries know the formats sent and accepted by different systems, and currently intercept and transform them to enhance safety.

These intermediaries also have standards development, maintenance and implementation support requirements to support their current business. Unless there is capacity within standards communities to address these current needs as well as the future ones, then the former are very likely to be undertaken by individual businesses in isolation, further widening standards gaps.

It is also important to note that, in addition to addressing safety in the current environment, these intermediaries employ people, have shareholders and fill other economic roles. The legitimacy and implications of these roles must be recognised in the design and development of, and transition to, a new standards development model.

Standards development programs need to take account of current interoperability needs as well as future ones, and provide a roadmap from the current to the future, to provide market certainty.

As a corollary, standards development in Australia is also currently very project oriented. For example, a project such as secure messaging is undertaken that delivers a standard. Even if the result is highly fit-for-purpose, all the project typically delivers is a standard that achieves consensus at a point-in-time. The project delivers what it was required to, then the resources are disbanded, re-oriented or moved on to the next project-based priority.

But what was delivered is a product at a point in time. As highlighted in section 2.2, products have lifecycles and these may be quite long. For example, HL7 V2.4 was published in October 2000 but is still used in Australia today, including as the primary pathology messaging format. This is an example of a standard that is being maintained – by HL7 Australia with strong involvement from the pathology industry. HL7AUSD-STD-OO-ADRM-2018.1 Australian Diagnostics and Referral Messaging – Localisation of HL7 Version 2.4 (available at http://site.hl7.org.au/news/diagnostic-and-referral-v2-localisation/) was updated and published in August 2018 and is managed as a product by an HL7 Australia Working Group.

In contrast, some products resulting from project-based approaches have not been maintained since they were first released as "standards". Examples include the CDA clinical document specifications developed by NEHTA for the PCEHR in 2011.

6.3 Unbalanced investment

Private markets, particularly of the size of Australia's, typically underinvest in standards due to market failures. Accordingly, public funding and other market interventions (e.g. regulation) are extremely important.

The development, maintenance and management of some standards are fully funded by taxpayers while others are not, and the logic for this, while perhaps historically understandable, seems far less clear today:

- The NCTS, provided from within ADHA, is fully taxpayer-funded. Funds are sourced from the Interoperability Program of the Agency's COAG funded work plan (ADHA, n.d.) since clinical terminology provides a foundation for successful delivery and realisation of the benefits of interoperability.
- Full public funding for AIHW's involvement in standards development is closely aligned to supporting Australia's health policy agenda though statistical measurement and to our international statistical reporting commitments. Metadata standards are simply seen as part of the lifecycle of generating data.
- Some other elements of standards development receive highly-targeted public funding or sponsorship for specific events/work:
  - Standards Australia is paid an annual fee by the Department of Health to make its health informatics standards free-of-charge, reducing a barrier to access for small software developers in particular.

- HL7 Australia, IHE Australia and others may receive limited sponsorship funding from time-to-time, or are supported in standards development projects by ADHA staff.

However, standards for access to and exchange of clinical and other health data are just as essential to interoperability as standards concerning the content and representation of clinical data. Indeed, substantial investment in developing standards for data content and representation is to some degree wasted if there is not also investment in how these data will be accessed and exchanged. The current standards investment portfolio is skewed, and Australia's interoperability ambitions are at risk as a result.

6.4 Political awareness and will

Australia's politicians seem silent on the critical importance of standards. While the National Digital Health Strategy was endorsed by Australian Health Ministers, political energies federally seem virtually exclusively directed to My Health Record and other rollouts at State and territory levels. This contrasts with the:

- USA, where unusual bipartisanship appears to exist around standards. Then Vice-President Joe Biden spoke directly and knowledgably on the criticality of data standards at the World Economic Forum's Annual meeting in Davos in January 2017, while FHIR's founder, Australian Grahame Grieve, has briefed senior White House officials at the invitation of the Trump administration.

- UK, where Secretary of State for Health and Social Care Matt Hancock has publicly stated that NHS digital services and IT systems will have to meet a specified set of open standards and conform to a modern architecture, in order to achieve the goal of interoperability.

The impact of strong, visible political leadership cannot be underestimated, and it is not surprising that industry-led standards initiatives have subsequently arisen in these two countries – Argonaut in the USA and InterOpen in the UK.

Australia's interoperability efforts have arguably also been impaired by politically motivated time frames. In 2005, then Health Minister Tony Abbott demanded functioning electronic health records and an accompanying smartcard system within 12 months, while in 2010 the Gillard government gave a deadline of less than two years for the initial development of the Personally Controlled Electronic Health Record (PCEHR, now My Health Record).

eHealth systems and services, and eHealth more generally, are complex endeavours that touch every part of the health sector and involve substantive disruption. Time frames such as those mentioned above, which seem designed to meet political rather than health sector goals, can have unintended consequences such as diverting all available resources towards a single solution, and putting longer-term broader agendas on the back-burner.

Standardisation for whole-of-health-system interoperability is a long-term endeavour that is simply not conducive to overly fast-tracking. Political leadership that recognizes and reinforces this, as in the USA and UK, is highly desirable.

It cannot be argued that Australia is incapable of taking a long term view. For example, Australia's new contract to procure contemporary submarines has delivery dates

extending into the late 2040s, and no-one seriously contemplates telling the Defence Department that construction should be finished by, say, 2025.

6.5 Orchestration

The role and functions of "orchestrating" standards development, maintenance and management are elaborated in section 3.6.2, but to summarise:

- In essence, the standards development, maintenance and management domains comprise a complex, adaptive ecosystem consisting of a large number of public and private, international and national, large and small, for-profit and not-for profit organisations whose ongoing interplay determines whether or not interoperability or other health policy goals are achieved through co-evolution. Intellectual property, relevant knowledge, skills and experience, infrastructure, relationships, resources and other capabilities are widely spread amongst the array of autonomous agents.
- Like other complex, adaptive systems, the standards ecosystem cannot be centrally controlled. Neither should any single player want central control. The problems that interoperability standards are trying to remedy are problems of the collective system, not any single player. Responsibility and accountability for the solutions – development of appropriate, effective and efficient standards and their adoption and ongoing use – must similarly be "owned" by the collective system.
- As in other complex, adaptive systems, leadership rather than management is the key to successful co-evolution. The wide array of autonomous agents must buy-in to a shared vision (for many different but coherent reasons), be aware of the pathways they and others are taking, and how these lead to the shared vision, and be aware of the impacts their choices and behaviours have on the path to convergence on this vision.

This is essentially the orchestration role, which in the USA is provided by the Office of the National Coordinator for Health Information Technology (ONCHIT). In Australia, however, no-one is currently undertaking this role. ADHA does not – rather, it develops, monitors and manages a small subsection of future-focused standards that are closely aligned to its annual work program. The Department of Health does not – it refers standards matters to ADHA. And at present, no-one else has the mandate, ambit of interest, credibility and/or other capabilities required.

Not only is there a lack of this orchestration, but the Australian health sector overall arguably demonstrates a preference for lack of standardisation – see the Managed Health Network case study, and procurement activities from State, Territory, not-for-profit and private health service providers often embody weak and inconsistent standards requirements.

The bottom line is this:

> *Ultimately, failure to make one choice is a purposeless decision to make a different one*. Lack of decisions to date to unify Australian standards requirements across jurisdictions, to build policy and market incentives to encourage co-evolution

towards standards, to sustain conformance and accreditation programs etc. are actually decisions *not* to work towards standardisation – to let other, shorter-term priorities dominate by default.

6.6 Analysis of Australia's current situation against success factors

The Global Digital Health Index (GDHI) is an interactive digital resource that tracks, monitors, and evaluates the use of digital technology for health across countries against a range of indicators (GDHI, n.d.a). The majority of the countries it covers are developing, though New Zealand participates. Australia does not.

GDHI indicator 14 concerns standards:

14 Are there digital health / health information standards for data exchange, transmission, messaging, security, privacy, and hardware?

Level 1:	There are no digital health / health information standards for data exchange, transmission, messaging, security, privacy, and hardware
Level 2:	There are some digital health / health information standards for data exchange, transmission, messaging, security, privacy, and hardware that have been adopted and/or are used
Level 3:	Digital health / health information standards for data exchange, transmission, messaging, security, privacy, and hardware have been published and disseminated in the country under the government's leadership
Level 4:	Digital health / health information industry-based technical standards for data exchange, transmission, messaging, security, privacy, and hardware are in use in the majority of applications and systems to ensure the availability of high-quality data. Conformance testing is routinely carried out to certify implementers
Level 5:	Data standards are routinely updated and data is actively used for monitoring and evaluating the health system and for national health strategic planning and budgeting

For information, New Zealand was rated in May 2018 at level 3 on indicator 14 (GDHI, n.d.b). Australia would be rated at level 2 by the author of this report. There are digital health / health information standards for data exchange, transmission, messaging, security, privacy, and hardware that have been adopted and/or are used, but recommendations about which standards to use in which scenarios, akin to ONCHIT's Interoperability Standards Advisories, are not disseminated in the country under the government's leadership.

Lessons emerging on standardisation compiled from sections 3 and 4 are converted into success factors in the following table, which also presents assessments of their current state in Australia.

Table 3 - Assessments of Australia's current state against standardisation success factors

Standardisation success factor (compiled from sections 3 and 4)	Assessment
User demand for compliance of standards / use of market power.	While there are undoubtedly some differences in local environments to be taken into account, many stakeholders have argued that there is excess variation in the use of standards across jurisdictions and in primary care and that latent market power is not being used.
Committed communities of practice.	While these exist (especially around secure messaging and pathology messaging), many stakeholders in standards development communities have been alienated by developments over the last decade and they not necessarily refreshed with new talent.
Pragmatic, practical, implementable standards involving agile processes of developing and testing.	This is the FHIR modus operandi, but some other approaches (e.g. IHE) have stalled in Australia.
National policies for standardisation.	While standardisation is cited as an underpinning of the National Digital Health Strategy, it requires considerably more visibility and potency in that context and others.
Funding needs to be part of a national eHealth strategy in order to sustain the implementation of standards.	Funding is inconsistent – e.g. content and terminology standards are funded but their exchange is generally not. This both limits the value of existing funding and slows interoperability standards development, as well as underfunding standards lifecycle management.

Standardisation success factor (compiled from sections 3 and 4)	Assessment
Competency-based workforce is essential for successful implementation of standards at national and sub-national levels.	Most health workforces could be described as standard-illiterate. There is no systematic approach to upskilling in this domain.
Demonstrated political will.	This seems substantially missing in Australia
A framework containing a fixed core set of maintained standards allowing for a degree of innovation outside that core set and allowing for development based on the capacity and maturity of eHealth systems and services; and regulate an appropriate degree of adoption.	This does not exist in Australia.
Use or adapt existing international standards where possible.	Australia has long committed to this approach, but our international presence has declined over recent years, reducing our ability to negotiate our requirements at source.
Ensure good governance, balancing top-down and bottom-up approaches and based on a shared vision.	Many stakeholders argue that governance, to the extent that it exists, is currently too top down, too project-oriented and that the overall vision (target architecture) is missing.
Market factors are likely to be more important than technical ones in determining standards adoption.	Although this seems increasingly understood, Australia has struggled to find sustainable, market-based incentives.

6.7 Strengths, weakness, opportunities and threats

The current situation is summarised into a SWOT format below, with Table 4 listing strengths and weaknesses – respectively, characteristics of the current situation that can be recognised, nurtured further and built upon, and characteristics that need to be recognised, mitigated and/or overcome.

Table 5 lists opportunities and threats – situations arising outside the Australian standards domain that respectively can be leveraged for Australia's benefit or that need to be addressed to ensure further deterioration from our current situation.

Table 4 - Current situation - Strengths and Weaknesses

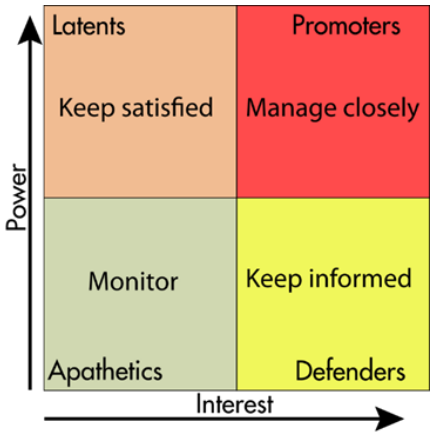
Strengths	Weaknesses
• ADHA has a mandate to ensure interoperability standards are in place and effective • Australia has some world-leading expertise • Australia has had, until recently, a good track record of influencing international standards development • Some recent successful experience in key standards development, ADHA-industry collaboration (secure messaging) and other forms of collaboration (CSIRO-industry collaboration on GP data set) • Health software industry willingness to participate collaboratively • Historical and international experience provide important learnings • Australia has local chapters of important international standards development organisations (SDOs)	• Lack of target architecture and roadmap – lack of coherent understanding of where the overall standards agenda is taking us • Lack of certainty re future health policy and funding (strategic) and/or market adjustment (tactical) directions • Inconsistent adoption and implementation of standards between major health software buyers – the Australian market, through this inconsistency, is expressing a preference for lack of standardisation • Thin expertise overall in interfacing expertise and standards development • Lack of industry representation in direction setting • Focus mostly on new development, not the whole standards lifecycle – project driven, while standards are products • Focus on outputs (standards) not the sustainable capacity to generate them • Lack of market-based incentives to standardise • Lack of resource continuity • No-one “in charge”. ADHA does not have the capabilities required for the orchestration role, and no-one else is doing it. • Some SDOs currently in weakened conditions • Apparent lack of political awareness of the importance of interoperability standards, and apparent lack of political will to engage in market-based industry adjustments • Some lack of trust in key players

Table 5 - Current situation - Opportunities and threats

Opportunities	Threats
• New standards directions being driven by the market, including new players • Some key organisations strengthening their governance and capabilities • Buyer requirements could be consolidated to influence large international vendors • Healthcare directions (e.g. value-based care, participative care, aged care-health care-social care integration) favour interoperability, standardisation and standards	• Political pressures drive unrealistic deadlines for standards development, priorities and the allocation of resources to standardisation • Lack of coherence/coordination amongst standards development agendas/organisations • No bipartisan approach, and implications of potential change of government unknown (increases lack of market certainty and lack of willingness to invest) • Standardisation seen as too hard, rather than an architectural vision driving standardisation • Major product refreshments underway now will leave long legacies • Large international vendors make decisions not necessarily reflective of Australia's needs

6.8 Stakeholder analysis

The standards development, maintenance and management ecosystem is replete with a wide array of stakeholders. These are categorised below and assigned to four quadrants mapping their power (degree of influence over outcomes) against interest (degree of desire for a successful outcome).



This presentation is highly generalised. There are many nuances between individual stakeholders – many different individual interests. However, overall patterns of power and interest can be mapped to generate broad conclusions.

Figure 13 - Stakeholder analysis matrix (Zirguezi, n.d.)

For the purposes of this analysis:

- "Interest" is defined as the interest in achieving the public good of health sector wide interoperability through the adoption and use of standards.
- Stakeholders are categorised into funders/policy-makers, regulators, public health service providers, private health service providers, large health software providers, smaller health service providers, peak organisations, clinicians, SDOs, the compilers of aggregated data and interested others (consultants, academia, commentators/media).

Stakeholders in the health interoperability standards ecosystem currently interact in ways that make progress slow and difficult. It is contended in this analysis that no-one behaves in bad faith – but their interests are not aligned.

Importantly, interests are categorised in the Table below by demonstrated behaviour, not rhetoric.

Table 6 - Stakeholder analysis summary

Stakeholder group	Extent of interest in interoperability*	Degree of influence**
Funders/policy-makers /eHealth agencies:		
Politicians	Low – interested in My Health Record but not visibly in interoperability	High – Have legislative powers but not inclined to use them thus far
ADHA	High – arguably charged with leading interoperability efforts	Neutral – influence largely related to ability to provide financial incentives
DoH	Neutral – interested, but "fiefdoms" not necessarily aligned	Neutral – influence largely confined to policy advice
DTA	Low – mandate is largely Commonwealth agencies. No health sector expertise	Low – little coercive power and low credibility in health
ACSQHC	Neutral – only from a safety and quality perspective	High – use of standards could be incorporated in national Standards

Stakeholder group	Extent of interest in interoperability*	Degree of influence**
Regulators: Accreditors (ACHS, AGPAL, TGA, etc.)	Low – standards do not include interoperability	High – have reputational levers if interoperability was incorporated into standards
DHS, health insurers	Neutral – some desire for interoperability, but in practice not well standardised themselves	High – touch most parts of the health system and able to impose and test against standards
Public health service providers	Neutral – interested in some interoperability at local levels and within bounded jurisdictions, but have taken little action over the last two decades to build interoperability between States & Territories or consistently adopt standards	High – collectively, have powerful procurement leverage over Australian software vendors
Private health service providers	Low to neutral – some interested in local interoperability, but by and large not leading interoperability initiatives	Neutral – collectively, private CIOs could exercise significant leverage over software vendors
Large health software providers	High – maintenance of variable standards load is high (expensive) and reduces speed to market	Neutral – multinational vendors use international versions of standards (and charge for localisation)
Small health software suppliers	Neutral – some show interest in standardising, but others threatened by cost and potential customer-switching	Neutral – subject to tension between public good and commercial realities

Stakeholder group	Extent of interest in interoperability*	Degree of influence**
Peak organisations:		
MSIA	Neutral – some evidence of mobilising members to common endeavours, but limited to acting in members' best commercial interests	High – has leadership potential and an independent, non-government voice
AIIA	Low – engagement with health currently relatively low	Neutral – has less health membership than MSIA
Clinical colleges	Low – not seemingly on their radars	High – able to influence their members, and thereby health software providers, policy-makers, etc. if they chose to do so
HISA/ACHI	Neutral – not traditionally well engaged in standards/ interoperability	Neutral – high credibility and independence but little political/health service impact to date The merged organisation does have potential to take a higher profile, however
Front-line clinicians	Low – some have expectations of interoperability but most have limited understanding of what's required	High – customer expectations are potentially a powerful lever

Stakeholder group	Extent of interest in interoperability*	Degree of influence**
SDOs:		
ADHA - NCTS	High – interoperability is core business	Neutral – clinical terminologies still a relatively hard sell
HL7 Australia	High – interoperability is core business	Neutral – has limited capability and resourcing
Standards Australia	Neutral – not much involved with interoperability standards now	Neutral – has limited capability and resourcing
AIHW	High – coherence between data standards for exchange and compilation desired (collect once, use often)	Neutral – limited influence on private health service providers in particular
Other (consultants, etc.)	Low – interested if there is momentum but not likely to create this	Neutral – essentially "preaching to the converted"
Consumers	Neutral – Little literacy about interoperability per se and entangled by privacy debates	High – customer expectations are potentially a powerful lever

* Categorised as:

Low (apathetic): Little interest in health sector wide interoperability. Other interests prevail.

Neutral (neither apathetic nor defender): Interests are either neutral, as in not specifically against not specifically for. Could be influenced either way.

High (defenders of interoperability): Strong advocates for interoperability, as evidenced by actions as well as words.

** Categorised as:

Low (apathetic): Having little influence over the actions of others.

Neutral (neither apathetic nor latent): Has some demonstrable influence over others.

High (latent power): Having the potential to significantly influence others.

This analysis is graphically depicted below. The point of stakeholder analysis is to determine which stakeholders can be most productively leveraged to be effective in generating change, and which stakeholder risks need to be mitigated.

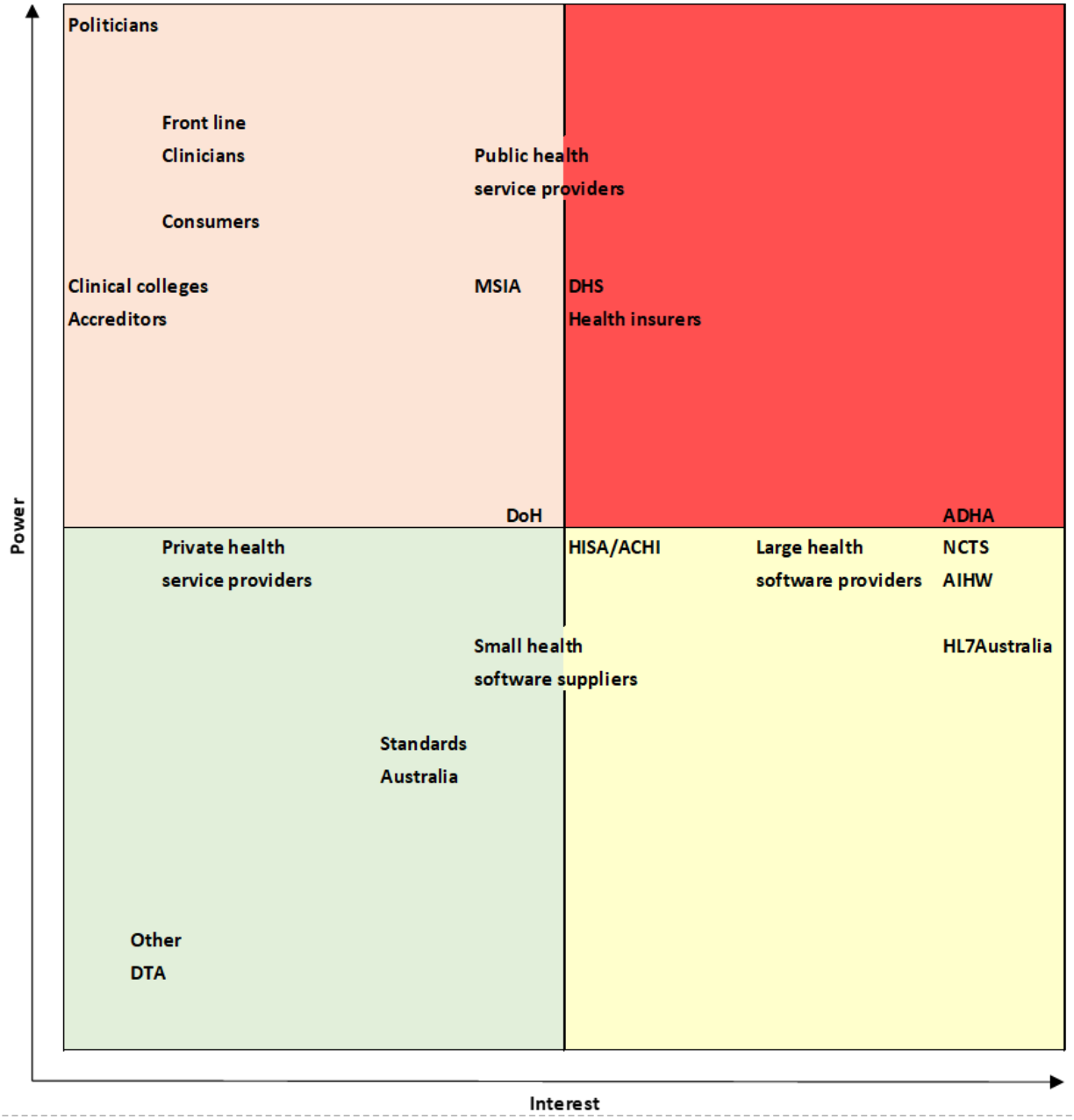


Figure 14 - Stakeholder analysis

7 Current State Summary

There are numerous and diverse drivers of demand for interoperability standards, and these represent some of the most critical issues facing the health sector. Strategic shifts such as value-based care, participatory health and precision medicine are utterly dependent on widespread interoperability, and so are making major inroads into critical business-as-usual factors such as productivity, safety, quality and access. The proliferation of new/maturing technologies such as big data analytics and IoT can be anticipated to raise consumer expectations of interoperability, and thereby standards. Demand for interoperability standards is likely to rise, not plateau or fall, for the foreseeable future.

Even though there is a sound platform of base standards available, these will continue to require profiling to Australian contexts, reflecting local regulations, workflows, service models, etc., ongoing whole-of-lifecycle maintenance and management, and integration with other standards to meet specific use cases.

Standards development, maintenance and management capabilities must be able to meet this demand.

There are undoubtedly areas of excellence in Australian standards development and maintenance. Of the four sub-domains involved:

- Data content standards are typically produced well, primarily by AIHW and ADHA, though there is some industry criticism that the AIHW does not deal directly (enough) with software suppliers, and that more should be done to satisfy the principle of balanced representation of those affected. ADHA appears to focus heavily on the initial development of standards, with little attention to ongoing, whole-of-lifecycle management. This is exemplified by failure to maintain CDA specifications since 2011, and the Clinical Informatics team currently working collaboratively on initial development of FHIR specifications with HL7 Australia, which has limited capacity to maintain them.
- Concept representation standards are also well produced overall, primarily by ADHA's NCTS. Its weakest point is currently international participation, which seems underinvested.
- The production and maintenance of data integrity standards also seem in control, with ADHA doing the heavy lifting.

Not uncoincidentally, standards development in these three sub-domains are primarily publicly funded. There is good private sector engagement in general, at least in part because there is effective support for the communities concerned.

However, two areas are currently lagging, and these pose risk for both the breadth and speed of standards development likely to be required:

- The development and ongoing maintenance of data exchange standards, which are primarily HL7, is constrained because there is little public investment in this sub-domain. HL7 Australia has no staff and its existing collaboration

infrastructure is minimalist. Its membership revenue enables it to purchase some episodic administrative support and a basic level of community support capability, but it is heavily dependent on the personal efforts of its volunteer Board members, most of whom are self-employed and may be subject to periodic lack of capacity, and members of its communities.

While the provision of labour/other services in kind to these communities, e.g. by ADHA, jurisdictional and private sector organisations, is important, HL7 Australia's capacity for ongoing management of the artefacts generated is a limiting factor.

- The integration of different standards into interoperability profiles is similarly constrained, for the same reasons, whether this is undertaken within the FHIR (HL7 Australia) or IHE Australia communities.

Neither ADHA nor any other agency can take over these functions. The intellectual property is owned and strictly protected by HL7 International and IHE International, and only the local Affiliates can produce "standards" in Australia. The alternative is to produce strictly proprietary interfaces for specific use cases, but this does not lead to an interoperability framework as advocated by ADHA and GDHP.

Public funding will be required to enable data exchange standards development and maintenance to keep pace with the other sub-domains, as is required for interoperability. This public funding, to redress portfolio imbalance, needs to be ongoing, at least for the foreseeable future, to enable ongoing *capability* that can support agile standards development in all the domains required and to sustain international participation. Project-based funding or annual funding submissions do not provide this.

This is not a new situation. Public funding was previously provided by DoH, from around 2002 – 2011, to support community development capabilities in both Standards Australia and HL7 Australia. While standards acceleration targets were identified, much of the funding was used to provide additional staff and support international standards development work. However, such funding was terminated in 2011 when the pressures of the PCEHR development program proved incompatible with standards development principles such as openness, transparency, balanced representation and consensus, and failed to address priorities other than those associated with the PCEHR.

Additional investment in 'sandpits" – tooling that allows developers to experiment with and refine their approaches to the adoption of standards, and for standards developers to learn from these processes, would be advisable. These do not currently exist for interoperability standardisation in general.

Additional investment is also required in the area of implementation support, to ensure standards are used consistently and interoperability eventuates. This is likely to be an area in which the private sector will come to the party, but only if there is market certainty that standardisation really is essential. The market drivers for this are currently largely absent, and the signals inconsistent.

Comprehensive stakeholder consultation encountered no one who considered digital health standards development and maintenance capabilities in Australia to be in robust shape overall at present. On the contrary, a wide range of stakeholders expressed the

view that these capabilities have been in overall decline for several years, despite areas of excellence and contrary to some international experiences, particularly in the USA.

In addition, some important roles including orchestration are completely missing in Australia at present, and the importance of standards seems under-recognised at political and policy levels.

Stakeholder consultation and research conducted indicates that the following roles and functions are required, and that their current state does not meet expectations.

Table 7 - Current State Assessment

Role	Functions	Current state
Orchestration of a complex, adaptive standards ecosystem	• System-wide oversight of the standards ecosystem, and road-mapping • Source of truth regarding standards requirements	• Missing
Funding	• Ensuring sufficient funds and other resources flow from all sources, public and private	• Less than required - market failures not fully addressed • Unbalanced
Commissioning	• Identifying where standards are needed and mobilising their supply	• Unbalanced
Standards development	• Development of specific, fit-for purpose standards and associated artefacts, sourced both internationally and locally	• Areas of excellence, but no stakeholder consulted considered standards development to be in good shape overall
SDO accreditation or endorsement	• Independent assurance that SDOs meet international and national requirements for standards development	• Missing
Support for standardisation	• Education and training • Authoritative technical support • Support for networking amongst developers and implementers	• Significantly lower than needed for consistent implementation

Role	Functions	Current state
	• Sandpits, reference sites, etc. • Knowledge translation and preservation • Community-building	(and thereby interoperability)
Conformance assessment and certification	• Assurance that specific products are standards-compliant	• Largely missing
Research and development	• Ongoing investigation into how standardisation can be best directed to achieve interoperability in a context of exponential growth of the Internet of Things and a data tsunami	• Very low

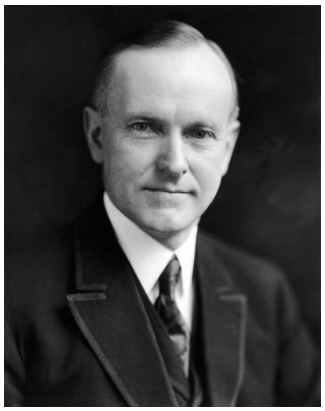
The regulatory function that Royle et al proposed has not been established, other than minimally as a component of the My Health Record program. Many stakeholders see this as a glaring omission, arguing that:

- Interoperability that is safe (with semantic integrity) and occurs without special effort is complex, given the number of systems and actors involved, and requires greater proof of conformance.
- Unless health software is required, at some point, to conform to defined interoperability standards, information blocking and cost-saving motivations are likely to slow progress to a crawl.

Conclusion

Australia's requirements for ongoing standards development, maintenance and management to support health sector interoperability should not be under-estimated. Despite some excellence, shortages in ongoing supply capabilities particularly in the data exchange sub-domain, represent a substantive risk to achievement of the health sector's strategic and tactical goals.

PART C: RECOMMENDATIONS



Nothing in the world can take the place of Persistence.

Talent will not; nothing is more common than unsuccessful men with talent.

Genius will not; unrewarded genius is almost a proverb.

Education will not; the world is full of educated derelicts.

Persistence and determination alone are omnipotent. The slogan 'Press On' has solved and always will solve the problems of the human race.

(Calvin Coolidge, as cited by The Quotations Page, n.d.)

8 Recommendations

Although the likely standardisation needs for Australian health sector interoperability are yet to be determined (consultation is currently underway), a gap between these needs and current capabilities can be confidently predicted, primarily because data exchange standard capabilities are currently thin, and little attention is being paid to the need for lifecycle management of standards products generated via national projects. Widespread adoption and use of standards identified as central to interoperability, required relatively rapidly to overcome network effects, is at risk without greater market certainty about bridging gaps between today's standards base and tomorrow's.

These gaps can be closed through a variety of relatively small actions and investments. But because standards development, maintenance and management constitute a complex, adaptive ecosystem, these actions must be undertaken in unison – a shared vision and objectives must be crafted, communication amongst the large number of independent agents improved, effective governance implemented, and incentives addressing a diverse set of behavioural drivers put in place. Interventions in complex adaptive systems need to support multiple decision points.

The changes recommended fall into three groupings: orchestration; capacity-building; and funding.

8.1 Orchestration

Overall orchestration of the standardisation ecosystem is currently completely missing, and has been since around 2010-11, when NEHTA effectively abandoned this role.

The need for orchestration has long been recognised in Australia. Deloitte's National E-Health Strategy from 2008 included commentary that (p.42):

- A consistent, robust and inclusive process was required for the development, endorsement and implementation of national e-health standards.
- Endorsement of existing e-health standards through engagement with vendors, care provider organisations and professional bodies was required.
- There was a need to identify and prioritise the next tranche of required national e-health standards, also requiring widespread engagement.
- A three year, rolling national e-health standards implementation plan (a roadmap) should be developed and published.

Other, high priority orchestration roles now include:

- Raising the profile of standardisation and securing sector-wide commitment to it, and leadership towards it.
- Providing the "source of truth" for the Australian health sector regarding standards requirements for various purposes – akin to the ONCHIT's annual Interoperability Standards Advisories (described in Appendix D).

- Overseeing governance of the national Standards Development, Maintenance and Management Model and proposing sector-wide standardisation policies;
- Liaison with other key digital health stakeholders to ensure overall architectural coherence and adequate sectoral capacity;
- Evaluating the success of interoperability standardisation initiatives.

This orchestration role has been key to the US becoming a global leader in health interoperability standardisation, despite the complexity and size of its health system. It has also been key to successes in other industries such as aviation, through IATA.

8.1.1 Orchestration options

There are various organisations that could be charged with taking the lead on this function of orchestration, falling into three groupings – orchestration by AHDA, by a central agency or by collaboration. The pros and cons of each model follow.

It is important to note that none of these options currently have the have the right mix of skills to undertake this orchestration function, so relative capabilities are not addressed as either pros or cons.

Option 1: Orchestration by ADHA

ADHA arguably has some mandate to undertake this function. Its charter positions it to be the "single accountable organisation for digital health in Australia" (Cormann, 2016, p.2). It is required to develop, implement, manage, operate and continuously innovate and improve standards, systems and services in relation to digital health, and to leverage existing standards and specifications to facilitate information sharing in digital health systems (p.4).

Accordingly, the Rule establishing ADHA states that the Agency's functions include (Australian Government, 2016):

- "to develop, implement, manage, operate and continuously innovate and improve specifications, standards, systems and services in relation to digital health, consistently with the national digital health work program" (Clause 9(1)(c));
- "to develop, monitor and manage specifications and standards to maximise effective interoperability of public and private sector digital health systems" (Clause 9(1)(e)); and that
- In performing the first of these functions, but interestingly not the second, "the Agency must, if appropriate, act collaboratively with:
  - (a) Commonwealth, State and Territory Governments; and
  - (b) other key stakeholders, such as peak health associations, health industry bodies, clinical groups, health consumer organisations and healthcare providers" (Clause 9(2)).

While the orchestration role is not explicitly referenced, it may be implied if ADHA is truly the single accountable organisation for digital health in Australia.

Pros

- ADHA has a substantive interest in promoting interoperability, and promoting standards as a critical enabler of interoperability;
- It has some of the requisite technical expertise, especially with regard to standards such as concept representation (clinical terminologies), data content and data exchange (including FHIR);
- Its industry engagement is seen by many stakeholders as very sound, within projects.
- Its viewpoints give it a wide overview of the health sector.

Cons

- The orchestration role requires impartiality that ADHA does not possess, and cannot possess as long as it is the developer and operator of some specific services, in particular My Health Record. ADHA is no more impartial in this respect than any other solution provider (e.g. the Department of Human Services or Cerner), since its specific standardisation needs are likely to top its priorities and resource allocations. It was exactly this conflict of interests that substantially damaged Australian standardisation from 2010-11 onwards, and that damaged the NHS's standardisation efforts.

  Even if the Agency could be agnostic to its own interests and managerial pressures, it is unlikely that it would be *perceived* to be impartial by many stakeholders. Many of the stakeholders consulted questioned ADHA's credibility for this role.

  Royle et al. noted in 2013 that "A revised governance body needs to have relative independence from State and Federal Government departments to ensure it is balanced and represents the needs of multiple key stakeholders to facilitate the elements of eHealth delivery by a healthy private sector in partnership with government provided services" (p.21). The Agency, despite having a diverse Board, does not enjoy this relative independence:

  - As a Commonwealth entity it has a reporting line to the Federal Health Minister and accountability to the Australian Parliament.
  - The Agency has a line-of-sight to COAG through the Health Services Principal Committee, but this still constitutes State and Federal Government interests.
  - Some members of the Board's Jurisdictional Advisory Committee (JAC) asserted, during consultations, that the JAC ensures the Board's balanced representation of interest. However, the JAC does not represent other interests such as industry's, and some other jurisdictions consulted suggested that the JAC is overly dominated by the larger States.

- ADHA's governing Rule also directs its attention specifically to the national digital health work program. However, not all interoperability building blocks are part of the national work program, and not all interoperability standards requirements are covered by it, since the work program is necessarily future focused and silent on the current needs of many stakeholders. For example, today's health sector is dominated by HL7 V2 standards and vocabularies other than SNOMED CT, and ADHA does not really play in these arenas.

Option 2: Orchestration by a central agency

The orchestration role could be undertaken by the Department of Health or another central agency such as the Digital Transformation Agency (DTA). This has a parallel – in the USA, this orchestration is undertaken by the ONCHIT, which is part of the Department of Health and Human Services. It could also be undertaken by another existing agency, such as the ACSQHC, or by a new agency.

Department of Health – Pros

- DoH's viewpoints give it a wide overview of the health sector.
- It has control (as far as anyone does) of the policy and funding levers that are likely to be required to encourage widespread adoption.

Department of Health – Cons

- DoH has a history of lack of orchestration of its own and DHS initiatives, and simultaneously introducing conflicting standards.
- It has low credibility in terms of meaningful industry engagement.
- It has already outsourced this kind of role to ADHA.

Digital Transformation Agency – Pros

- DTA is geared to provide strategic leadership on whole-of-government and shared ICT and digital services.

Digital Transformation Agency – Cons

- DTA's ambit is Australian government services, not the health sector and not the private sector. While there is some overlap, it has very limited expertise in the extraordinarily complex health system.

ACSQHC – Pros

- The Commission contributes to e-health by optimising safety and quality in the rollout of clinical systems. It focuses on hospital medication management programs and discharge summaries, and using e-health initiatives to improve the safety and quality of health care. It develops national guidelines such as for the On-Screen Display of Medicines Information and On-Screen Presentation of Discharge Summaries.

- It also recommends national data sets for safety and quality, including dataset and indicator specifications, and e-health standards.
- Safety and quality are primary drivers for interoperability and standards.

ACSQHC – Cons

- The subject matter involved in interoperability standardisation goes well beyond the current ambit of the Commission. It includes very technical content and much deeper IT industry involvement.
- Its purview provides only a singular, albeit crucial, perspective. Digital health is much broader.
- It has similar lines of control to the Federal Government as for ADHA.

A new agency - Pros

- A new agency could be purpose-built (highly focussed) and unencumbered with other agendas.
- It would not carry any baggage (though its staff could of course bring some).

A new agency - Cons

- A new agency would have no track record (though its staff could of course bring some). It would need to build credibility from scratch.
- It would need to build a new organisation, systems and processes.

Option 3: Orchestration through collaboration

The orchestration function could be undertaken under the ADHA's mandate, but via collaboration with another partner or partners. Variants of this model include outsourcing the function and participating in a collaborative venture.

Outsourcing – Pros

- Outsourcing has the advantage of relative contractual simplicity (compared with a collaborative venture).
- ADHA has experience with this "owner-operator" model – for example in contracting with Accenture for the delivery of PCEHR/My Health Record development.
- Outsourcing to a highly credible/trusted collaborator could remediate ADHA's current lack of impartiality.

Outsourcing – Cons

- It is questionable whether any single organisation currently brings the right mix of credibility and capabilities. The orchestration function requires collaboration between government, clinical and technical perspectives.

- Outsourcing means that ADHA retains sole control over the orchestration agenda – a contracted agency would likely have little freedom to publicly question the purchaser of its services.

Collaborative venture – Pros

- A collaborative venture is not restricted to one partner, so a wider mix of credibility and capabilities could be attracted.
- It enables the requisite impartiality to be delivered.
- It introduces countervailing powers and thereby encourages debate and negotiation and compromise at the most fundamental level.

Collaborative venture – Cons

- A collaborative venture is potentially more difficult to establish and manage than an outsourcing arrangement. It has the potential to be unstable.

Recommended option

Collaboration and consensus building are key to successful standardisation. Based on learnings from our own past, the US and stakeholder perceptions, so is the need to separate overall orchestration of standardisation from the delivery of e-health solutions. This is consistent with the IATA model – IATA does not operate airline services.

The option recommended is the collaborative venture. It borrows from the UK's InterOpen model, and is adapted for the Australian context. InterOpen grew from industry up, motivated strongly by discontent, to build a collaborative of government, clinical and technical interests in the context of a single NHS. The collaborative venture recommended here proposes a collaborative of government, clinical and technical interests in the context of federated health services, and motivated not by discontent but by a widespread desire to learn from experience and improve.

The proposed orchestrator borrows from ingredients that have demonstrated success in other jurisdictions. It comprises:

- A new entity – the Health Interoperability Standards Office (HISO) – formed as a collaborative venture of interested partners with countervailing powers and complementary capabilities, with responsibilities as described above. This new entity would *not*, however:
  - Develop standards – there are others very capable of doing that;
  - Certify products, as ONCHIT does, at least at this stage. Conformance and certification are beyond the scope of this project.
- A HISO-supported, broadly constituted Health Interoperability Standards Technical Council, comprising stakeholder representatives and relevant expertise.

Specifically, a collaborative, multi-organisational venture is proposed between ADHA, the Medical Software Industry Association (MSIA), the Digital Health CRC and the (likely merging) Health Informatics Society of Australia and Australasian College of Health Informatics (HISA/ACHI), with the latter hosting the equivalent of the UK PRSB.

In this collaboration of governments, industry and clinical and informatics communities:

- ADHA would bring linkages to the Department of Health (DoH) and the Council of Australian Governments (COAG) Health Services Principal Committee as well as technical expertise.
- The MSIA would bring substantive industry participation.
- The Digital Health CRC would bring neutrality, research and development capability and an organisation set up to constructively blend government, industry and academic expertise.
- HISA/ACHI would bring Australia's largest digital health expert community, and strong independence as well as knowledge translation capabilities.

This represents both blended capabilities and a balance of countervailing powers. The proposed organisation is depicted at high level below.

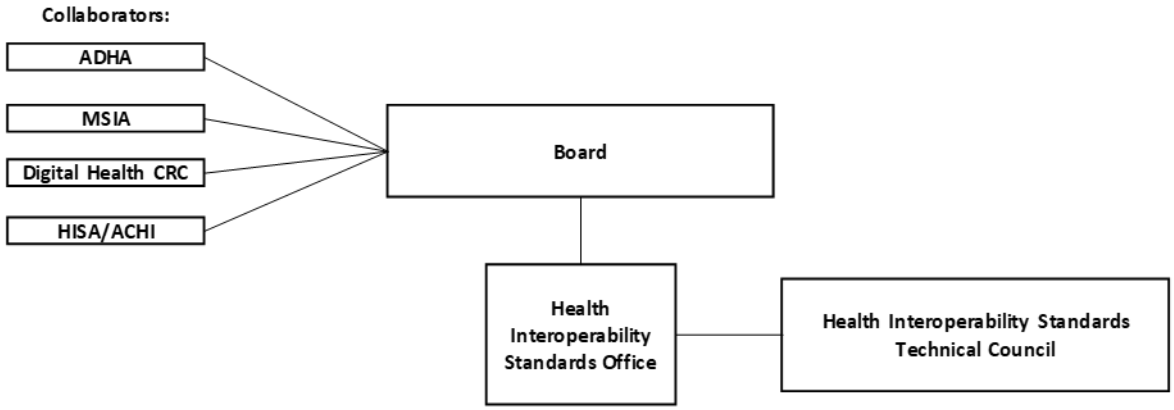


Figure 15 - Health Interoperability Standards Office

This Health Interoperability Standards Office (HISO) would be managed by a Board including representatives from the collaborators as well as independent members, and be guided on standardisation by the Technical Council. HISO would be a small office, but a vital one.

In this model, the Board is responsible to its stakeholders (ADHA, MSIA and HISA/ACHI), and through them, their constituent communities. It provides continuity for HISO through oversight of its policies, strategies, priorities and business models, and is accountable for the use of its resources. It is a high-level advocate for standardisation.

This new entity's charter should incorporate principles of good practice in standardisation and be readily accessible (open) to the public.

The proposed Technical Council comprises the full array of technical standards experts required to build consensus on which standards should be used for various health interoperability purposes, and identify and advise on standardisation issues.

HISO should maintain strong linkages with other peak groups, as indicatively illustrated at Figure 16. This would include an agency taking the role akin to the UK's Professional Record Standards Body – described at Appendix E.

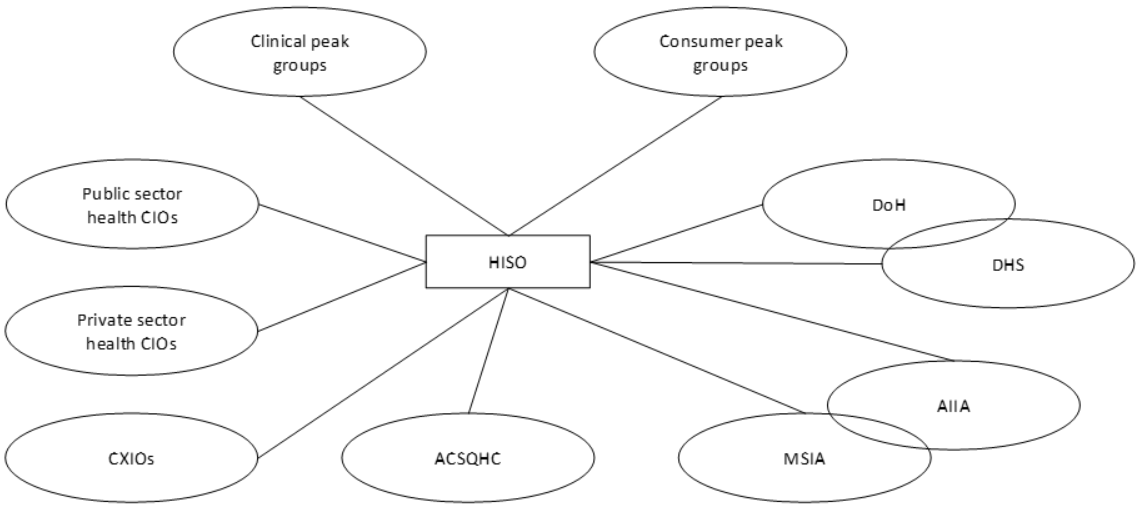


Figure 16 - Indicative linkages (Not intended to be comprehensive, nor to imply that all linkages are intermediated by HISO)

8.1.2 Visibility and stakeholders

Every stakeholder consulted during this project affirmed the critical importance of standards to health sector interoperability – although this is to be expected, since it was key stakeholders who were consulted. More widely, however, it is unlikely that standards are high on the agendas of, or even thought about at all, by many other stakeholders, including many important decision-makers and direction-setters.

While standardisation is cited as an underpinning of the National Digital Health Strategy, it requires considerably more visibility in that context and others. WHO is clear that standardisation must be embedded in national *health* plans – i.e. be explicitly recognised in discussions of the health system sought, not just plans for the technologies for the health system.

In the USA, which is arguably the current world leader in large-scale efforts to secure health sector interoperability:

- The ONCHIT is required to report annually to Congress on sectoral actions taken to facilitate adoption of electronic use and exchange of health information, barriers to such adoption and recommendations for improvement. Standards, implementation specifications and certification criteria are central to these reports (e.g. ONCHIT, n.d.b).

- The 21st Century Cures Act includes a section on "Ensuring Interoperability of Health Information Technology".
- The Bipartisan Policy Center and Health Leadership Council's Interoperability Policy Brief (2019) insists that "interoperability is an urgent healthcare and health information technology (health IT) priority" and that "interoperability is made possible by implementation of standards" (p.4).

These and many other examples demonstrate that leadership about interoperability and the criticality of standards is highly visible at the highest political levels in the USA. This is supported with ongoing resourcing and mirrored by funders and regulators, health service providers and the health software industry.

Similarly, UK Secretary for Health and Social Care Matt Hancock has been leading from the front on "a set of open standards and a focus on interoperability" (Macaulay, 2018). NHS Digital has published a draft NHS digital, data and technology standards framework, and "all health and social care organisations and suppliers will have to adopt the standards when they're published" – new health IT systems will need to meet the standards and existing systems will have to be upgraded.

Few stakeholders consulted in this project considered that the role of standards in enabling interoperability is well recognised or made visible by Australia's politicians or health policy-makers.

The aims here are greater visibility of the standards agenda, recognition of its criticality, declaration of serious intent, and action. Without these, investments in standards are likely to remain sub-optimal and piecemeal.

Addressing this is not difficult but it does require persistence. ADHA and other digital health leadership organisations could include statements that highlight the unique role of standards (as ONCHIT does per Figure 17 below), and rename "interoperability" initiatives and outputs as "interoperability and standards" initiatives.

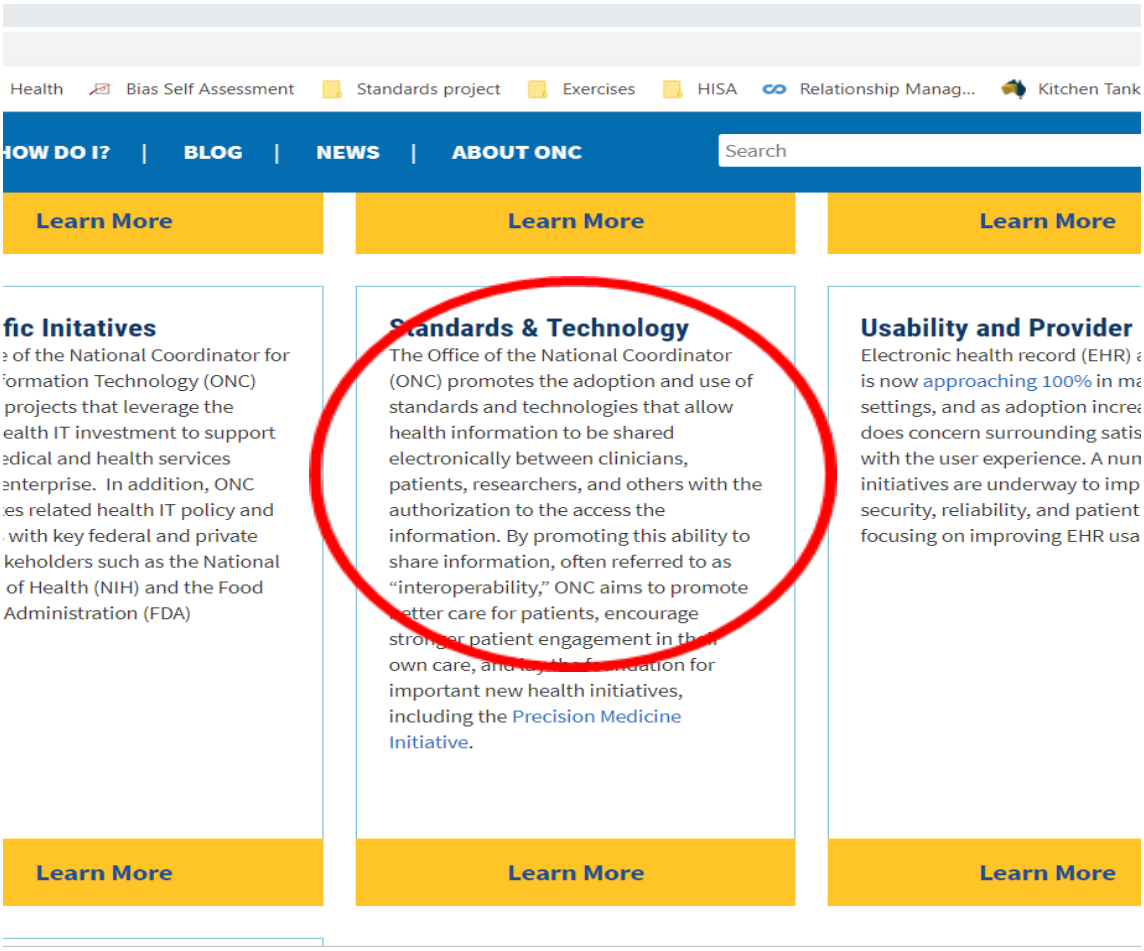


Figure 17 - ONCHIT website, Topics (ONCHIT, n.d.c)

Other visibility raising tactics could include: Support for the use of and discussion about interoperability standards at HIC and other high-profile conferences/seminars; release of a plan and knowledge resources on standardisation; and explicitly including information on standardisation in briefing papers.

Most importantly though, dialogue about making strategic shifts in the health system and responding to tactical pressures such as productivity, safety and quality should consistently include references to the criticality of interoperability and standards.

8.1.3 Stakeholder management

Underlying the need to increase visibility is the need to encourage stakeholder empowerment and motivation, and the exercise of power. Suggested priorities are depicted below.

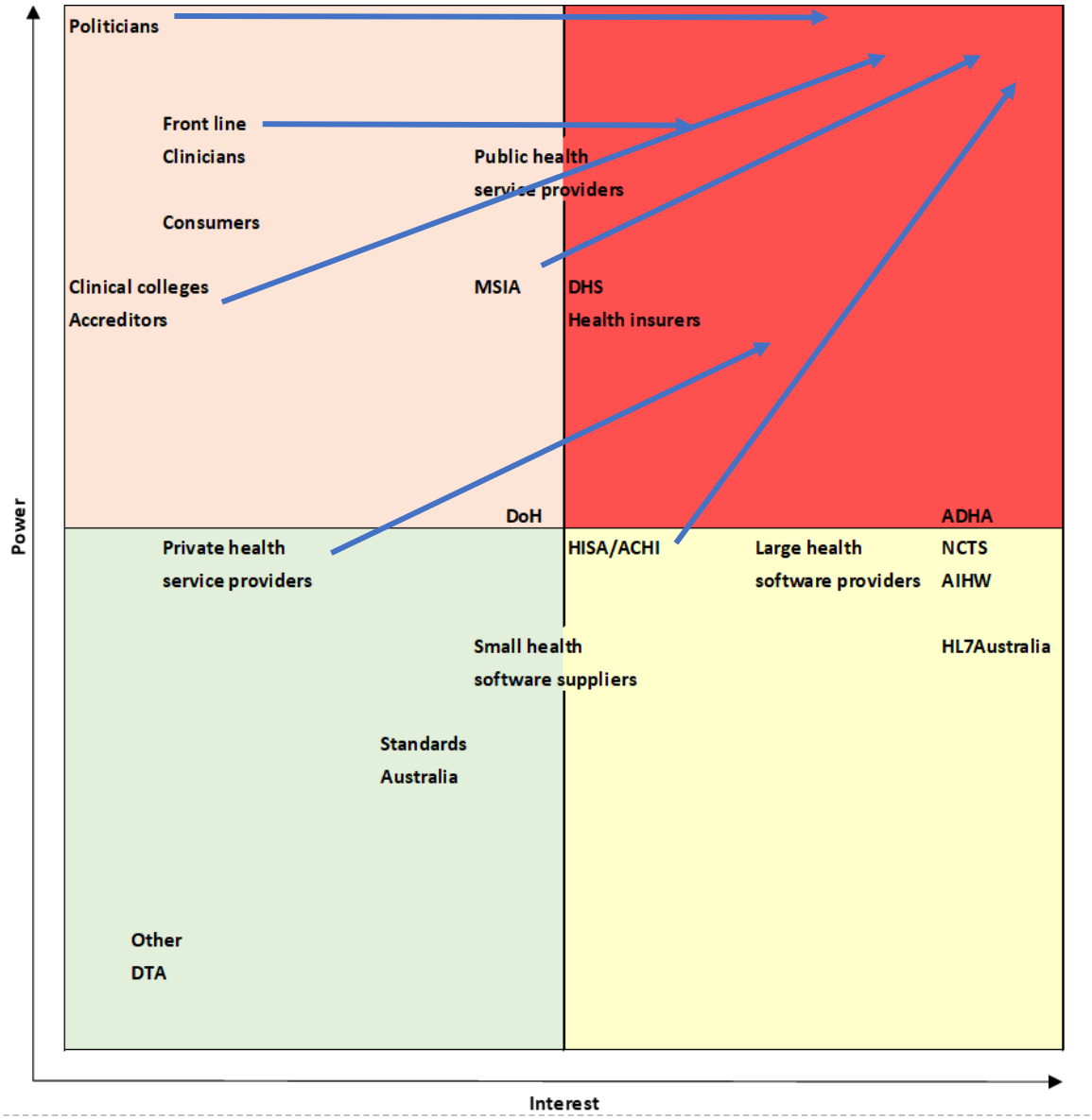


Figure 18 - Shifts required in stakeholder positioning

8.1.4 Conformance and accreditation

As highlighted earlier, conformance and accreditation are beyond the scope of this report but are criticality important to the adoption and use of standards. Australia has struggled to find sustainable, market-based incentives for the widespread, consistent implementation of standards, and better strategies are required.

Recommendations concerning orchestration

Recommendation 1:	ADHA should establish a Health Interoperability Standards Office to undertake the following roles and functions: • Raising the profile of standardisation and securing sector-wide commitment to it, and leadership towards it. • Building a standards roadmap and providing the "source of truth" for the Australian health sector regarding standards requirements for various purposes – akin to the ONCHIT's annual Interoperability Standards Advisories. • Overseeing governance of the national Standards Development, Maintenance and Management Model and proposing sector-wide standardisation policies. • Liaising with other key digital health stakeholders to ensure overall architectural coherence and adequate sectoral capacity. • Providing independent assurance that SDOs meet international and national requirements for standards development • Evaluating the success of interoperability standardisation initiatives.
Recommendation 2:	ADHA should seek revision of the Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016 to ensure that Clause 9(2) applies to Clause 9(1)(e) as well as to Clauses 9(1)(a) and (c).
Recommendation 3:	ADHA should seek to establish the Health Interoperability Standards Office as a collaborative venture with the Medical Software Industry Association), the Digital Health CRC and the (likely merging) Health Informatics Society of Australia and Australasian College of Health Informatics (HISA/ACHI), with the latter establishing and hosting an equivalent of the UK's Professional Records Standards Body.

Recommendation 4:	The Health Interoperability Standards Office should be supported by a broadly constituted Technical Council, comprising stakeholder representatives and relevant expertise.
Recommendation 5:	The charter for and operations of the Health Interoperability Standards Office should be consistent with the principles of Openness, Transparency, Representation, Impartiality, Consensus, Market need and net benefit, Timeliness, Internationality, Compliance, Coherence, Availability, Support, as described in section 3.6.1 of this report.
Recommendation 6:	The Health Interoperability Standards Office should develop a communication plan on standardisation and its criticality to effective and efficient health service delivery.
Recommendation 7:	The Health Interoperability Standards Office should prepare briefing material for Governments and policy-makers on the importance of making standardisation visible in all strategies that depend on interoperability.
Recommendation 8:	ADHA should commission a strategy for conformance testing and accreditation of standards-based health software.

8.2 Capacity-building

One of NEHTA's objectives back in 2006 was to "build long-term capacities within the sector to sustain ongoing development and maintenance of e-health standards" (NEHTA, 2006).

Capacity building in this report refers to the processes via which the entire ecosystem can obtain, continuously improve and retain the human (knowledge, skills, experience), physical and informational resources required for effective and sustainable standards development, maintenance and management, specifically to support health sector interoperability.

NEHTA's 2006 objective, dimmed from 2010-11 but revitalised by the Agency since 2016 and with ongoing effort by AIHW in particular, has been relatively successful in relation to data content standards, concept representation standards and data integrity standards, all of which are supported by substantial public investments.

As noted above, however, this portfolio of public investments is unbalanced, and is unlikely to meet interoperability needs until all four sub-domains are receiving roughly equal attention, and the integration of standards is routinely addressed.

Several of the standardisation success factors described in Table 3 also require attention. International participation in standards development is particularly noteworthy, since public funding to support this has substantially declined:

- ADHA participation in SNOMED International's activities is now minimal, stifling succession planning as well as minimising Australia's ability to embed our requirements into international terminology versions. CSIRO funds some participation, and although this delivers some public benefit it is nonetheless commercially-oriented and not necessarily directed to ADHA's, and Australia's highest priorities;
- Participation in HL7 International is now extremely thin, with just a few private enterprises (particularly Telstra health) supporting this.

It is possible that this funding decline is due to fear of mis-perception – fear of being asked "why is the Australian Government funding international travel?".

The answer is this: Multinational vendors use international standards, not Australian ones. We pay twice when we then require software localisation – once within standards communities when we need to develop Australian extensions to or deviations from the international standards, and again when the software must be customised to meet these. The further the distance between international standards, in particular SNOMED CT and HL7/FHIR, and Australian requirements, the more cost we incur – and conversely the higher the barriers for our potential health software exporters.

The Australian Government states (2017, p.17):

> "We cannot impose our views or our will overseas. Our ability to protect and advance our interests rests on the quality of our engagement with the world. This includes the ideas we bring to the table, our ability to persuade others to our point of view and the strength of the relationships we build with other governments and, increasingly, with influential non-government actors."

This foreign policy white paper notes the importance of soft skills – nurturing relationships – to successful trade-related outcomes and to the achievement of common objectives.

The cheapest and most effective way to ensure multi-national vendors meet Australian needs, and assist Australian vendors to meet the needs of other nations, is to minimise the distance between international standards and Australian requirements, by embedding our requirements in those international standards as far as possible. And that requires active participation at and between international working meetings.

These are not called "working meetings" for nothing. They involve long days of intensive negotiation of technical issues and problem-solving, many additional hours of geo-political and inter-company consultation, and relationship building on top of that. They are supported by a great deal of work between meetings, often including weekly, middle of the night conference calls. Many of the most expert (potential) participants are also small business-people who experience opportunity costs associated with attendance, as well as disruption to their lives. These are far from "international junkets".

Recommendations concerning capacity building

Recommendation 9:	In accordance with the Intergovernmental Agreement on National Digital Health in relation to establishing and maintaining specifications and standards for digital health (COAG, 2018, Clause 16), ADHA should seek to ensure a more balanced portfolio of public funding across the four interoperability standard sub-domains of data content, concept representation, data exchange and data integrity standards, by: • Redistributing existing funds in favour of data exchange, and/or • Seeking additional COAG or Australian Government funding for data exchange standards. These funds should be multi-year, targeted at ensuring ongoing capabilities, rather than project-funded, and include funds supporting a higher level of international participation in data exchange standards development.
Recommendation 10:	ADHA should increase its level of support for participation in SNOMED International Business Meetings, in recognition that: • It is both feasible and more cost-effective to incorporate Australian requirements into international versions of standards than to localise here, taking into account the need to customise multi-national software. • This provides greater capacity for Australia health software suppliers to enter global markets. • The nature of such meetings is that they comprise multiple, parallel streams, requiring sufficient numbers to accommodate prioritised agendas. It takes time and continuity of participation to build power and influence, and failure of succession planning constitutes unnecessary longer-term risk.
Recommendation 11:	ADHA should encourage the (likely to merge) Health Informatics Society of Australia and Australasian College of Health Informatics to establish an Australian equivalent of the UK's Professional Records Standards Body.

8.3 Funding

An estimated $5.5 million dollars per annum is required to implement these recommendations – high-level costings are provided at Appendix F. This could be delivered through either additional public funding or redistribution of some existing resources. Additional private contributions are likely, over time, to follow this but are also more likely to be in-kind and focus on capacity building.

While there may initially be savings on staffing and other capability provision in the first year, these may be offset by costs associated with establishment and contracting in lieu.

Recommendations concerning funding

Recommendation 12:	ADHA should consider the extent to which it can redistribute resources to fund this report's recommendation and/or source funds from collaborating partners, and prepare a submission to COAG for the remainder.

9 Consolidated List of Recommendations

Recommendation 1: ADHA should establish a Health Interoperability Standards Office to undertake the following roles and functions:

- Raising the profile of standardisation and securing sector-wide commitment to it, and leadership towards it.
- Building a standards roadmap and providing the "source of truth" for the Australian health sector regarding standards requirements for various purposes – akin to the ONCHIT's annual Interoperability Standards Advisories.
- Overseeing governance of the national Standards Development, Maintenance and Management Model and proposing sector-wide standardisation policies.
- Liaising with other key digital health stakeholders to ensure overall architectural coherence and adequate sectoral capacity.
- Providing independent assurance that SDOs meet international and national requirements for standards development
- Evaluating the success of interoperability standardisation initiatives.

Recommendation 2: ADHA should seek revision of the Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016 to ensure that Clause 9(2) applies to Clause 9(1)(e) as well as to Clauses 9(1)(a) and (c).

Recommendation 3: ADHA should seek to establish the Health Interoperability Standards Office as a collaborative venture with the Medical Software Industry Association), the Digital Health CRC and the (likely merging) Health Informatics Society of Australia and Australasian College of Health Informatics (HISA/ACHI), with the latter establishing and hosting an equivalent of the UK's Professional Records Standards Body.

Recommendation 4: The Health Interoperability Standards Office should be supported by a broadly constituted Technical Council, comprising stakeholder representatives and relevant expertise.

Recommendation 5:	The charter for and operations of the Health Interoperability Standards Office should be consistent with the principles of Openness, Transparency, Representation, Impartiality, Consensus, Market need and net benefit, Timeliness, Internationality, Compliance, Coherence, Availability, Support, as described in section 3.6.1 of this report.
Recommendation 6:	The Health Interoperability Standards Office should develop a communication plan on standardisation and its criticality to effective and efficient health service delivery.
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Recommendation 11:	ADHA should encourage the (likely to merge) Health Informatics Society of Australia and Australasian College of Health Informatics to establish an Australian equivalent of the UK's Professional Records Standards Body.
Recommendation 12:	ADHA should consider the extent to which it can redistribute resources to fund this report's recommendation and/or source funds from collaborating partners, and prepare a submission to COAG for the remainder.

10 Next Steps

If the recommendations above are accepted by ADHA, then the immediate next steps are:

- Socialise the recommendations with the Department of Health (widely) and AHMAC Members to prepare the ground for a submission to COAG for funding (likely to be required). Ensure CMIOs are engaged as well as CIOs.
- Draft an amendment the Public Governance, Performance and Accountability (Establishing the Australian Digital Health Agency) Rule 2016 (see Recommendation 2) and build a funding submission.
- Explore the collaboration in detail with potential collaborators. MSIA, the Digital Health CRC and HISA are positive concerning the concept but would need to collaborate on building the detail.
- Encourage HISA/ACHI to establish an Australian equivalent of the UK's Professional Records Standards Body, and to request associated funding.
- Commission a strategy for conformance testing and accreditation of standards-based health software.

10.1 Risks

Major risks associated with the recommendations above are:

- Lack of will to address the issues raised. The Economist Intelligence Unit describes Australia as having "little appetite for systemic change within the healthcare system" (2016), and standardisation is not broadly discussed outside technology circles.
  Mitigation: Address visibility and stakeholder engagement issues.
- Recommendations are "cherry-picked". The recommendations are designed to move a complex adaptive system, which requires interventions at a range of points.
  Mitigation: Implement holistically.
- Further community disillusionment if expectations have been raised through this project but action does not follow.
  Mitigation: Communicate progress.
- Failure to address the market drivers for adoption and use of standards.
  Mitigation: Develop a conformance and accreditation strategy per the national Digital Health Strategy (2017, p.31).

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List of acronyms

ACHI	Australasian College of Health Informatics
ACIITC	Aged Care Industry IT Council
ACSQHC	Australian Commission on Safety and Quality in Health Care
ADHA	Australian Digital Health Agency
AGPAL	Australian General Practice Accreditation Limited
AHMAC	Australian Health Ministers' Advisory Council
AI	Artificial intelligence
AIHW	Australian Institute of Health and Welfare
AMHCC	Australian Mental Health Care Classification
AMIA	American Medical Informatics Association
AMT	Australian Medicines Terminology
ANSI	American National Standards Institute
API	Application programming interface
AS/NZS	Australian and New Zealand Standard
AuCT-UG	Australian Clinical Terminology User Group
BSI	British Standards Institution
CDA	Clinical Document Architecture
CDISC	Clinical Data Interchange Standards Consortium
CEN	Committee European de Normalization
COAG	Council of Australian Governments
DoH	[Australian Government] Department of Health
DHS	[Australian Government] Department of Human Services
DIIS	Department of Industry, Innovation and Science
DTA	[Australian Government] Digital Transformation Agency
DVA	Department of Veterans' Affairs
EC	European Commission
FHIR	Fast Healthcare Interoperability Resources
FRAND	Fair, Reasonable and Non-Discriminatory
GDHI	Global Digital Health Index
GDHP	Global Digital Health Partnership
GP	General Practitioner, General Practice
HISA	Health Informatics Society of Australia

HISO	Health Information Standards Office (Australia)
HISO	Health Information Standards Organisation (New Zealand)
HL7	Health Level Seven [International]
IATA	International Air Transport Association
IBAN	International Bank Account Number
ICD	International Classification of Diseases
ICF	International Classification of Functioning, Disability and Health
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IETF	Internet Engineering Task Force
IHE	Integrating the Healthcare Enterprise
IHPA	Independent Hospital Pricing Authority
IHTSDO	International Health Terminologies Standards Development Organization
IP	Intellectual Property
IOSA	IATA Operational Safety Audit
IoT	Internet of Things
ISA	Interoperability Standards Advisory
ISO	International Organization for Standardization
IT-014	Standards Australia's Health Informatics Technical Committee – the 14th Technical Committee it established in the IT domain
ITU	International Telecommunications Union
JAC	Jurisdictional Advisory Committee
JIC	Joint Initiative Council
METeOR	[AIHW] Metadata Online Registry
mHealth	Mobile health
ML	Machine learning
MSIA	Medical Software Industry Association
NATA	National Association of Testing Authorities
NCC	National Construction Code
NCTS	National Clinical Terminology Service
NEHRT	National Electronic Health Records Taskforce
NEHTA	National E-Health Transition Authority Ltd
NHDISC	National Health Data and Information Standards Committee

NHS	[UK] National Health Service
NIH	[US] National Institutes of Health
OMG	Object Management Group
ONCHIT	Office of the National Coordinator for Health Information Technology
OSI	Open Systems Interconnection
PCEHR	Personally-Controlled Electronic Health Record
PRSB	Professional Records Standards Body
RCPA	Royal College of Pathologists of Australasia
REST	Representational State Transfer
RIM	[HL7 International] Reference Information Model
SDO	Standards Development Organisation
SMD	Secure Message Delivery
SNOMED	Systematic Nomenclature of Medicine
SOA	Service Oriented Architecture
SWOT	Strengths, weakness, opportunities and threats
TCP/IP	Transmission Control Protocol/Internet Protocol
W3C	World Wide Web Consortium
WEF	World Economic Forum
WHO	World Health Organization
WTO	World Trade Organization

APPENDECES

Appendix A Stakeholders consulted

The following stakeholders, listed in alphabetical order, were consulted during this project.

Tony Abbenante	Department of Health and Human Services, Victoria
Dani Arousi	Allscripts
Dr Richard Ashby	eHealth Queensland
Matthew Bardsley	Medical Director
Vicky Bennett	AIHW
Tim Blake	Semantic Consulting
Neville Board	Department of Health and Human Services, Victoria
Dr Andy Bond	Queensland University of technology / Genie Software
Dr Zoran Bolevitch and team	eHealth NSW
Jo Buckland	Queensland Health
Markos Chouris	SA Health
Grahame Coles	St John of God
Paul Creech	Department of Human Services
Richard Dixon-Hughes	Standards Australia IT-014
Kate Ebrill	CSIRO
Rodney Ecclestone	ADHA
Brett Esler	HL7 Australia
Heath Frankel	Ocean Informatics
Isobel Frean	BUPA
Grahame Grieve	Health Intersections
John Gottschalk	ADHA
Rafic Habib	Clinic to Cloud
Dr David Hanson	CSIRO

Tanya Harch	Queensland Health
Marcia Healy	Mercy Health
Dr Sam Heard	Ocean Informatics
Emma Hossack	MSIA
Steve Hughes	Mater, Townsville
Alex Ilias	Professional Records Standards Body
Holger Kaufmann	WA Health
Brian Kelleher	Department of Health
David Kempson	Mater Hospital, Brisbane
Edmund Kienast	ADHA
Karen Kinmont	Epworth Health
Andy Kinnear	InterOpen
Michael Lawley	CSIRO
Bill LeBlanc	SA Health
Rupert Lee	ADHA
Michael Legg	Royal Australian College of Pathologists
Phillip Loya	Cerner
Dr Peter MacIsaac	IHE Australia
Prof Anthony Maeder	Flinders University
George Margelis	Aged Care IT Council
Dr Vince McCauley	Telstra Health
Dr Andrew McIntyre	Medical Objects
David McKillop	ADHA
Bettina McMahon	ADHA
Dion McMurtrie	ADHA
Dr Keith McNeil	Queensland Health
Dr Amir Mehrkar	InterOpen

Emilie Mortensen	Standards Australia
Victor Pantano	Digital Health CRC
Dr Nathan Pinksier	ADHA
Peter O'Halloran and team	ACT Health
Anthony O'Neill	ADHA
Michael Osbourne	Mater Hospital, Brisbane
Tony Piazza	Department of Human Services
Shane Porter	Department of Health
Brian Postlethwaite	Telstra Health
Dr Frank Pyefinch	Best Practice
Jarrod Rivers	Medical Objects
Prof Tim Shaw	University of Sydney
Dr Mark Simpson	NSW Health
Shane Solomon	ADHA Project Sponsor
Dr Peter Sprivulus	WA Health
Dr Andrew Staib	Queensland Health
Jason Steen	HL7 Australia
Gary Trytell	Epworth Health
Jessica White and team	Best Practice
Barbara Whitlock	Department of Health
Prof Trish Williams	Flinders University
Phil Woolley	NT Health
Andrew Zander	ADHA

Appendix B Standards Australia's product types (Standards Australia, 2016)

Product Type	Transparency	Consensus	SDAC Approval	Comments
Australian Standard (AS)	High – Public Comment (PC) is required	High – Ballot is required	Yes	See Note 3
Australian Interim Standard (AS (Int))	Medium – Peer Review only (PC not required)	High – Ballot is required	Yes	2 + 2 year life maximum
Australian Technical Specification (SA TS)	Medium – Peer Review only (PC is optional)	Low – Limited peer review	Info only	Used if full Standard cannot be prepared within time constraints
Australian Technical Report (SA TR)	Low – No PC required	Low – Informal endorsement[4] is required	Info only	May include publication of research data. See Note 4
Handbook (SA HB)	AS only: Medium – Peer Review only (PC not required)	Low – Limited peer review	Info only	If the topic is related to a TC the TC is to be part of the peer review group
Miscellaneous Publication (SA MP)	Low – No PC required	Low – Limited peer review	Info only	If the topic is related to a TC the TC is to be part of the peer review group
Ruling (RUL)	Low – No PC required	High – Ballot and Formal endorsement[4] are both required	Yes	To clarify intent or application of a Standard or sections of a Standard in specific instances
Reconfirmation Notice[5]	Medium – Peer Review only (PC not required)	Medium – Formal endorsement[4] is required	Info only	See Notes 3 and 4

Product Type	Transparency	Consensus	SDAC Approval	Comments
Supplement (Normative)	High – PC is required	High – Ballot is required	Yes	See Note 3
Supplement (Informative) Includes commentaries.	Low – No PC required	High – Ballot is required	Yes	Issued with the parent Standard or within 12 months of its publication date
Correction Amendment	Low – No PC required	Medium – Formal endorsement[4] is required	Info only	See Note 2
Revised Text Amendment	High – PC is required	High – Ballot is required	Yes	See Note 2
Australian Standard Certified Reference Material (ASCRM)	N/A	N/A	N/A	Should always be accompanied by an SA TR to provide details of their source, preparation and chemical composition

NOTES:

1. *The processes indicated in the table show minimum levels only. Higher consensus and transparency levels may be required where warranted.*
2. *Amendments may be applied to a Standard, Interim Standard, Supplement, Technical Specification, Technical Report, Miscellaneous Publication and Handbook. Amendments should normally only be issued within 2 years of the initial publication of the product and should not have more than 2 amendments issued for the one document. Amendments to Rulings are not permitted, instead a replacement Ruling is issued.*
3. *Reconfirmation of a Standard or Supplement does not require Public Comment, does require formal endorsement (see below) and is sent to the Standards Development and Accreditation Committee (SDAC) for information only.*
4. *Formal endorsement means that the committee does not undertake a formal Committee Ballot process, but the endorsement with unanimous general agreement is documented, usually in the form of a 'letter of no objection' or minuted agreement at a committee meeting. Informal endorsement means general verbal discussion and direction without documentation.*

Appendix C ONCHIT's maturity levels for interoperability standards (USA)

ONCHIT uses three forms of maturity assessment in its Interoperability Standards Advisory (ISA) processes.

1. Standards Process Maturity

   This characteristic conveys a standard or implementation specification's maturity in terms of its stage within a particular organization's approval/voting process. Its categories are:

   "Final" – when this designation is assigned, the standard or implementation specification is considered "final text" or "normative" by the organization that maintains it. This also includes approved "ANSI Informative" specifications.

   "Balloted Draft" – when this designation is assigned, the standard or implementation specification is considered to be a Draft Standard for Trial Use (DSTU), Standard for Trial Use (STU), or in a "trial implementation" status by the organization that maintains it and has been voted on or approved by its membership as such. This designation does not include standards and implementation guides that are unofficial drafts and early "works in progress".

   "In Development" – when this designation is assigned, the standard or implementation specification is currently in development. It also includes those that are in the midst of being balloted. These standards would generally benefit from lessons learned through development and pilots.

2. Implementation Maturity

   This characteristic conveys a standard or implementation specification's maturity based upon its implementation state. Where available, a link to published maturity assessments based on known published criteria about the standards is also provided.

   "Production" – when this designation is assigned, the standard or implementation specification is being used in production to meet a health care interoperability need.

   "Pilot" – when this designation is assigned, the standard or implementation specification is being used on a limited scale or only as part of pilots to meet a health care interoperability need.

3. Adoption Level

   This characteristic conveys a standard or implementation specification's approximate, average adoption level for that specific interoperability need in health care within the United States. The adoption level attempts to consider all implemented technology that would be used to address the identified interoperability need and is not limited to EHRs. Adoption means that the standard or implementation specification is being used in health IT in the field by end users to address the specific interoperability need. Presently, the adoption levels listed are based on ONC's analysis of several factors, including, but not limited to: 1) whether and/or how long a standard or implementation specification has been included in regulation for health IT certification (if applicable) or another HHS regulatory or

program requirement which is used only as a proxy for industry adoption; 2) feedback from subject matter experts and 3) public comments.

The adoption level also considers the variety of stakeholders and stakeholder groups that would use the standard and implementation specification to address the specified interoperability need and attempts to display it as such, with the understanding that the designation is a generality or "best guess" and not a pre-defined measured value. Where available, annotated references or links to publicly available documentation known about adoption levels for listed standards are also provided.

The following scale is used to indicate the approximate, average adoption level among the stakeholders that would use a standard or implementation specification to meet the specified interoperability need:

"Feedback Requested" – Indicates the status for the current level of adoption in health care is not known.

Rating 1 – Indicates low adoption.

Rating 2 – Indicates low-medium adoption.

Rating 3 – Indicates medium adoption.

Rating 4 – Indicates medium-high adoption.

Rating 5 – Indicates high or widespread adoption.

Appendix D The Office of the National Coordinator for Health Information Technology (ONCHIT) (USA)

ONCHIT is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information. The position of National Coordinator was created in 2004, through an Executive Order, and legislatively mandated in the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009.

ONCHIT promotes the adoption and use of standards. It publishes the Interoperability Standards Advisory (ISA) as a way of recognizing interoperability standards and implementation specifications for industry use to fulfil specific clinical health IT interoperability needs.

The ISA process represents the model by which ONCHIT coordinates the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used to address specific interoperability needs.

The ISA is not exhaustive but is expected to be incrementally updated to include a broader range of health IT interoperability needs. When more than one standard or implementation specification is listed it is intended to prompt industry dialogue as to whether one standard or implementation specification is necessary or if the industry can efficiently interoperate more than one. It may also reflect the fact that there is an ongoing transition from the use of one standard towards a new version or even next-generation approach.

The ISA is meant to serve at least the following purposes:

- To provide the industry with a single, public list of the standards and implementation specifications that can best be used to address specific clinical health information interoperability needs. Currently, the ISA is focused on interoperability for sharing information between entities and not on intra-organizational uses.
- To reflect the results of ongoing dialogue, debate, and consensus among industry stakeholders when more than one standard or implementation specification could be used to address a specific interoperability need, discussion will take place through the ISA public comments process. The web-version of the ISA improves upon existing processes, making comments more transparent, and allowing for threaded discussions to promote further dialogue.
- To document known limitations, preconditions, and dependencies as well as provide suggestions for security best practices in the form of security patterns for referenced standards and implementation specifications when they are used to address a specific clinical health IT interoperability need.

ONCHIT's Tech Lab coordinates interactions with standards development organizations and industry stakeholders and targets priority investments to advance standards development. It also looks to connect new program, policy, and business requirements to technical standards and infrastructure needs.

The Tech lab also supports a collaborative work environment for health IT developers and providers to test tools, test their health IT functionality in the field, and coordinate with leading industry experts on the development of additional testing resources and testing events.

Appendix E The Professional Records Standards Body (PRSB) role in standards (UK)

The PRSB develops and helps to implement standards for the structure and content of health and social care records. These cover, for example, hospital referral letters, handover communications, discharge summaries, and inpatient and outpatient letters.

PRSB Members include:

Academy of Medical Royal Colleges

Allied Health Professionals Scotland

Allied Health Professions Federation

Association of Directors of Adult Social Services

Association of Directors of Children's Services

British Computer Society

British Dietetic Society

British Orthodontics Society

British Psychological Society

Care Provider Alliance

CCIO Network

Chartered Society of Physiotherapy

Community Practitioners and Health Visitors Assoc.

Compassion in Dying

eHealth Ireland

Faculty of Clinical Informatics

Faculty of Public Health

Health and Social Care Alliance Scotland

Institute of Health Records

Intensive Care Society

INTEROPen

National Institute of Health and Care Excellence (NICE)

National Voices

Patient Information Forum

Public Health England

Resuscitation Council (UK)

Royal College of Anaesthetists

Royal College of Emergency Medicine

Royal College of General Practitioners

Royal College of Midwives

Royal College of Nursing

Royal College of Obstetricians & Gynaecologists

Royal College of Occupational Therapists

Royal College of Ophthalmologists

Royal College of Paediatrics and Child Health

Royal College of Pathologists

Royal College of Physicians

Royal College of Psychiatrists

Royal College of Radiologists

Royal College of Speech and Language Therapists

Royal College of Surgeons of England

Royal Pharmaceutical Society

Tech UK

The Queen's Nursing Institute

PRSB standards comprise information headings for clinical and professional records and a description of the information that should be recorded under each heading. These standards for digital care records are intended for use by all health and care organisations, and they support better sharing of information between organisations and individuals.

PRSB:

- Creates expert user groups of all those who need to be involved in defining a record standard for a particular area of care. These would typically include members of the public, carers, patients, organisations that represent their interests, doctors, nurses, social workers and other health professionals.
- Researches literature and current practice and ensure that the standards we define are robust and based on clear evidence of what works best.
- Conducts workshops and national surveys to ensure that all the issues and angles are explored, everybody's voice is heard and the standards are truly representative of the views of people and professionals across the UK.

- Works closely with technical teams and IT system suppliers so that standards are faithfully reflected in implementable systems.
- Undertakes independent assurance and scrutinise work at every stage to ensure standards are fit for purpose and worthy of national endorsement.
- Standards are formally endorsed through sign off by PRSB's Advisory Board and the professional bodies represented on it.
- Standards are kept up to date and reflect current best practice by regularly monitoring, maintaining and updating them.
- Provides responsive support services to receive comments, provide help and answer questions from anyone involved in defining or using the standards.

Appendix F Costings

Costings in support of the recommendations made in this report are as follows.

Health Interoperability Standards Organisation (HISO)

Salaries:

Head of Program	$400,000
Chief Architect	$250,000
Standards Liaison Officer x 2	$350,000
Project Officer x 2	$250,000
Knowledge Manager	$100,000
Communications Officer	$150,000
IT support	$150,000
Administrative support x 2	$150,000
On costs	$360,000
Salaries sub-total	$2,160,000
Operating expenses:	$1,800,000
HISO annual total	**$3,960,000**

Capacity building:

Support for HL7	$850,000
Support for IHE/other integration activities	$200,000
Annual interoperability and standards summit/showcase	$400,000
Capacity building annual sub-total	**$1,450,000**

Annual total (rounded)	**$5,500,000**