



National E-Health Standards Development

A Management Framework

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Executive Summary

This Management Framework has been developed by NEHTA to guide changes in the Australian e-health standards development environment. These changes include the establishment of a new national effort to develop, maintain and disseminate a range of clinical data standards and terminologies. Its purposes are to inform key stakeholders – the suppliers, purchasers and implementers of e-health technologies as well as organisations associated with standardization – and other interested parties about future directions for the development of e-health standards in Australia, and to encourage wider participation.

E-health standards have substantial benefit potential on two fronts. They underpin cross-sectoral health service improvement. Until health information technology (IT) standards are more fully implemented, the health care industry cannot ensure that its systems will be capable of exchanging data with other systems when needed, and consequently will not be able to reap the efficiency, clinical care, and public health benefits associated with interoperability. Standards can also provide a lever for economic development via greater and faster expansion of health software markets.

Standards development organisations (SDOs) worldwide are facing challenges to their traditional modes of operation. They are not restricted to e-health, but are associated with factors such as globalisation, the increasing pace of change and greater use of market mechanisms by governments. These challenges include perceptions that standards development is too slow; over-reliance on “voluntary” involvement from individuals or organisations, and steady, long-term declines in the resourcing provided by governments and large corporations. There are also many different organisations engaged in e-health standardization, and their activities are not always well coordinated. An additional challenge for Australia is that a substantial amount of health software is imported, embodying international standards and potentially requiring expensive modification to meet Australian requirements.

Responses to these changes and challenges in Australia will include:

1. Clarifying the roles and responsibilities of standards development organisations, particularly NEHTA and Standards Australia.

In managing clinical terminologies and clinical data sets for electronic communication nationally, NEHTA is likely to become Australia’s largest source of e-health specifications, and will publish, manage and maintain standards and related material on an ongoing basis. NEHTA will also develop or commission a range of technical specifications and a standards catalogue, the latter providing national direction on standards adoption and application.

Standards Australia will continue to develop health informatics standards through its Health Informatics Technical Committee (IT-014).

2. Establishing an E-Health Standards Forum, involving the participation of peak agencies engaged in standardization, to assist with ensuring a coherent national agenda that spans the public and private health sectors as well as the health information technology industry.
3. For standards required for national e-health infrastructure, encouraging strong adherence to the disciplines of project management and the active engagement of all interested parties, rather than just the more motivated. Closer alignment will also be sought between health IT projects and standards development. This will require suppliers, purchasers and implementers to schedule standards development activities into their work programs, but is nonetheless more efficient and effective than subsequent modification to incorporate standards.
4. Using existing international and national standards where feasible. This means seeking to ensure that Australian requirements are incorporated into high priority international standards, and that the multiple uses of standards e.g., as a basis for administrative reporting and research as well as electronic communication and

decision support, are taken into account during their development. Selecting the most appropriate standards products is also important. Technical specifications and reports based on lower levels of consensus but delivered more rapidly will be appropriate in some circumstances.

5. Resourcing standards development at a level commensurate with expectations.

This document is the first in a series of three outputs that will comprise NEHTA's National E-Health Standards Plan. The others will address the support necessary for implementation of national e-health standards, and provide a catalogue of standards to which public sector and publicly funded health services will be expected to migrate.

Progress towards this Management Framework will commence with:

- Organising the first E-Health Standards Forum;
- Elaborating the arrangements between NEHTA and Standards Australia; and
- Raising awareness amongst key stakeholders (suppliers, purchasers, implementers and SDOs) about standards development and the processes and mechanisms for participation.

Greater standardization is central to Australia's e-health agenda.

1 Introduction

E-Health may be defined as the use of information and communication technologies (ICT) to improve or enable health and healthcare. Australian Governments have collectively established a national e-health agenda, led by the National E-Health Transition Authority (NEHTA).

Standards may be defined as qualities, measures, performance specifications or other attributes of goods or services to which their production and implementation should conform. Their purposes generally include greater safety and reliability, lower costs, economic development and facilitation of trade, and they are generally articulated in published documents.

Standards are necessary for the widespread deployment of e-health capabilities. Without the adoption of common standards, information and communication technologies cannot be integrated to work together and the information and functionalities they provide cannot interoperate at the scale of the entire health sector.

Greater standardization is central to Australia's e-health agenda.

This Management Framework has been developed by NEHTA to guide changes in the Australian e-health standards development environment. These changes include:

- The establishment of a new national effort to develop, maintain and disseminate a range of clinical data standards and terminologies, with the latter linked to a new international standards development organisation, the SNOMED SDO;
- The role of NEHTA in developing technical specifications for inclusion in Government procurement processes, and the likely establishment of a national certification program to encourage conformance with a range of standards and specifications;
- The increasing application to health of information and communication technologies such as service oriented architectures and web services, many of which have been standardized via new industry collaboration rather than traditional standards organisations; and
- The need for NEHTA, which has been established as a transitional agency with a finite lifespan, to build long-term capacities within the sector to sustain ongoing development and maintenance of e-health standards after its objectives are met.

The purposes of this Framework are to inform key stakeholders – suppliers, purchasers and implementers of e-health technologies as well as organisations associated with standardization – and other interested parties about future directions for the development of e-health standards in Australia, and to encourage wider participation in standards development.

This Management Framework has been developed by NEHTA in association with Standards Australia and targeted consultation with a range of stakeholders and e-health standards experts. It describes the roles and functions of Australian e-health standards developers and proposes mechanisms for maintaining coherence between them.

The document is the first of three outputs that comprise the National E-Health Standards Plan, being produced by NEHTA. The other two outputs will address standards implementation support and include a Standards Catalogue. These subsequent papers will be completed during 2006.

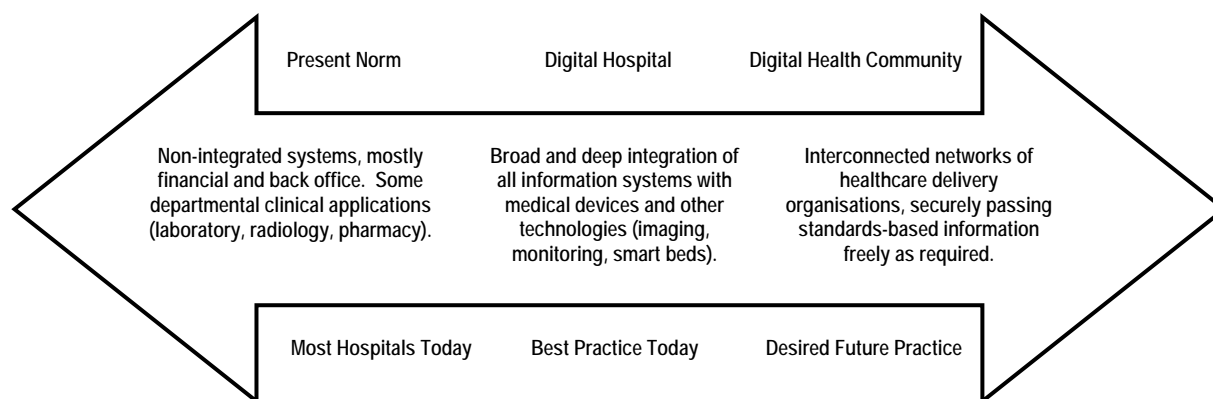
2 The Nature and Importance of Standards

E-health standards have substantial benefit potential on two fronts: to underpin cross-sectoral health service improvement; and as a lever for economic development via greater and faster expansion of health software markets.

2.1 Health Service Improvement

Health service delivery is both information rich and information critical. Modern healthcare is increasingly recognised as an information business as well as a set of services, although investment remains relatively low. PricewaterhouseCoopers (PWC) depict the digital health system continuum¹ as follows.

Figure 1 – The Digital Health System Continuum



It is difficult to envisage how the transformation of the health care system – with higher quality, patient-centric and cost-effective care - could possibly take place without the capacities ICT brings. Health ICT can bind the system together, while preserving its diversity.

The US-based Rand Health, in a comprehensive study of health information technology diffusion, gave strong support for the US National Committee on Vital and Health Statistics finding that “the greatest impediment to the adoption of healthcare information technology is the lack of complete and comprehensive standards for patient medical record information”². The Rand report listed immediate coordination of standards activities as its first (of seven) policy recommendations. The Lewin Group’s Health Information Technology Leadership Panel also noted recently that inadequate standards are a significant inhibitor of health information technology diffusion and benefit realisation³.

¹ PriceWaterhouseCoopers Global Technology Centre, Health Research Institute, March 2005, [Reactive To Adaptive - Transforming Hospitals with Digital Technology](#). While PWC’s context for this diagram was hospitals, it is extensible to the broader health economy.

² Bower, 2005, p.76.

³ The Lewin Group Inc., March 2005, [Health Information Technology Leadership Panel – Final Report](#). (The Leadership Panel was convened by the U.S. National Coordinator for Health Information Technology to evaluate the urgency of investment in Health Information Technology.)

Some efforts have been made to quantify the impacts of standardization in e-health. A study conducted by the Center for Information Technology Leadership (CITL) inferred that interoperability standards could be valued at \$US60billion per year in the USA⁴, and two Australian studies have applied the CITL methodology to the Australian context. Schloeffel estimates the extrapolated annual benefit of interoperability standards in Australia at \$A3.7 billion, representing approximately 5% of total Australian health expenditure⁵, while Sprivulis et al estimate total net savings from the national implementation of fully standardized interoperability for health information exchange transactions in which Australian Governments have a financial interest at over \$2 billion annually or 4.1% of the expenditure by Australian Governments on healthcare⁶.

These study findings align with decisions in many countries⁷, and in other industries/sectors, that greater standardization is a prerequisite to unlocking service and productivity improvements. As articulated by the US Government Accountability Office:

“... much work remains to reach further consensus on the definition and use of standards. Until this successfully occurs and health IT standards are more fully implemented, ... agencies and others throughout the health care industry cannot ensure that their systems will be capable of exchanging data with other systems when needed, and consequently will not be able to reap the cost, clinical care, and public health benefits associated with interoperability.”⁸

2.2 Trade

A variety of economic analyses in relation to international trade have suggested that substantial economic benefits can flow from standardization via the expansion and faster growth of markets. The World Trade Report, 2005⁹ notes:

- That when network externalities are large i.e., when the benefits from collective action are greater than those from private action, as is the case in e-health (see footnote¹⁰) there are benefits to standardization and the adoption of standards facilitates market expansion;

⁴ HIMSS Standards Insight, 2004, HIMSS 2004: Interoperability And The \$87 Billion Question, Health Information and Management Systems Society.

⁵ Schloeffel, P., 13 July 2005, The Value Of Standards-Based Semantic Interoperability Of Healthcare Information In Australia, Ocean Informatics, Australia.

⁶ Sprivulis, P., Walker, J., Johnston, D., Pan, E., Adler-Milstein, J., Middleton, B., Bates, D.W., 2005, Australia Needs A National Health Information Nomenclature, Center for Information Technology Leadership.

⁷ For example, the US Department of Health and Human Services “is focusing on several key actions: harmonizing health information standards; certifying health IT products to assure consistency with standards; addressing variations in privacy and security policies that can hinder interoperability; and, developing an architecture for nationwide sharing of electronic health information. HHS has allocated \$86.5 million to achieve these and other goals in FY 2005 and has requested \$125 million in FY 2006.” Brailer, D.J., June 2005, Activities of the Office of the National Coordinator For Health Information Technology, Testimony before the Committee on Commerce, Science and Transportation Subcommittee on Technology, Innovation and Competitiveness, United States Senate.

⁸ Powner, D.A., September 2005, Health Care: Continued Leadership Needed To Define and Implement Information Technology Standards, United States Government Accountability Office, Testimony before the Committee on Government Reform, House of Representatives, Preface.

⁹ World Trade Report, 2005, Trade, Standards and the WTO, World Trade Organisation.

¹⁰ In economic theory, network externalities arise when the marginal social (collective) benefit exceeds the marginal private benefit. They may be direct or indirect. A telephone network is a direct example – its value increases as the number of people joined in increases. Computers are an indirect example – their value increases as the range and quality of complementary or substitutable goods e.g., software, peripherals, increases. In health, it may be very costly for individuals to join an e-health network, and the benefits will remain limited until a critical mass of participants are joined in. At this stage, joining in also brings little in the way of complementary services or substitutability. The private benefits are relatively low compared to the costs. But the collective, social benefits are potentially huge if critical mass can be achieved.

- A recent study attributing one percent of Germany's GDP and one third of its economic growth over the period 1960-96 to standards – "Standards are at least as important as patents for growth"¹¹;
- A range of studies suggesting that standardization does not significantly increase costs, though the impact will differ between suppliers;
- That while the empirical literature is still limited, the adoption of standards, even national ones, can increase international trade; and
- When network externalities are involved, markets will tend to oversupply variety and the case for international standards is much stronger.

The 2003 *Enabling Our Future*¹² report notes that:

- Countries like Australia may have much greater opportunities to grow new internationally-competitive companies in areas of ICT based on new technologies where standards are evolving (such as in e-health);
- Componentisation of service delivery will provide an opportunity for the creation of the 'off-the-shelf' networked components capable of easy amalgamation, and Australia has strengths in specialist areas including health applications; and
- Longer-term strategic advantage can accrue to firms, sectors and nations from early engagement in standards-setting activities for new technologies.

In this context, Austrade has noted that the highest rates of growth in internet usage are expected to occur in developing Asian countries, providing a relatively optimistic picture for Australian exporters in Asia¹³. Asia Pacific Economic Cooperation (APEC) has recently established an e-health initiative, of which standardization is a central platform, for both health service improvement and economic development reasons.

In summary, there are potentially significant economic development advantages from standardization in e-health.

2.3 Stakeholders

The key stakeholders in relation to this Framework are health software suppliers, purchasers and implementers; and standards development organisations. Greater standardization in e-health offers the following opportunities and challenges to each group:

1. For suppliers

*"...the existence and use of standards makes it easier to produce, sell and buy products and services. Standards enable a market. They are part of the infrastructure for innovation-led growth."*¹⁴

Benefits of standardization for suppliers include:

- Greater market certainty, which translates to lower business risk and cost
- Greater uniformity of purchaser requirements, which translates to lower supply costs;
- A basis for certification – a marketable asset;
- Simpler and more rapid procurement processes; and

¹¹ World Trade Report, 2005, p. 41.

¹² Report of the Framework for the Future Steering Committee to the Minister for Communications, Information Technology and the Arts, April 2003, [Enabling Our Future, A Framework for the Information and Communications Technology Industry](#).

¹³ Harcourt, T., August 1999, [Wiring Australian Exporters To The Information Age](#), Austrade presentation to the Research Institute for Asia and the Pacific (RIAP), University of Sydney, August 1999 (accessed at www.austrade.gov.au/corporate/layout/0,,0_S1-1_CORPXID0029-2_-3_PWB1180908-4_-5_-6_-7_,00.html)

¹⁴ Swann, G.M.P., 2000, [The Economics of Standardization](#), Final report for Standards and Technical Regulations Directorate, U.K. Department of Trade and Industry, University of Manchester, p. 23.

- The prospect of growth in export markets, particularly within the Asia-Pacific region.

For some, the selection of specific standards will mean that their existing or planned technology strategies are out of step, and realignment may be costly as has been the case in other areas of microeconomic reform.

2. For purchasers and implementers:

- More rapid and cheaper procurement, by being able to reference standards requirements rather than develop them anew;
- Improved bases for assessing the conformance of product offerings;
- Improved confidence that purchased software will meet interoperability specifications; and
- Greater potential to avoid vendor “lock-in”.

Challenges for purchasers and implementers are likely to include sustaining commitment to standardize within a sector characterised by fragmentation, meeting the initial costs of standards implementation and managing change – in particular in work practices and business processes.

3. For standards developers:

- Greater role clarity upon which to develop sustainable business models; and
- A higher profile within the sector.

Challenges to standards developers are likely to include process improvements that ensure responsiveness to the sector’s needs; harmonising work programs and managing the potential for territoriality; and targeting the application of limited standards development expertise.

Ultimately, health service users and providers at large will also benefit through more available, better quality and more productive health service delivery.

2.4 Current Challenges in Standards Development

Standards development organisations worldwide are facing challenges to their traditional modes of operation. These are not restricted to e-health, but are associated with factors such as globalisation, the increasing pace of change and greater use of market mechanisms by governments. These challenges to traditional standards development include:

- Perceptions that standards development is too slow and the processes employed are too complex to encourage greater participation;
- Over-reliance on “voluntary” involvement from individuals or organisations, often at their own expense, and the associated risk that ability/willingness to pay may be a poor proxy for ability to contribute;
- Steady, long-term declines in the resourcing provided by governments and large corporations;
- Greater competition from industry collaborations and between standards organisations that rely on revenue from the sale of standards;
- Separation of standards development from implementation, generating the risk that development can be overly academic and lack market feedback; and
- Lack of infrastructure for managing compliance.

These challenges are faced by standards organisations worldwide and across all sectors of the economy. They are also specifically faced by NEHTA and Standards Australia.

Additional challenges in the e-health arena include:

- The fusion of technologies e.g., mobile telephony, the internet, medical devices and computers, each founded upon their own base of standards, now requiring harmonisation; and
- Often dissociated processes for data standardization for aggregation (reporting) and for clinical decision making and communication purposes.

3 Guidance for E-Health Standards Development in Australia

3.1 Types of Standards

Standards can be classified by the way in which they are created:

- *Proprietary standards* sometimes emerge when a single vendor controls a large share of the market for a particular item e.g., the Windows operating system for personal computers.
- *Consensus standards* are developed by expert representatives of those with a stake in the outcome, who have arrived at a general agreement for a consistent approach. Representation should include vendors, health professionals, consumers, government and other interested parties who choose to participate in writing and agreeing on standards. Such standards are sometimes called *open standards*.

Consensus standards uniquely and importantly promote competition and innovation.

Consensus standards are strongly preferred to underpin national e-health capabilities.

3.2 Guiding Principles

The following principles are proposed to guide standards development for e-health in Australia.

1. Development of standards, technical specifications and supporting materials designed to support national e-health capabilities will be based on and compliant with the WTO Code of Good Practice for the Preparation, Adoption and Application of Standards.
2. Open (consensus) standards will be supported in preference to proprietary ones, and international standards adopted where feasible.
3. Leadership, direction setting, planning and coordination of standards development activities will be collaborative across the sector. The aim is to ensure a high level of coherence and consistency in approach, eliminate duplication and wasted effort, and encourage wide participation in standards development and subsequent implementation.
4. Standards development will be tightly coupled with and validated through working implementations, and where possible will be developed in association with system development and/or implementation initiatives.
5. Standards development will:
 - commence with the preparation of formal requirements specifications¹⁵ and a comprehensive scan for existing candidate standards;

¹⁵ While it may be argued that this will slow standards development, good practice in design and development generally demonstrates that basing development on a clear and widely accepted understanding of requirements is likely to decrease development time overall, and does not preclude the use of fast-track processes.

- be cognisant of both industry development and health service delivery opportunities;
 - comprise specifications; guidance on technical, human behavioural and organisational implementation; and conformance protocols;
 - be designed for re-use wherever possible; and
 - be geared to minimising the costs of compliance while meeting the specified requirements.
6. Assessment of the impacts of standardization in e-health should be undertaken and should incorporate review of standards development processes so as to drive quality improvement.

Key elements of these principles are detailed below.

3.2.1 Code of Good Practice

Standards development in e-health occurs within wider economic, social and legal frameworks. A Code of Good Practice for the Preparation, Adoption and Application of Standards is annexed to the World Trade Organization (WTO) Agreement on Technical Barriers to Trade. Australia is a signatory to this Agreement and its companion document, the WTO Agreement on Government Procurement. These Agreements require the Australian Government to encourage other Government and non-Government standardization bodies to comply with the Code of Good Practice.

Key elements of the Code of Good Practice include:

- Transparency, including publishing the work program; and enabling all stakeholders to access and comment on standards developed – including via public comment periods of at least 60 days¹⁶;
- Making “every effort” to achieve consensus, including clear processes for reconciling comments received;
- Coordination/harmonisation of the work of national standardization bodies, to avoid duplication or conflict;
- Use of international standards, where they exist or their completion is imminent, in preference to local developments;
- Participating in the development of international standards, and not duplicating the work of other standards agencies;
- Focusing on specification of requirements based on performance rather than design or descriptive characteristics¹⁷; and
- Prompt publication of and non-discriminatory charging for standards.

The Agreement on Technical Barriers to Trade requires WTO Members to use relevant international standards rather than developed local alternatives unless these are demonstrated to be inappropriate in the proposed context¹⁸. In that case, the local alternative should document the reasons for inappropriateness. This requirement is mirrored in the Agreement on Government Procurement¹⁹.

¹⁶ Unless there are compelling reasons for a shorter period e.g., public safety.

¹⁷ For example, a fire-resistant door must have a minimum burn-through time, rather than be made of certain materials or be of minimum thickness.

¹⁸ “Where technical regulations are required and relevant international standards exist or their completion is imminent, (WTO) Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.” (Agreement on Technical Barriers to Trade, World Trade Organisation, Article I, Clause 2.4.)

¹⁹ “Technical specifications prescribed by procuring (Government) entities shall, where appropriate ... be based on international standards, where such exist”. (Agreement on Government Procurement, World Trade Organisation, Article VI, Clause 2). “Appropriate” has the same meaning as in the previous footnote.

3.2.2 Consensus

Developing consensus standards is an inherently complex process. Interested parties need to become aware of a Standard under development, understand its contents, explore the potential consequences and provide reasoned feedback. There may be considerable negotiation between the stakeholders when striking a balance between competing factors.

Thus although there are ways to accelerate the development of standards²⁰, there are natural limits associated with the processes of transparency and consensus. It should be noted, however, that this is quite analogous to policy, strategy or system development processes, where good practice during the requirement analysis and development phases can circumvent much more time consuming and costly implementation issues.

Means of accelerating standards development in a consensus environment include sponsorship of the development process or targeted components of it e.g. initial drafting, consultation, enabling full-time resources to be deployed rather than the more usual volunteer-based, part-time efforts²¹. NEHTA is an example of this approach, by providing full-time resources to priority areas.

Further means of accelerating standards development include:

- Interim Standards, which are sometimes prepared where there are still some issues to be decided or where national consensus has yet to be achieved. They provide both a guide to the direction that future standardization may take, and a mechanism to collect public feedback on the subject;
- Technical Specifications, which are normative²² documents that do not have full consensus. They may be prepared where the subject matter is undergoing rapid technical development and speed of delivery, rather than full consensus, is of paramount importance;
- Technical Reports, Handbooks, Rulings and Interpretations and other miscellaneous publications are informative documents that contain supplementary information.

The speed of standards development is not universally accepted as problematic, however. Swann, in a work on the economics of standardization produced for the British Department of Trade and Industry, notes that:

“When the rate of change is rapid, producers need standards quickly, but customers need the confidence offered by high quality standardization. What appears to be undue slowness on the part of standards institutions could equally well be re-interpreted as excess haste by those who would set standards. There is a mismatch between the rate of innovation, the requirements for rapid standardization on the part of suppliers and the need for quality standardization on the part of empowered customers. Speeding up the standardization process is not necessarily the right answer to this mismatch.”²³

²⁰ The processes of developing standards broadly fall into six phases – identification of requirement; inclusion in a work program; development of a draft for public comment; public comment and reconciliation of comments; formal ballot; and preparation for publication. Lifecycle maintenance and management form a seventh, post-development phase.

²¹ Sponsorship was used to great effect by HL7 in the United States in the development of the EHR System Functional Model and Specification in 2003/04. The sponsors/funders for this project were the US Department of Health & Human Services (DHHS), the Veterans Administration (VA), and a private philanthropic organisation. This approach not only resulted in a greatly reduced development time, it also had the largest expert volunteer participation and the largest ballot response of any standard in the history of HL7. Other high priority e-health standards projects within HL7 have subsequently received funding from a variety of US government agencies.

²² That is, giving directives or rules. Normative documents are characterized by words such as “shall” or “must” rather than “should” or “may”. Note, however, that compliance with Australian Standards is voluntary unless invoked via statute or contract. Accordingly, compliance with a normative but voluntary standard could be stated as “if you are going to comply with this standard, you shall ...”

²³ Swann, 2000, p. v.

3.2.3 Collaboration

E-health standards development is characterised by:

- A variety of standards development organisations (SDOs)²⁴, nationally and internationally, with differing business models, membership and capabilities producing standards and specifications that must integrate, interoperate or be rationalised. This is compounded by the fusion of computing and other technologies - e.g. mobile telephony, the internet, and medical devices - each bringing with them existing standards that must also be harmonised. The majority of these standards development organisations are non-Government, not for profit, and they are funded from a variety of sources;
- Standards developers traditionally consist of those individuals or organisations that have available time, resources and interest and developer committees and groups are surrounded by a large number of interested parties with few systematic means of engaging them productively;
- A plethora of stakeholder objectives and interests, generally not well articulated and in some cases not explicitly acknowledged, including health service improvement, industry development, market positioning and academic research; and
- Processes and systems that are complex and difficult to engage without considerable persistence, notwithstanding principles of transparency, and widespread perceptions of structural disconnection between project-based health IT initiatives and standardization efforts.

Currently, there is no forum through which e-health standards developers and other key stakeholders share information about their activities. NEHTA has been working closely with Standards Australia to enhance its capacity to meet national e-health needs. However, there are multiple SDOs relevant to e-health, and bi-lateral approaches to coordination are inherently limited.

Accordingly, an E-Health Standards Forum will be organised to facilitate information exchange amongst relevant standards development organisations. Standards Australia's facilitation processes and its access to broad health and ICT sector representation positions it to host such a Forum.

This Forum will involve participation of groups such as NEHTA, IT-014, the Health Data Standards Committee, Statistical Information Management Committee, HL7 Australia and health information technology industry. The Forum will provide a focussing mechanism via which national e-health priorities articulated via NEHTA can be translated into the annual work programs and priorities of a variety of standards development organisations and their efforts mobilised.

The E-Health Standards Forum in 2006 will be funded via the NEHTA Work Program as an investment by Australian Governments supporting the centrality of standardization to the national e-health agenda.

NEHTA's aim for the Forum is to assist the delivery of national e-health priorities as articulated by Australian Governments and contribute to identifying the standards development needs arising; and to encourage coordination on standards on a multi-lateral basis.

3.2.4 NEHTA's Involvement in Standards Development

NEHTA recognises Standards Australia's unique role in standards development in Australia and will collaborate with Standards Australia in the following ways to ensure a comprehensive, coherent and navigable e-health standards development program for Australia:

²⁴ refer to Appendix 1 for those of significance to e-health in Australia

1. Clinical Terminologies developed and contextualised by NEHTA are expected to be published and through the SNOMED Standards Development Organisation. It is currently anticipated that clinical data standards developed by NEHTA will be published as Australian Standards.
2. NEHTA will also produce a standards catalogue, providing guidance as to which standards should be used in the e-health domain.
3. NEHTA may also, from time to time, produce or commission other technical specifications. These may also be published via Standards Australia as lower level consensus documents following their fast tracked development. IT-014 will then assume responsibility for the ongoing maintenance and lifecycle management for those specifications that are published formally as Australian Standards. Harmonisation with existing standards will be undertaken where feasible, and any differences between NEHTA's technical specifications and existing standards will be documented in the published specifications, along with their rationale and a summary of the expected implications, in order to minimise market uncertainty.
4. NEHTA's other major role is to develop design specifications for national services such as individual and health provider identification services and health-related product catalogues. As far as possible these designs will adopt international and Australian standards. Both as a major user of standards and an agent for Australian Governments, NEHTA will provide feedback to standards developers on any perceived issues with existing and proposed standards from an implementation perspective so as to enable the enhancement of those standards for the benefit of all stakeholders. NEHTA will also identify areas where additional standards and specifications are required and, where appropriate, act as a lead agency for their development in accordance with the Guiding Principles above.

3.2.5 Quality

Standardization is a cyclical process that must incorporate continuous quality improvement. A systematic approach and consistent, widespread commitment are required to deliver benefits. Key result areas for effective standardization generally include:

1. Clear and well communicated national agreement on e-health implementation priorities;
2. Timely, efficient and sustainable standards development processes, including clear articulation of requirements;
3. Consistent and coherent policy settings driving the uptake of national e-health standards i.e., agendas must be aligned to ensure that intentions are clear and unambiguous, and the incentives to standardize outweigh the disincentives;
4. Capacity and leadership within the health sector to support standardization;
5. Conformance assessment and certification;
6. Impact assessment and feedback; and
7. Effective governance.

Critical success factors for the achievement of desired results in these key areas will include:

- Consistent and concerted leadership from people who make decisions about the availability, acquisition and deployment of health information systems and standards across the sector;
- Availability of resources for standardization, including economic, human, and knowledge;
- Communication and feedback between standards organisations and other stakeholders.

3.3 Compliance

NEHTA's role includes the development of specifications for inclusion in Government and potentially other health sector procurement processes. These specifications will be technical in nature, normative, and incorporated into commercial contracts.

On their own standards or technical specifications have no legal status and are free to be followed or not by manufacturers, consumers or the public. However, if a Standard or specification is referenced in legislation or written into a commercial contract it becomes enforceable by virtue of that legislation or contract. When this happens, Standards become mandatory and their reasonableness, quality and impact can be subject to the scrutiny of the courts. Accordingly, standards development organisations make every attempt to ensure that the principles and processes used to develop standards are based on good practice.

In respect of "specifications" such as those produced by NEHTA, the WTO Agreement on Government Procurement states that:

"Technical specifications prescribed by procuring entities shall, where appropriate:
(a) be in terms of performance rather than design or descriptive characteristics; and
*(b) be based on international standards, where such exist; otherwise, on national technical regulations, recognized national standards, or building codes."*²⁵

Further to this the Council of Australian Governments (COAG) recently committed to:

*"promoting compliance with nationally-agreed standards in future government procurement related to electronic health systems and in areas of healthcare receiving government funding."*²⁶

²⁵ Agreement on Government Procurement, World Trade Organisation, Article VI, Clauses 1 and 2.

²⁶ Council of Australian Governments' Meeting, 10 February 2006, Attachment D, Better Health For All Australians: Action Plan.

4 Next Steps

Implementation of the proposed Management Framework will require:

- Organising the E-Health Standards Forum;
- Developing and documenting an Agreement between NEHTA and Standards Australia concerning the publication, maintenance and management of technical specifications and other NEHTA products, and their public availability. Supporting processes will also need to be developed and documented;
- Raising awareness amongst key stakeholders (suppliers, purchasers, implementers and SDOs) about standards development and the processes and mechanisms for participation, including the development of targeted resource materials; and
- Ongoing monitoring and assessment of the level of resourcing for national e-health standards development.

Appendix 1: Standards Organisations

A variety of organisations develop standards or specifications that have application to e-health in Australia.

NEHTA

NEHTA Limited is a not-for-profit company established by the Australian Federal, State and Territory governments in July 2005 to develop better ways of electronically collecting and securely exchanging health information.

A key task of NEHTA is to establish the fundamental standards necessary to progress e-health. These standards will need to be adopted by software developers in their e-health products, so that the promise of e-health can be delivered on a national scale. NEHTA will assist the adoption of NEHTA specifications and standards to which public sector and publicly-funded health services will be expected to migrate.

NEHTA's role in standardization to date has been primarily as a catalyst, stimulating the development and implementation of standards required to enable electronic communication across the health sector in areas designated as national priorities by Australian Governments. However, NEHTA's work program comprises a series of deliverables that will contribute more directly to standards development over the next two years. Its roles in standards development may be categorised as below.

Development of Clinical Terminology and Data Standards

Based on NEHTA's recommendation, the Australian Health Ministers' Advisory Council (AHMAC) has determined that the SNOMED Clinical Terminology (SNOMED CT) is the preferred national terminology for Australia. The Council of Australian Governments decision on 10 February 2006 committed Australia's healthcare system to adopt SNOMED CT, and provided \$32 million towards Australia's management of SNOMED, including its ongoing development and maintenance, contextualisation and mapping to the Australian family of classifications. This work will initially be undertaken by NEHTA.

Internationally, a new SNOMED Standards Development Organisation (SNOMED SDO) has been established to manage SNOMED CT. The SNOMED SDO will be responsible for SNOMED's international governance, maintenance, licensing and distribution.

Australia is committed to becoming a Charter Member of the SNOMED SDO and will be represented on the SNOMED SDO Management Board. It should be noted that the detailed operational model for the SNOMED SDO has not yet been fully specified, and neither has the modus operandi for its relationships with other global standards development organisations. Clarification of these arrangements is a high priority for NEHTA.

NEHTA will also retain ongoing responsibility for the development of data standards for the purposes of clinical communication – an extension of the current Clinical Information Initiative. These two areas of health concept representation (terminology and content) are closely linked.

Development and Endorsement of other Standards

In other high priority areas such as secure messaging, NEHTA will identify specific standards or specifications to be included in public sector and public sector-funded ICT acquisition processes. In some cases, NEHTA will nominate existing standards or specifications, and in other cases it will develop or commission specifications.

NEHTA will also produce a Standards Catalogue describing which standards are available and endorsed for implementation in the Australian e-health sector.

Development and Implementation of National Directories

NEHTA is currently designing national directories to identify recipients of health services, health service providers and products used in delivering care, within Australia.

In this area of responsibility, NEHTA will primarily be a standards “taker”, using existing national and international standards to the maximum extent possible. As with other major users, NEHTA will engage with standards developers to ensure that relevant standards are cognisant of and responsive to its needs and will seek consensus solutions to accommodating disparate needs.

Prioritising and Catalysing Standards Development

This role includes articulating health ICT infrastructure priorities for publicly operated and funded health services; identifying the standards required to support them; and advising Australian Governments and other key stakeholders on their development and implementation. It also includes providing direction and leadership in migration to new standards; and encouraging coherence between standards developers, suppliers, purchasers and implementers.

Standards Australia

Standards Australia is recognised by the Australian Government as the peak, non-government standards body in Australia. It develops and maintains more than 7000 Australian Standards and related publications which are prepared by 1700 committees, involving more than 9000 committee members who span all sectors of the economy. These documents, used in countless daily business transactions, facilitate communication and trade between individuals, corporations and nations.

Standards Australia ensures the effective development of standards and recognition of other standardization bodies by providing an active forum for discussion, debate and consensus-building. It uses a facilitation process based on transparency, consensus and stakeholder representation from interest groups including governments, industry bodies, trade and professional associations, academia and consumer groups.

Standards Australia is Australia’s representative on the International Organization for Standardization [ISO], the International Electrotechnical Commission [IEC], and the Pacific Area Standards Congress [PASC].

Standards Australia is currently upgrading its roles and responsibilities in some areas to a more contemporary model of operation emphasising coordination and orchestration, and accreditation and facilitation of issue resolution rather than solely standards development.

Health Informatics Technical Committee (IT-014)

Established in 1995, IT-014 had published 34 Australian Standards and related documents to the end of 2005, and another 15 are currently in preparation for publication by the end of 2006. These include publications on health concept representation, electronic health records, security, messaging and communication and supply chain. IT-014’s annual work program has been part-funded by the Australian Government Department of Health and Ageing since 1999. In addition to publishing within Australia, IT-014 has strongly contributed to the development of health informatics standards in international fora where this has represented the most appropriate sphere of influence. In particular, IT-014 has played a leading role in the development of electronic health record standards in CEN (the European standards organisation) and ISO; and in EHR, patient administration, pathology and patient care messaging within HL7. The key objective of this involvement is to ensure that global

standards meet Australian needs and are consistent with Australian Standards, facilitating the use of imported software and the entry of Australian companies into global markets.

IT-014 comprises a widely representative group of over 40 members, including public and private sector health service providers, vendors, professional colleges and academics. It is currently supported by 15 active sub-committees and working groups (see below). In addition, a Genomics interest group has been formed to explore the need for and potential of informatics standards specific to this specialty area.

Standards Accreditation Board

The Standards Accreditation Board is an independent Board reporting to the Council of Standards Australia, with the role of accrediting Standards Development Organisations that wish to develop a Standard(s) to be published as an Australian Standard.

The Standards Accreditation Board was established following a recommendation of the Kean Report on Australia's Technical Infrastructure²⁷. The Australian Communications Industry Forum (ACIF) and the Australian Forestry Standard Ltd are examples of currently accredited standards development organisations.

The accreditation process determines the competency of an organisation to develop Australian Standards. While the organisation may use procedures not necessarily identical to Standards Australia's, it must ensure transparency and openness commensurate with good practice. This applies particularly to the manner in which decisions are reached.

The approval of Standards to be published as Australian Standards is the prerogative of Standards Australia and is normally exercised by the Standards Policy Boards. However, where a Standards Development Organisation has an equivalent balanced policy oversight structure, responsibility for process approval, as arranged by the Standards Accreditation Board, may be assigned as a part of the accreditation process.

The best known example of this model operating in the health domain is Health Level Seven (HL7), which is described below. HL7 is a US-based health informatics standards developer, which is accredited by the American National Standards Institute (the US equivalent of the Standards Accreditation Board). HL7 standards are published as Approved ANSI Standards.

Access to Standards and related publications

Since 2004, Australian health informatics Standards and related publications published by Standards Australia²⁸ have been made available free of charge in electronic format via block funding from the Department of Health and Ageing. This strategy aims to promote wide accessibility to e-health standards, akin to the arrangements being pursued for national health terminologies. It is envisaged that this model will continue for the foreseeable future.

²⁷ Kean, B., 1995, [Linking Industry Globally](#), Report of the Committee of Inquiry into the Standards and Conformance Infrastructure of Australia.

²⁸ With the exception of direct text adoption of standards for which the copyright is owned by other standards development organisations.

Health Data Standards Committee and Statistical Information Management Committee

The Health Data Standards Committee (HDSC) is a standing committee of the National Health Information Group - a body established by the Australian Health Ministers Advisory Council to oversee development of health data standards for the purposes of administrative reporting and research in the health sector. All data element definitions to be included in the National Health Data Dictionary (NHDD) require approval by the Health Data Standards Committee and endorsement by the National Health Information Group. The Secretariat for the HDSC is provided by the Australian Institute of Health and Welfare (AIHW) - Australia's national agency for health and welfare statistics.

The Statistical Information Management Committee (SIMC) advises NHIG on national health statistics, in particular on data collection, storage, linkage and usage and national minimum data sets. The SIMC also develops national health information development plans; oversees the direction development, review and implementation of the National Health Information Agreement; and oversees METeOR, Australia's Health and Community Services Data Register (the electronic version of the National Health Data Dictionary).

Interactions with other SDOs

Data standards for clinical communication and related operational purposes will be within NEHTA's sphere of responsibility, while clinical data standards for administrative reporting and research are HDSC/SIMC responsibilities. However, some data are used for both clinical communication and reporting purposes – in fact good information management principles suggest that statistical data should be derived from operational sources as far as possible. This overlap of responsibilities must be closely monitored to ensure health information systems in practice are to support both sets of purposes,

ISO and IEC

ISO (International Organization for Standardization) is the world's largest developer of standards. ISO is a network of the national standards institutes of 156 countries, on the basis of one member per country, with a central secretariat in Geneva, Switzerland that coordinates the system.

Since 1947 ISO has published more than 15,000 International Standards. Its work program ranges from standards for traditional activities, such as agriculture and construction, through mechanical engineering, to medical devices, information technology developments and quality management systems. ISO collaborates with the United Nations Organization and its specialised agencies and commissions, particularly those involved in the harmonisation of regulations and public policies, including the World Health Organization (WHO), in respect of health technologies.

ISO's Health Informatics Technical Committee (TC-215) has published standards on health concept representation, electronic health records, security, messaging and communication and health (smart) cards. ISO TC215 has eight expert Working Groups - see below.

Australia currently chairs and through Standards Australia provides secretariat services for TC215's Working Group on Business Requirements for Electronic Health Records, and has taken a leading role in the development of a range of standards relevant to the national e-health agenda²⁹.

²⁹ Examples include the development of ISO Standards and/or related publications on the Identification of Subjects of Care and Health Service Providers, Requirements for Electronic Health Record Architecture, and Definition, Scope and Context for Electronic Health Records.

ISO TC215's strategic directions include greater emphasis on identifying business requirements for standards and collaboration with other SDOs. ISO has in place memoranda of understanding with CEN and HL7 that facilitate fast-tracking of their respective standards into ISO.

In the ICT arena, the International Electrotechnical Commission (IEC), one of the world's longest standing standards bodies with national membership focussed on industry suppliers, works closely with ISO through Joint Technical Committee 1 (JTC1). JTC1 is responsible for many commonly accepted coding, programming, database and data management standards.

HL7 and HL7 Australia

Health Level Seven (HL7.org) is one of several American National Standards Institute (ANSI)-accredited Standards Developing Organisations (SDOs) operating in the healthcare arena. Most SDOs produce standards (sometimes called specifications or protocols) for a particular healthcare domain such as pharmacy, medical devices, imaging or insurance (claim processing) transactions. HL7's domain is clinical and administrative data.

Health Level Seven is a not-for-profit volunteer organisation. Its members - providers, vendors, payers, consultants, government groups and others who have an interest in the development and advancement of clinical and administrative standards for healthcare - develop the standards. Like all ANSI-accredited SDOs, HL7 adheres to a well-defined set of operating procedures that ensures consensus, openness and balance of interest.

HL7 operates over 50 Technical Committees and Special Interest Groups. Australian standards representatives currently Co-Chair or facilitate a range of Technical Committees and Special Interest Groups of particular importance to the national e-health agenda, including Patient Administration, Patient Care, Community Based Health Services and Templates.

HL7 collaborates with a range of other standards development organisations via memoranda of understanding and commercial arrangements.

HL7 Australia is a separately incorporated Australian body established to perform the role of the HL7 Affiliate organisation in Australia. Its role since its inception in 2002 has been to support the Australian HL7 user community by developing skills and knowledge exchange amongst its members and the wider informatics community, and promoting HL7 standards. As the contracted Australian HL7 Affiliate, HL7 Australia is contractually responsible for localisations of HL7 property and property rights within Australia. However, HL7 implementation guides for Australia are developed by IT-014, under a Memorandum of Understanding between HL7 Australia and Standards Australia.

The European Committee for Standardization

CEN, the European Committee for Standardization, was founded in 1961 by the national standards bodies in the European Economic Community and EFTA countries, and currently has 28 member countries. CEN is in effect a regional equivalent of ISO, but there are requirements for European Union countries to utilise CEN standards where they exist. Accordingly, Australian software developers targeting European markets need to be aware of CEN standards and Australian importers of European software will be better positioned if Australian requirements are reflected in CEN standards.

For these reasons, and because there are particular compatibilities between the business problems faced by European countries and Australian jurisdictions in respect of electronic health records, Standards Australia has worked closely with CEN in recent years on the development of EHR-related standards.

Like other standards organisations, CEN has a large number of Technical Committees. Its Health Informatics Technical committee is TC251.

Collaborations for Standardisation

There are several collaborations via which members jointly develop standardized specifications for the ICT industry. Those of particular relevance to e-health include:

- The *World Wide Web Consortium (W3C)*. W3C Members include vendors of technology products and services, web content providers, corporate users, research laboratories, standards bodies, and governments, all of whom work to reach consensus on a direction for the Web. Adoption of W3C standards and reliance of global commerce and information exchange upon W3C Web standards continue to grow. The Semantic Web for Health Care and Life Sciences Interest Group (HCLSIG) is chartered to develop and support the use of Semantic Web technologies and practices to improve collaboration, research and development, and innovation adoption in the of Health Care and Life Science domains.
- The *Web Services Interoperability Organization (WS-I)* aims to promote Web services interoperability across platforms, operating systems and programming languages. WS-I creates, promotes and supports generic protocols for the interoperable exchange of messages between Web services. In this context, "generic protocols" are protocols that are independent of any action indicated by a message, other than those actions necessary for its secure, reliable and efficient delivery; and "interoperable" means suitable for multiple operating systems and multiple programming languages.
- *OASIS* (Organization for the Advancement of Structured Information Standards) strives for the development, convergence, and adoption of e-business standards. OASIS has an International Health Continuum Technical Committee - a "forum for companies on the Healthcare continuum internationally to voice their needs and requirements with respect to XML and Web Services". The committee's work will include the use of OASIS and other standards (both healthcare and non-healthcare related) for interoperability utilising web services as practical.
- The *Object Management Group (OMG)* produces and maintains computer industry specifications for interoperable enterprise applications. OMG has a Healthcare Domain Task Force that aims to utilise the OMG technology adoption processes to standardize interfaces for healthcare objects. OMG and HL7 are currently collaborating on a project to develop a range of common service specifications for health.
- The *Institute of Electrical and Electronics Engineers (IEEE)* has recently formed a consortium with the American Medical Association and others to progress e-health standards. In the e-health arena, IEEE is mainly concerned with standards for medical device communications.

Other

A range of other organisations are also associated with standardization in aspects of e-health, including Digital Imaging and Communications in Medicine (DICOM), Integrating the Healthcare Enterprise (IHE), the American Society for Testing and Materials (ASTM). In general, these organisations address specific health sub-domains.

Standards Australia's and ISO's Health Informatics Technical Committees

Standards Australia's Health Informatics Committees

IT-014:	Health Informatics
IT-014-02:	Health Concept Representation
IT-014-02-01:	Pharmacy Concept Terminology
IT-014-04:	System and Data Security, Integrity and Privacy
IT-014-06:	Messaging and Communication
IT-014-06-03:	HL7 Messages
IT-014-06-04:	Prescription Messages
IT-014-06-05:	Pathology Messages
IT-014-06-06:	Collaborative Care Communications
IT-014-06-07:	Telehealth
IT-014-06-08:	Electronic Communications In Health
IT-014-09:	Electronic Health Records and Harmonisation
IT-014-09-02:	Electronic Health Records
IT-014-09-03:	Person Identification and Linkage
IT-014-10:	Electronic Commerce
IT-014-11:	Financial Messages

ISO's Health Informatics Committees

TC215:	Health Informatics
WG1:	Data Structures
WG2:	Data Interchange
WG3:	Semantic Content
WG4:	Security
WG5:	Health Cards
WG6:	Pharmacy and Medicines Business
WG7:	Devices
WG8:	Business Requirements for Electronic Health Records