IT-014 Health Informatics Committee

HL7 International Standards and Education Meeting

11th – 16th September 2011

San Diego, USA

Version: FINAL 1.0

Date Issued: 11/11/2011
Head Author: Heather Grain
Collated by: Standards Australia

With input from Australian Delegation and other employer funded Australians at the meeting:

- *Heather Grain (Delegate)*
- *Vince McCauley (Delegate)*
- *David Rowed (Delegate)*
- *Grahame Grieve (Delegate)*
- *Hugh Leslie (Delegate)*
- *Richard Dixon Hughes (Delegate)*
- *Patricia Williams (Delegate)*

With additional input from:

- *Stephen Chu (NEHTA)*
- *Andy Bond (NEHTA)*
- *Sarah Gaunt (NEHTA)*
- *Stephen Royce (NEHTA)*

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1 EXECUTIVE SUMMARY

This report has been produced by the unpaid expert members of the Australian Delegation participation in the HL7 International Standards and Education Meeting, 11-16th September 2011 in San Diego, California, USA with additional input from NEHTA staff who participated in the meeting.

The co-funding and support of Australian expert volunteer attendance at the HL7 International Standards and Education Meeting by the Australian Department of Health and Ageing and Standards Australia is gratefully acknowledged.

2 INTRODUCTION

This report summarises the committee proceedings, issues, actions and outcomes for consideration by Australia from the HL7 International Standards and Education Meeting that was held 11-16th September 2011 in USA. A total of four hundred and fifty-seven participants from twenty-four countries took part in the meetings of sixty-six individual Task Forces, Working Groups, Committees and other activities as well as twenty-five tutorials and four certification examinations all of which were held concurrently.

Given the participatory natures of the HL7 committee work, it is vital that Australians are present and participate in the committee work. Intensive work is done in the committees and often two or three Australian subject matter experts are required to get the Australian requirements into the consensus-based processes. Most work is done via teleconference between meetings but it is only in a face-to-face environment that the difficult issues that have the potential for greatest national impact can be effectively resolved. Most of the work done in committee is "leading edge" standards development work that often cannot be locally previewed, assessed and commented on beforehand. As a result, the selection process of the funded participants focuses on their expertise and interests as well as their ability to effectively communicate complex technical issues and achieve the desired outcomes for Australia in a collaborative consensus-based committee environment.

It should be noted that the HL7 International standards work is not structured as "Work Items" that are put forward to the HL7 body for approval, rather most projects arise from the work within the many domain and specialist committees. However, these proposed projects need to be well-defined and documented and require approval by the respective Steering Division and the Technical Steering Committee to ensure appropriate internal (HL7) and external (international standards development organisations) harmonisation.

As is customary, the Australian participants[1] met on a daily basis to plan and monitor involvement, identify any additional sessions and/or activities that should be covered and to identify emerging issues - particularly those that are relevant to the Standards Australia IT-014 and/or National eHealth Transition Authority (NEHTA) work plans. Australian participants also coordinate their activities through Skype.

[1] This included those Australian (and NZ) attendees who were not funded from the DOHA contract administered by Standards Australia.

3 SUMMARY OF KEY OUTCOMES AND ACTIONS

The principal issues/actions and recommendations identified by the Australian delegation at the September 2011 HL7 Meeting are summarised in this section. This table suggests relevant members of IT-014 Community or IT-014 Committee Structure for follow up of these items.

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
epSOS trans-European electronic prescription project	The epSOS project is expanding rapidly and being implemented. This is based on the IHE profiles, whilst some flexibility within a jurisdiction is possible. This is rapidly being adopted as a de facto standard for Europe and for the proposed US system. **Action: A review of the current status and architecture implemented in epSOS should be considered to inform design and more importantly implementation of e-prescribing and cross jurisdiction (public/private) prescription transfer.**	**NEHTA,** **IT-014-06-04**
Health Information Exchange (HIE) initiative in Indiana	The success of projects such as the Indiana Health Information exchange could provide a valuable insight into the infrastructure, structure and processes implemented to create innovative and successful uses of various existing silos of health information. **Action: A review and investigation of the applicability of projects such as the Indiana HIE project to the Australian environment, and for potential future uses of our Australian health data.**	**IT-014**
Consent directives	Currently there are no regulations around consent directives although there are international standards for use through IHE, OASIS and continued development via HL7. Australia needs to ensure that its intended use of e-consent is consistent with international work (such as IHE profiles) to enable interoperability across jurisdictional and international boundaries. **Action: Ensure that work in the area of consent directives are consistent with international standards, or can define international standards where these are not yet in place.**	**IT-014, NEHTA**
Confidentiality codes	Australia should input to this discussion in relation to how confidentiality codes are being implemented in Australia. This would provide a useful insight into the Australian use case for HL7. **Action: NEHTA should provide IT-014 with information on how the confidentiality codes are being implemented currently and how they are proposed to be used in the PCEHR and e-health information exchange. This would inform and contribute to the international discussion which is important for future cross boundary information exchange.**	**IT-014, NEHTA**
Metadata definitions for patient information transfer	The US currently has an advance notice of proposed rulemaking (ANPRM) for 'Metadata Standards' to Support Nationwide Electronic Health Information Exchange. The relevance to Australia is in regard to the metadata requirements specifically for information (as in the ANPRM), where the patient obtains a summary care record from a health care provider's electronic health record system and requests for it to be transmitted to their personal health record (PCEHR). It is assumed that this is already defined (or will be) in the composition of the PCEHR message transfer format. **Action: Review whether or not the outcomes from this ANPRM have relevance for Australia and the PCEHR in relation to the standardisation of metadata for patient information exchange.**	**IT-014, NEHTA**

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Harmonisation of ISO and HL7	From ISO updates it is apparent that security voting and nomination of national experts is not regularly occurring and this is impacting ISO's ability to further new work items. During this meeting this was followed up with Standards Australia. **Action: Review list of experts in security that can be offered for ISO new work item proposals.**	**IT-014, Standards Australia**
Use of existing health information databases (silos)	The US Query Health model for interrogating and querying silos of information is being adopted by several states. **Action: Review the Query Health model to see if it has relevance to Australian and the use of existing health information databases, and its potential for use in any national programs.**	**IT-014, NEHTA**
Security Ontology	The security ontology is very robust and detailed. It covers many aspects of security, privacy and access control that apply to the whole transfer of information for e-health. **Action: The HL7 Security Ontology should be trialled for its potential application to aspects of the Australian e-health initiative and in particular to inform work on the NESAF.**	**NEHTA**
Application of security models to e-health implementations	With the knowledge of the current NESAF which is a risk based approach, the HL7 model (Security and Privacy DAM as implemented by the EHR workgroup) is significantly more specific and provides the mechanism for a robust and defensible method for security and privacy. It is particularly relevant to the integration of NESAF to the development of systems that will support and deliver the services of the Australian e-health system. **Action: IT-14 should review the HL7 security and privacy work as a perspective to strengthen and inform the NESAF. This should include a review of how the HL7 EHR-FM is defining the security requirements and how these are enunciated.**	**IT-014**
HL7 Templates Registry Project	HL7 Templates working group is working on the specification of a templates registry. Review and input into the business requirements specifically the metadata requirements, to ensure that it contains the potential Australian requirements. **Action: Investigate the use of the HL7 Templates Registry and provide feedback of lessons learned and information obtained as part of the Australian Template Server project, to inform the international work.**	**NEHTA**
Template exchange format project	NEHTA is one of the few major national programs that is not a sponsor of this project. **Action: NEHTA should engage with this project to ensure that any template implementation in Australia is compatible with future international standards.**	**NEHTA, DoHA**
Terminology Conformance Principles	Principles to be used when testing terminology conformance. **Action: Ensure the newly formed Australian Terminology Conformance Working group established by the CCAG is aware of the agreed terminology conformance principles and practice.**	**IT-014-02, IT-014, Conformance and Compliance Task Force**
Proposals phase for HL7 V2.9	HL7 is currently gathering proposals for the next version of HL7 (2.9). **Action: Ensure Standards Committees and vendors are aware of the opportunity to put forward new V2 proposals at the next HL7 WGM and any new proposals are communicated to the delegates.**	**HL7 Australia,** **IT-014, MSIA**

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hData DSTU	hData HL7 draft standard for trial use needs to be considered for inclusion in the Australian international work program as it may be relevant to national infrastructure initiatives **Action: Examine the relevance of hData HL7 DSTU for future simplified Service specifications**	**NEHTA**
CTS2 implementations	A National Terminology Service would reduce resource investment required to distribute, use and maintain eHealth terminologies. It would also facilitate term and termset searching and provide an underpinning for conformance testing of terminology There are now two open source implementations for a Common Terminology Service. One is a "toolbox approach" that allows rapid development of CTS2 compliant software and the other is the French (Phast) implementation as a "read-only" terminology source. **Action: Assess benefits of implementing and deploying a standards based Terminology Service. The CTS2 implementations would enable a rapid, low-cost, standards based rollout in Australia.**	**IT-014, DoHA, NEHTA, MSIA**
DSS Implementation	The decision support service has now been implemented by the Mayo clinic and the code is available as open source. **Action: Ensure that groups considering decision support are aware of this highly functional, standards based, low-cost implementation pathway for Decision support.**	**NPS, NEHTA, MSIA, DoHA, AMA, RACGP**
HCSPD service	Database Consultants Australia (DCA) is submitting an OMG implementation of the Human Services Directory. This is the first time an Australian company has taken part in this part of the HSSP process. **Action: Provide support as required to facilitate DCAs involvement**	**IT-014, DoHA**
Devices - Updated NIST Testing Tools	NIST is rolling out new tools. **Action: Communicate the availability and functionality of this tooling to Australian Healthcare device manufacturers**	**DoHA,** **IHE Australia, NATA**
Advisory Council - input	HL7 Advisory Council comprises a select group of individuals from the healthcare industry that provides strategic input to the HL7 Board. The Council has been an important influence on HL7 becoming a more professional and business-like organisation and provides input on the thinking of major stakeholders on HL7 and the environment in which it operates. **Action: HL7 Australia and any other Australian interests with comments or suggestions about general matters of potential strategic importance to HL7 International that might usefully be the subject of advice from the Advisory Council to the HL7 Board to advise Richard Dixon Hughes.**	**HL7 Australia** **IT-014** **others as appropriate**

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Affiliate Agreement Task Force (AATF) and renewal of Affiliate Agreement	The affiliate agreement that governs the arrangements between HL7 International and its affiliates (including HL7 Australia) is being updated for 2012 through 2013 to better reflect the contractual relationships between the parties and provide greater clarity around the use of HL7 International intellectual property. The changes are being negotiated through the AATF, of which David Rowlands is a member, with assistance from Richard Dixon Hughes and oversight by the HL7 Australia Board and with the aim of ensuring that existing rights such as member access to HL7 specifications and the ability to produce and publish Australian HL7 implementation guides as Australian Standards and other issues raised by HL7 receive favourable consideration and are incorporated into the draft agreement. **Action: HL7 Australia to continue with negotiation of a suitable affiliate agreement for 2012 through 2013 with the aim of facilitating the continued availability of HL7 materials in Australia under reasonable commercial terms and allowing the continued publication of HL7 Implementation Guides as Australian Standards.**	**HL7 Australia others as appropriate**
International Membership & Affiliation Task Force (IMATF)	The IMATF is considering the medium to longer-term membership structure of HL7 and its affiliates, including the desire of some in HL7 International to become a more unitary organisation, whether there should continue to be affiliates and, if so, what role they should play. These discussions overlap consideration by the HL7 Board of its forward business plan and potentially impact the role of HL7 Australia and the benefits currently received by its members and the Australian eHealth community. **Action: HL7 Australia to continue engagement on HL7 membership model through IMATF with view to ensuring Australian stakeholders can continue to obtain HL7 membership benefits cost-effectively and have their interests in HL7 represented locally and at the global level.**	**HL7 Australia others as appropriate**
Strategic Initiatives	Australia should be involved in the Strategic Initiatives ballot to make sure that it aligns with national priorities in Australia. **Action: Join Strategic Initiatives Ballot**	**Australian Delegation**
Protection and use of HL7 intellectual property	The stability of HL7 International's financial position is likely to continue to depend on organisations paying a reasonable price for use of its intellectual property (IP), at least for the next few years. Without other sources of revenue, ongoing protection of its IP therefore remains a priority for HL7 International, and this needs to be respected where HL7 IP is used in Australia. **Action: HL7 Australia, Standards Australia and NEHTA to ensure that effective measures are in place to protect HL7 International's IP when distributed and used within Australia.**	**HL7 Australia, Standards Australia & IT-014 NEHTA**
Australian support for IHIC 2012 in Singapore	HL7 Singapore sought support from HL7 Australia in its bid to hold IHIC 2012 in Singapore on 20-21 September and is looking to Australia to come in as a co-sponsor particularly to provide assistance with organisation and ensuring there is good promotion, support, speakers/faculty etc. **Action: HL7 Australia to assist HL7 Singapore with promotion, support and raising sponsorship for IHIC 2012, assisting with organisation as required and working with IT-014 and NEHTA to maximise potential Australian interest and benefit to Australia.**	**HL7 Australia in collaboration with IT-014, NEHTA and HL7 Singapore**

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HL7 Activities with other SDOs	There is an ongoing need to monitor and promote harmonisation between the various health informatics standards development organisations (SDOs). **Action: As Australian ISO/TC215 Head of Delegation and observer for HL7 affiliates on the Joint Initiative Council (JIC), Richard Dixon Hughes to monitor progress in harmonisation of HL7, ISO, CEN, IHTSDO, GS1 and CDISC activities and report on it regularly to IT-014.**	**IT-014** **Richard Dixon Hughes** **Heather Grain**
EHR Systems Functional Model Release 2 (EHR-S FM R2)	Since Australia last had significant involvement in producing release 1.0 and the subsequent international standard release 1.1 of EHR-S FM (ISO 10781), the document has been extensively revised and restructured based on implementation experience, primarily in the US with some in Canada and Europe. Australian delegates have provided some input on WG teleconferences and through working on reconciliation at HL7 WGMs. However, this involvement has been limited and has highlighted the need for the resulting output to be thoroughly reviewed in Australia, once released for ballot. This work is tracked by IT-014-09. The model provides a framework for functional assessment of EHR systems widely used in systems certification and assurance. **Action: IT-014-09 to continue monitoring development of EHR-S FM R2, contributing where possible, but with a view to ensuring that there is strong Australian engagement.**	**IT-014-09**
PHR Systems Functional Model (PHR-S FM)	In the process of progressing from DSTU to a full ANSI/HL7 normative specification, this HL7 specification is also set to become an international standard providing a functional framework for specifying the characteristics of shared personal health record systems. It is potentially applicable to conformant PCEHR repositories but is still some way from completion. **Action: There are no specific actions for Australia at this time other than to monitor and have oversight of progress.**	**IT-014-09**
Clinical Modelling – strategic directions	Grahame Grieve and representatives of Ocean Informatics are both invited members of the Clinical Information Modelling Initiative (CIMI), which was formed within HL7 but is presently operating independently of HL7. There is also growing interest in the potential application of the Resources for Health (RFH) philosophy developed by Grahame both inside HL7 and in the wider health informatics community. Significant advances and changes are possible. **Action: IT-014 (through IT-014-09 and IT-014-06), HL7 Australia and NEHTA CTI/Standards to track, monitor and, where possible, participate in influencing and defining a well-structured approach to future standardisation of clinical models and their implementation in messages, documents and processes.**	**IT-014-09** **IT-014-06** **HL7 Australia** **NEHTA (CTI Standards)** **Grahame Grieve**

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Specification of business requirements for a templates registry.	An updated project proposal is being put forward to carry out a business requirements analysis for a templates registry, which can be an authoritative source of information about HL7 templates being used around the world and similar artefacts developed using other modelling paradigms. The proposal seems to be proceeding by default without strong support and connection to other existing work in the field and likely commitment of the resources needed to implement and maintain such a registry within the global eHealth community. **Action: IT-014 monitor developments with a view to supporting harmonisation of this proposed work with other activities within HL7, the ISO work on DCM quality processes.**	**IT-014 (through IT-014-09 and IT-014-02)**
Update of HL7 Templates DSTU	A project proposal was submitted in August 2011 to update the (now expired) HL7 Templates DSTU with a recommendation to change the name to reflect the fact that the document defines an interchange format for templates. Volunteers are being sought to assist in the work. **Action: There is no specific action for Australia at this time other than to monitor progress.**	**IT-014**
Management changes at AHIMA	Recent management changes at the American Health Information Management Association (AHIMA) threaten the smooth transfer of the secretariat of ISO TC 215 Health informatics from the Health Information Management Systems Society (HIMSS) and the ongoing level of support and resources needed to provide an effective secretariat service into the future. **Action: Richard Dixon Hughes (as Australian ISO/TC 215 HoD) and Heather Grain (Convenor TC 215/WG3) to monitor the situation, provide counsel to the incoming secretariat. There is no specific action for Australia at this time other than to monitor progress.**	**Richard Dixon Hughes** **Heather Grain**
Implementation Guides and Technical Specifications	While Standards are delivered as convergences from models and development processes there is risk of derivatives e.g. Implementation Guides proliferating and hindering uptake. **Action: Advise committees and members to carefully assess and justify new IGs, Technical Specifications, Message types etc. which could be better delivered as general products.**	**IT-014 to advise committees and submitting organisations**
Services Based Framework for Diverse Clinical Applications	Diversity of deployments, User Requirements, National Program data needs, Consumer Involvement in Health IT. **Action: Groups review how their standards, implementing applications and stakeholder needs can be delivered in the evolving environment of componentised services across device variability. Review past and existing initiatives.**	**IT-014, Health IT Industry (notably MSIA), HL7 Australia and RACGP**
Public Health Surveillance	Proven Benefits from HL7 V2 Messaging in Community Health for Environmental toxins and Infection detection **Action: State jurisdictions' Community Health groups re-activate initiatives taken through Standards Australia IT-014-06-06 and Community Based Health at HL7 International**	**IT-014-06-06 with Jurisdictions and Quality and Safety groups.**
TermInfo R2	This work has a direct impact upon CDA work and as such Australia should be actively engaged in this work. **Action: Include this work item on IT-014 international work program and ensure that delegations have suitable skills to contribute and represent the Australian position**	**IT-014, NEHTA, DOHA**

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Vocabulary education needs	**Action: Australia to consider our priorities for tutorial development for Vocabulary**	**HL7 Australia**
Value Set Migration	The maintenance of value set information and where relevant migration to SNOMED CT based concepts (as HL7 migrate their data content to the HL7 namespace of SNOMED CT) will need to be considered for Australian content. This is an issue for non-clinical data, not just content one would normally consider using SNOMED CT for. **Action: Consider the impact of HL7 migration and the changes this may require for Australian Implementation Guides and other data components.**	**IT-014, IT-014-06, HL7 Australia and AIHW**
Value Set Migration	Identification of Australia's priorities for data migration should be undertaken in order to influence the decisions made for international migration. **Action: Identify priorities**	**IT-014, NEHTA, DOHA**
V2 Vocabulary Model development - Terminology Binding	Is this a priority issue for Australia? If so it is essential that we maintain active engagement in these processes. **Action: Determine national priority for this project and engagement.**	**IT-014**
Terminology Binding Project	ISO terminology binding project being led by HL7 vocabulary and modelling needs to be actively followed by Australia as a work item on our international engagement. **Action: Consider national priority for this project and ensure delegation skills are adequate to cover this work item**	**IT-014, NEHTA, DOHA**
Education Plan for Australia	Identification of educational strategy for HI7 in Australia is needed. This plan should include quality provisions. It should also include priority educational needs to build the workforce and support national initiatives. **Action: Develop an education strategy for both HL7 provided education and education through suitable educational organisations.**	**HL7 Australia, NEHTA, DOHA**
Fresh Look Task Force – Clinical Information Modelling Initiative	Australia should monitor the outcomes of the Clinical modelling initiative as this is likely to drive the DCM approach in the future. **Action: Monitor outcome of Fresh Look Clinical Information Modelling initiative**	**Hugh Leslie, Sam Heard**
Fresh Look Task Force	This group has the potential to steer delivery of new products which leverage HL7's organisational and technical strengths while addressing major model, interaction, and content-based limitations in Clinical Communications, Decision Support, and workflows. **Action: HL7 Australia, and IT-014 should consider how best to be updated on progress and encouraged to contribute any Australia specific issues. Oversight should be established with a relevant IT-014 committee.**	**IT-014** **HL7 Australia**
Detailed Clinical Models (DCM)	Australia should continue to have input to discussions within HL7 about this important topic. **Action: Australia should remain involved in DCM work.**	**IT-014**

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HL7 Australia Nominee Representation, Funding, and Accountability	It is vital that HL7 Australia have a consistently funded nominee at the International Affiliates meetings and that accountability to HL7 Australia, DoHA, and Standards Australia be agreed and clear. This has been problematic recently. **Action: HL7 Australia, consistent with its membership support and governance requirements, ensure it has resources to independently, and consistently fund the HL7 Australia nominee delegate to Working Group meetings and effects this involvement with agreed accountabilities in place.**	**HL7 Australia, Standards Australia and DoHA**
HL7 Board – proposed new business plan	Building on previous considerations including work by a Business Plan Task Force, the HL7 CEO has put forward a proposed new business plan. This plan potentially impacts the role of HL7 Australia and the benefits currently received by its members and the Australian eHealth community.	**HL7 Australia others as appropriate**
Clinical Decision Support Standards	Clinical Decision Support is widely used in clinical practice and systems in Australia (e.g. prescribing software, RACGP Red book, GP sidebar add-on, National Health Call Centre, College of Pathology Guidelines) but is not standards-based and there are no compliance criteria to ensure safety, reliability, and accessibility of interfaces. Many guidelines are in textual form that are not machine processable and are unable to leverage off existing EHRs and productivity tools. **Recommendation and Action: Formation of CDS Standards WG in Standards Australia with close linkage and cross representation from other WGs, vendors and knowledge providers (especially Drug and Pathology Knowledge providers and Therapeutic Guidelines). Discussion required at IT-014.**	**IT-014** **RACGP as leads**
Virtual Medical Record vMR Project	vMR reduces costs, turnaround time at point of care, frees vendors of difficult design and maintenance; it enhances quality and competition in available CDS delivery and focuses directly on Patient and Community outcomes and safety. Its technology independence ensures general applicability and lasting investment value. **Recommendation and Action: Find a Standards Australia home for this together with other CDS needs. Set-up a project to link this in with Australian initiatives.**	**IT-014 leading MSIA, Professional Groups, HL7 Australia**
Multiplicity of CDS WGs standards	Australia support CDS WG's progress on its next generation which should have a uniform model and methodology. **Action: CDS Delegates to take this to future meetings.**	**HL7 Australia,** **IT-014 via directions to future Delegates**
Multiplicity of CDS WGs standards	With vMR, Gello and Arden as CDS standards and HL7 Version 2 and CDA used in input and output to CDS systems, it is not clear which standards are best suited for which tasks. **Action: CDS Delegates, and collaborating CDS workers in Australia to work with the WG to do comparative analyses and deliver guidelines for use of different approaches.**	**IT-014, CDS Community in Australia**
Development of CDS Standards	Australia does not generally take part in HL7 ballots of CDS standards. **Recommendation: Australia take part more inclusively in CDS ballots.** **Action: Standards Australia circulate ballot notifications throughout the IT-014 community and recommend balloting.**	**IT-014**

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Development of CDS Standards	Australian involvement at HL7 CDS has been ad hoc and piecemeal, usually by clinician delegates with prime responsibilities across Patient Care, Structured Documents, SOA and Community Based Health. This limits Australia's ability to progress in this key direction. **Recommendation: Australia includes Clinical Decision Support as an ongoing area of prime responsibility for its HL7 delegation.** **Action: Assignment of CDS for comprehensive cover by HL7 delegations.**	**IT-014, HL7 Delegates**
Interfacing CDS with Applications	Clinical Applications are mostly closed systems with CDS supplied by the vendor resulting in severe limitations on scope and optimisation of CDS package utilisation, as well as impeding innovation, development, competition and commerce by industry and expert groups. **Recommendation: Progressing initiatives to develop standards for service based interfacing, including the Australian-driven Patient Care Services Project, and engaging knowledge vendors and DSS vendors in requirements specification. "Integration Points" be identified.** **Action: The three groups convene a meeting to develop a strategy for stakeholder engagement and proceed with the requirements gathering phase.**	**MSIA, HL7 Australia, IT-014**
Priority of CDS	There is lack of appreciation of the prime importance of Clinical Decision Support by policymakers. It needs to be understood as the final pathway integrating all the accepted standards initiatives including EHR, communications, terminology, structured data, knowledge and evidence for the benefit of optimal patient care, outcomes and safety together with environmental and population health. **Recommendation: Promotion to government funding and policy implementers of CDS development with a view to supporting a standards WG and taking steps to require appropriate deployments in funded projects.** **Action: Seek Engagement of key funders and policy makers.**	**IT-014, RACGP, College of Pathologists**
CDS and HL7 V2 Referral Messaging	CDS input and output, like our Referral and Discharge HL7 V2 messaging, requires rich clinical structured data in its payload. This has been difficult and is ongoing work which has been led by Australia. We have a large investment and stakeholder dependence on V2 and cannot allow proliferation of methods to develop as CDS goes down a parallel V2 path in the same problem space. **Recommendation: Australia work with CDS , Patient Care and OO to ensure that we reach a single solution for structured clinical data in version 2, that it satisfies our requirements and is consistent with our Discharge and Referral messages.** **Action: IT-014-06-06 take a watching brief on the CDS V2 work and engage as needed.**	**IT-014,** **IT-014-06-06**

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Community Based Health – focus of the group	Community Based Collaborative Care WG was set up by Australia to address the need of mainly state jurisdictionally-provided services covering allied health, mental health, community nursing, aged care, and social support services. It has done exceptional work in Aged and Residential Care messaging and in developing the Human Services Directory SOA/HSSP standards deployed in Australia. It has been difficult for us to keep the focus and to maintain our jurisdictional involvement commensurate with our needs. The group has become focussed on privacy and security/consent directives which might be better addressed in the Security WG. This is diverting the work away from our needs. **Recommendation: Australia makes a serious effort to have this WG again address our needs and takes steps at HL7 to review the best location for the security work. Alternatively we move to bring the Community Health Provision work back to Patient Care (its original sponsoring group) with the appointment of an additional co-chair from our jurisdictional community health sector.** **Action: Key stakeholders in Australia meet to review our needs and strategies in this area and aim to ensure ongoing involvement in these standards.**	**Standards Australia, NSW and Victorian Dept of Health,** **IT-014-06-06 co-chairs**
Referral Message representation of Medication History	The Version 2 REF message managed by CBCC cannot properly represent Medication History **Recommendation: IT-014-06-06 work program be extended to re-install HL 7 V2 in Patient Care Messaging (recently dropped from the work program) and that this together with other needs for clinical content be addressed by IT-014-06-06 in collaboration with IT-014-06-04, with view to bringing proposals to Patient Care and CBCC WGs.** **Action: IT-014 be requested to put HL7 V2 in Patient Care Messaging back onto the work program for IT-014-06-06.**	**Standards Australia,** **IT-014,** **IT-014-06-06,** **014-06-04**
Modelling and Methodology	**Action: Australia should track the development of RFH closely and see how it aligns with other work that is proceeding.**	**IT-014**
Patient Care WG **General**	The Patient Care WG is key to all clinical communication standards to be used in Australia and has been the WG through which we have taken change requests covering Referral, Collaborative Care and Community Health. It is the group most closely paralleling IT14-6-6. It covers a wide area and has a huge workload. Our needs could easily be neglected in this resource competitive environment. **Recommendation: Australian delegates maintain high priority on being active in, and reporting on, this WG. Multiple delegates need to have this in their areas of responsibility. Australia should maintain leadership through holding 1-2 co-chair positions. This should keep our requirements paramount.** **Action: Delegate nominations continue being sought to cover this area and it to be included in responsibilities for multiple delegates. Australia to support its filling of 1-2 co-chair positions.**	**IT-014**

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Care Plan	Care Planning is a critical process in Collaborative Care and has requirements for Collaborative Care Communications. It is significantly funded via Medicare and General Practice co-ordinating across Allied and Mental Health. **Action:** **Collaborative Care messages and CDA documents be tested against current IGs which should be enhanced to accommodate Care Plan content, where relevant, interactions and trigger events if found necessary. More widespread involvement in the PC Care Planning projects be sought from our clinical communities.**	**NEHTA,** **IT-014-06-06,** **IT-014,** **RACGP, Allied Health**
Clinical Decision Support in Information within Structured Documents and EHRs	Clinical information will be contained in NEHTA-specified Structured Documents, being brought through IT14-6-6 for use in data exchange, as it currently is within deployed EHR-based applications in Australia. It is important that this information meets requirements of CDS and can be extracted accordingly. HL7 CDS projects have found that this is not straight forward **Action: Groups working on CDA , EHR, Knowledge representation, Guidelines, and CDS review their requirements against CDA Implementation Guides, and that the this be done in conjunction with HL7 CDS-CDA work.**	**IT-014-09,** **IT-014-06-06 Knowledge Vendors, MSIA, RACGP**
Template registration and management Project	Issue: This new project is looking for detailed input and resources **Action: Consideration should be given to providing feedback, "lessons learned" and information obtained as part of the Australian Template Server project, to inform the International work.**	**NEHTA, DoHA**

4 MEETING LOGISTICS

In line with standard HL7 practice, decisions and outcomes are voted on and documented in the various committees. This is different to ISO/TC215 and International Health Terminology Standards Development Organisation (IHTSDO) where countries effectively vote as a block, HL7 International does not 'pass resolutions' in a plenary session as the number of committees would make this extremely impractical, though it is recognised that this process can make harmonisation more difficult. For this reason co-chairs of some of the Working Groups meet on Thursday evening to discuss decisions and ensure all are familiar with directions. The attendees came from twenty-four different countries and the graph below (Figure 1) shows the difference in attendance at this meeting to the previous meetings in January and May 2011.

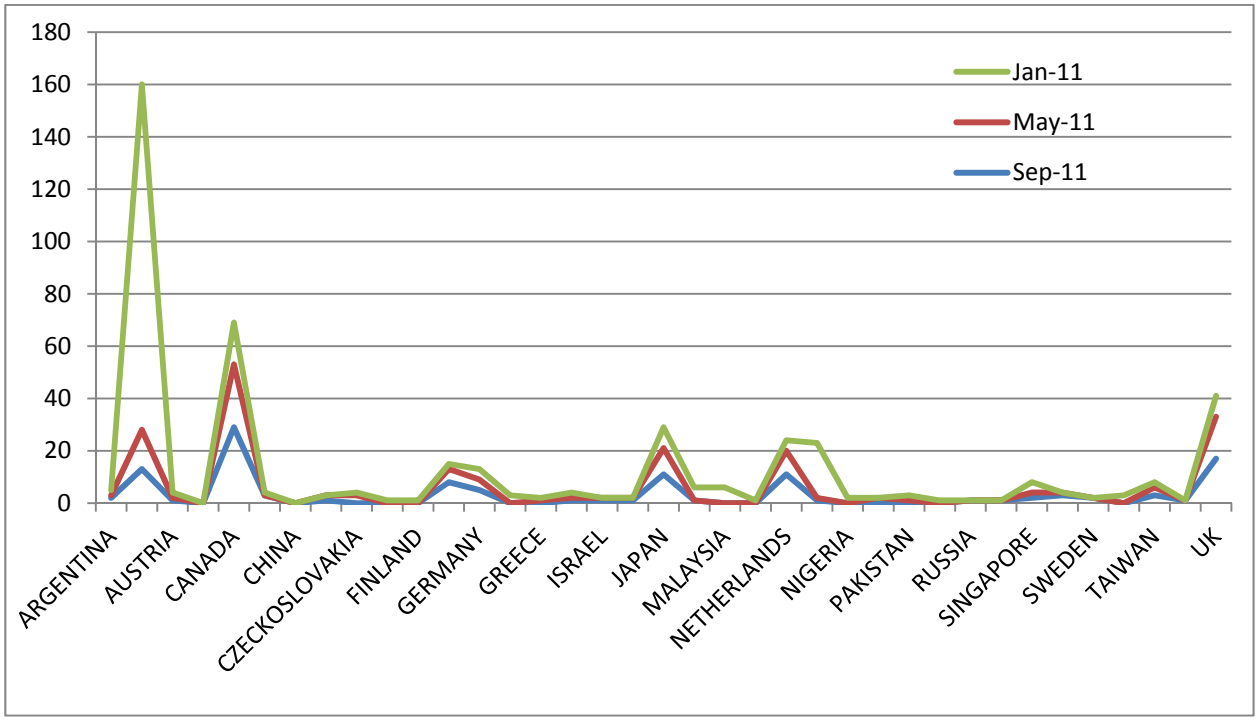

Figure 1 Attendance from non US countries

The table below shows an extract of the meeting schedule for some of the larger meeting groups. There were sixty-six individual (often concurrent) meetings held at this working group meeting.

Meeting	Sun	Mon	Tue	Wed	Thu	Fri
Anatomic Pathology			X			
Architecture Review Board (ArB)	X		X			X
Clinical Decision Support				X	X	
Clinical Genomics			X	X		X
Clinical Interoperability Council		X	X	X	X	
Clinical Statement					X	
Community Based Collaborative Care		X	X	X		
Education & Marketing		X	X		X	
Electronic Health Records		X	X	X	X	
Emergency Care		X	X	X	X	
Fresh Look Taskforce		X				
HL7/CEN/ISO/IHTSDO/ GS1/CDISC	X					
Health Care Devices		X	X	X	X	

Meeting	Sun	Mon	Tue	Wed	Thu	Fri
Implementation / Conformance						
Infrastructure and Messaging			X			
International Council	X				X	
Modelling and Methodology	X	X	X	X	X	X
Orders and Observations		X	X	X	X	X
Patient Administration		X	X	X	X	
Patient Care		X	X	X		
Patient Safety		X	X	X	X	
Pharmacy		X	X	X	X	X
Public Health Emergency Response		X	X	X	X	
Regulated clinical research information management			X	X	X	
Security			X		X	
Services Oriented Architecture		X	X	X	X	
Steering Divisions (for leadership only)		X			X	
Structured Documents		X	X	X	X	X
Templates						X
Terminfo Project (held within Vocabulary WG)						X
Tooling			X		X	
Vocabulary	X	X	X	X	X	X

Note: 'X' indicates days the Task Forces / Committees and Working Groups met.
These groups represent areas of interest to Australia and it is noted that the minimum number of concurrent sessions of these groups (the minimum number of people needed in a delegation to cover all areas) would be twenty-three on Tuesday – the day with the most sessions. This figure and this table does not represent tutorials or other groups which might also include relevant material to Australia.

4.1 Delegation and Attendance

Attendance at this meeting was normal for a meeting in the USA. There were thirteen Australians (eleven in the delegation including NEHTA staff) in attendance. The delegation would like to thank all of the sponsors, with special thanks to the Department of Health and Ageing for fiscal assistance and to NEHTA for their fiscal and staff support.

In summary, the work at the HL7 International Standards and Education Meeting offers a real opportunity to further the alignment of Australian Personally Controlled Electronic Health Records (PCEHR) standards and international standards, and to further the alignment of European and American developments.

4.2 Funding Source Summary and Australian Attendance

Thirteen Australians attended for the duration of this meeting, eleven of who were in the formal 'delegation'. The funding source for these delegate numbers is indicated in the table below.

Funding Source	Number	Change from Previous meeting
Full funding by employer: Private	2	-1
Full funding by employer: States/Territories or National Initiatives (NEHTA)	4	-1
Funding assistance – DOHA through Standards Australia contract	7	0
Total:	13	-2

AUSTRALIAN DELEGATES - WORK PRIORITY AREAS

The table below shows the difficulty in covering the multiplicity of issues discussed concurrently. Delegation members attended as many of the relevant sessions as physically possible, but it is not possible to cover the broad requirements in depth with the current delegation size. Members of the delegation seek to support each other and back each other up to ensure coverage wherever possible.

Recommendations of previous delegations have included the need to address the issues of coverage and skills within the delegation to ensure appropriate coverage.

Action: That the Standards Roundtable, which consists of NEHTA, Standards Australia, IT-014, DOHA and HL7 develop a skills matrix associated with national priority work items to support appropriate delegation membership.

Meeting	Sat	Sun	Mon	Tue	Wed	Thu	Fri
Advisory Council				RDH			RDH
Affiliate agreement and access to HL7 IP	RDH		RDH	RDH	RDH	RDH	RDH
Anatomic Pathology							
Architecture Review Board (ArB)		GG					
Arden Syntax				DR			
Attachments							
Board				RDH, GG			
CDISC / BRIDG							
Child Health							
CCOW							
Clinical Decision Support				DR	DR	DR	
Clinical Genomics							
Clinical Interoperability Council						HL	
Clinical Statement						SC	
Community Based Collaborative Care			TW		TW		
Detailed Clinical Models							HG
Education & Marketing							
Electronic Health Records				RDH	RDH, TW, HL		

Meeting	Sat	Sun	Mon	Tue	Wed	Thu	Fri
Electronic Services							
Emergency Care							
Financial Management							
Generation of Anaesthetics Standards							
Governance and Operations							
US Government Projects							
HL7/CEN/ISO		RDH					
Health Care Devices			VM	VM	GG	VM	
Imaging Integration							
Implementation / Conformance				VM	VM	VM	
Implementation Technology Specification				GG			
Infrastructure and Messaging							
International Council		RDH, DR, TW, VM, HL, SC, SG				RDH	
International Mentoring Committee							
ISO TC215 Organisation & Business Plan Task Force, and liaison meetings		RDH	RDH				
JIC liaison		RDH	RDH			RDH	
Laboratory							
Modelling and Methodology		GG	GG				
Orders and Observations				HL, GG, SC			
Organisational Relations							
Outreach Committee for Clinical Research							
Patient Administration							
Patient Care		HL	HL, SC	HL, SC	DR, HL,	DR, HL,	

Meeting	Sat	Sun	Mon	Tue	Wed	Thu	Fri
					SC	SC	
Patient Safety							
Pharmacy				SC	VM, SC		
Plenary Sessions			DR, TW, RDH, VM, HG, GG, SC, AB, SG				
Policy Advisory Committee							
Process Improvement Committee							
Project Services							
Public Health Emergency Response							
Publishing							
Recognition and Awards							
RIMBAA					RDH, GG		
Security			TW	TW	TW	TW	
Sensor Networks							
Services Oriented Architecture			DR, VM	DR, VM	TW, VM	VM	
Standards Development Organisations (SDO) collaboration		VM					
Structured Documents				GG	DR	GG	GG
Templates							RDH, TW, VM, HG, GG, SC
Terminfo Project / Terminology							HG
Tooling				HG		HG	
US Government Projects							

Meeting	Sat	Sun	Mon	Tue	Wed	Thu	Fri
Vocabulary		HG	HG, SC	HG	HG	HG, GG	HG
V2/V3/V4 Taskforce (now HL7 Fresh Look)		RDH, HL, GG	DR, HL, GG	RDH	RDH		

Attendees:

Heather Grain **HG**

Richard Dixon Hughes **RDH**

Vince McCauley **VM**

Trish Williams **TW**

Grahame Grieve **GG**

Hugh Leslie **HL**

David Rowed **DR**

Stephen Chu **SC**

Andy Bond **AB**

Sarah Gaunt **SG**

In some cases delegates appear to be listed in two places at once. This reflected joining a session only for the Australian relevant content when there were competing priorities. This is not optimal, as it potentially disrupts the meeting, but is tolerated to a small degree.

4.3 Australian Leadership Positions

The table below lists leadership positions held by Australians at the HL7 meeting in September 2011.

Attendee	Position (held at the meeting)	Funding Source	Work Group or Committee
David Rowlands	Chair	Did not attend	HL7 Australia
Grahame Grieve	Co-Chair Invited Member Co-Chair Invited Member	Standards Australia via the DoHA Funding Agreement	Structured Documents (Developers of CDA) Architectural Review Board Modelling and Methodology Work Group HL7 Fresh Look Taskforce

Heather Grain	Co-Chair	Standards Australia via the DoHA Funding Agreement	Vocabulary
Richard Dixon Hughes	Co-chair & Invited Member Nominated rep HL7 Australia Alternate Representative of HL7 Affiliates	Standards Australia via the DoHA Funding Agreement	Advisory Council to the Board of HL7 International HL7 International Board of Directors International Council – including Affiliate Chairs Meeting, AATF & IMATF Joint Initiative Council (JIC) for Health Informatics SDO Harmonisation
Stephen Chu	Co-chair	NEHTA	Patient Care
Andy Bond	Invited Member	NEHTA	Architectural Review Board
Klaus Veil	Co-chair Co-chair	Did not attend	Publishing Patient Care

5 PLENARY SESSIONS

The topic for this, the 25th HL7 Plenary year, was a review of HL7's involvement in the improvement of health and healthcare around the world – including lessons learned and where HL7 is able to add value, with external viewpoints being added by:

- Richard Alvarez, President and CEO, Canada Health Infoway
- J. Marc Overhage, MD, PhD, Chief Medical Informatics Officer, Siemens Healthcare
- Jamie Ferguson, VP Health IT Strategy and Policy, Kaiser Permanente
- Robert Stegwee, PhD, Chair, HL7 The Netherlands & Cap Gemini, Consultants
- Daniel Pollock, MD, Surveillance Branch Chief, Division of Healthcare Quality Promotion
- Centers for Disease Control and Prevention, US Department of Health & Social Services
- Robert Kolodner, MD President, Collaborative Transformations, LLC and Executive VP & Chief Health Informatics Officer, Open Health Tools, Inc.
- Charles Jaffe, MD, PhD, CEO, Health Level Seven International

Copies of the presentations may be downloaded from the HL7 website at:
http://www.hl7.org/plenary/index.cfm

The plenary session opened with a visual presentation to celebrate the 25th anniversary of HL7 and demonstrated how the healthcare, and the integration of computing into healthcare, has evolved over the past twenty-five years. This was supported by a lesson in history by Ed Hammond entitled '25 Years in Review: The Good, The Bad and The Ugly', in how HL7 came into being and how the various aspects of the standards and groups came together. The initial mission of HL7 saw a '*problem to be solved: interfacing departmental systems with components of a hospital information system to create a single integrated system'*. Over time, an increased formalisation of

HL7's place and aim, and the services, support, members, positioning and consumer objectives were developed.

The second keynote was given by Richard Alvarez, the President and CEO of Health Infoway (Canada). Richard spoke as a representative of the International Affiliates. Richard reiterated that e-health is hard and is the paradigm of change. Also that going from paper legacy systems to fully integrated, modern healthcare is a step by step process. The process for this is:

1. Define the business problem
2. Establish a sense of urgency
3. Form a powerful guiding coalition
4. Create a vision and communicate it broadly
5. Empower others to act on the vision
6. Plan for and create short terms wins
7. Reflecting its enablers
8. Dealing with the challenges

The benefits and value of electronic health information technologies (cost $10-12 billion) access quality and productivity. An issue of meeting the vision is the number of systems to integrate from thousands to millions with mobile devices – tablets, phones etc. Infoway employs a common architecture. As of March, 2011 there are three hundred and fifteen active and completed projects with an estimated value of 2.006 billion. Signposts for success are assessed using a benefit framework – for Canada in 2010 these were specifically in imaging, drug management and telehealth. HL7 has greatly influenced their approach, and they have been using v3 and V3 CDA because of the wide intellectual base and standards work. The challenges for Canada are interoperability as well as the clinician requirements and workflow and development of standards. They use a Standards Collaborative (Pan-Canadian).
The Infoway Process:

- International Standards (HL7, ISO, IHTSDO);
- Standards Collaborative (adapts international standards for Canadian specific use);
- Pan-Canadian Standards (implementation guidance);
- Jurisdictional Standards; and
- Implementation.

Benefits were identified from supporting implementers with deployable standards and tools in an evolving environment of millions of interconnected devices requiring a services framework for interoperation and need to *resist proliferation of specifications.*

Marc Overhage MD, PhD gave a presentation of the Indiana health information exchange (HIE). He spoke on the data silos challenge because of the spread of information repositories and the location of this data. For health information exchange this is one of the fundamental challenges and this has been successfully addressed using a Health Information Exchange (HIE) Queue model. Currently, Indiana has twenty-five million information artefacts (equating to data for twelve million people enrolled). Four billion structured observations and one billion unstructured in the HIE repository. 'DOCS4DOCS' contains six million results everyday processed (saving

USD$3 million per day using this method). It also includes the INPC, the electronic laboratory reporting system, which leverages the data in the patient care process. This has resulted in a reduction in costs of USD$26 per visit to emergency departments by simply printing a one page sheet from the database.

The Regional HIE is using HL7 v2.4 messaging. The repository data uses CDA documents provided to external clinical decision support provider. Its benefits are being realised in many areas including public health and reportable diseases. In addition, using electronic surveillance and (Quality Health First) reports it can provide primary care quality and performance measures and feedback. Another initiative has been for clinical research, for instance in drug safety.

Panel Sessions at the Plenary

The first panel at the plenary session entitled 'How HL7 has delivered value and the value HL7 has enabled through facilitating collaboration with different stakeholders', provided four individual perspectives on the value proposition of HL7 to a private healthcare organisation, a country, public health, and the US Veteran Affairs. This was initiated by Jamie Ferguson, Vice President Health IT Strategy and Policy at Keiser Permanente. Jamie stated that HL7 has been successful internally to clinicians within the organisation for system communications using standard V2 messaging. In addition, it has been fundamental to the CDA based patient information exchange in real time for patient care in San Diego.

A second perspective was from Robert Stegwee, Chair of HL7 Netherlands, who provided a history of HL7 Netherlands and current work and advancements. Refer to International Affiliates Meeting - Around the World (Netherlands) for further details.

From the public health perspective, Daniel Pollock from the USA Center for Disease Control (CDC) explained the success of CDA for reporting to the CDC on healthcare associated infections (HAI) e.g. central line associated bloodstream infections, surgical site infections. The National Healthcare Safety Network (NHSN) is the national system launched by the CDC in 2005, built on CDA as it provides templates to essentially deal with the complexities of V3. CDA files of HAI are used to submit data to the NHSN. CDA is the lynchpin as an interoperability solution to connect hospitals and other healthcare facilities that use vendor systems for HAI data collection.

Lastly, Robert Kolodner, President of Collaborative Transformations and retired from government, outlined how for a large government organisation, the US Veteran Affairs, HL7 has given the organisation a vision and stability in developing healthcare communication.

The second panel session consisted of past HL7 Board Chairs recounting the history and development of HL7 over the past twenty-five years.

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Health Information Exchange (HIE) initiative in Indiana	The success of projects such as the Indiana Health Information exchange could provide a valuable insight into the infrastructure, structure and processes implemented to create innovative and successful uses of various existing silos of health information. **Action: A review and investigation of the applicability of projects such as the Indiana HIE project to the Australian environment, and for potential future uses of our Australian health data.**	**IT-014**
Implementation Guides and Technical Specifications	While Standards are delivered as convergences from models and development processes there is risk of derivatives e.g. Implementation Guides proliferating and hindering uptake. **Action: Advise committees and members to carefully assess and justify new IGs, Technical Specifications, Message types etc. which could be better delivered as general products.**	**IT-014 to advise committees and submitting organisations**
Services Based Framework for Diverse Clinical Applications	Diversity of deployments, User Requirements, National Program data needs, Consumer Involvement in Health IT. **Action: Groups review how their standards, implementing applications and stakeholder needs can be delivered in the evolving environment of componentised services across device variability. Review past and existing initiatives.**	**IT-014, Health IT Industry (notably MSIA), HL7 Australia and RACGP**
Public Health Surveillance	Proven Benefits from HL7 V2 Messaging in Community Health for Environmental toxins and Infection detection **Action: State jurisdictions' Community Health groups re-activate initiatives taken through Standards Australia IT-014-06-06 and Community Based Health at HL7 International**	**IT-014-06-06 with Jurisdictions and Quality and Safety groups.**

6 ADVISORY COUNCIL

DESCRIPTION

The Advisory Council comprises a select group of individuals from the healthcare industry that provides strategic input to the HL7 Board. Individuals are selected for service on the Council based on their personal experience and background and their ability to work with others to provide useful strategic advice to the Board.

Most members of the Council are senior executives and are not involved with HL7 Working Group Meetings. The Council meets monthly by teleconference with a face-to-face meeting at the annual HL7 Board retreat which is held in July each year.

Richard Dixon Hughes has been Co-chair of the Council since January 2010 and is the first person from outside the United States to perform the role. In this capacity he participated in the face-to-face meeting of the HL7 Board at the September 2011 WGM and was also involved in separate discussions with the CEO and Chair of HL7 about topics for discussion at upcoming Advisory Council meetings on which advice from the Council might be of assistance to the HL7 leadership.

In recent times, the Advisory Council has provided advice and feedback on a variety of topics, including:

- pathways for revenue growth;
- engagement with major stakeholder groups including government, the health IT industry and clinicians;
- being more business-like in the protection and management of intellectual property;
- strategic planning including review of HL7 vision, mission, objectives and processes for developing and maintaining the strategic plan and roadmap; and
- improved communications and marketing.

At the recent board retreat in July the Advisory Council reviewed emerging developments likely to impact HL7 and provided feedback on various elements and alternative approaches being proposed as part of the business models that had been developed to support the proposed new HL7 business plan.

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Advisory Council - input	HL7 Advisory Council comprises a select group of individuals from the healthcare industry that provides strategic input to the HL7 Board. The Council has been an important influence on HL7 becoming a more professional and business-like organisation and provides input on the thinking of major stakeholders on HL7 and the environment in which it operates. **Action: HL7 Australia and any other Australian interests with comments or suggestions about general matters of potential strategic importance to HL7 International that might usefully be the subject of advice from the Advisory Council to the HL7 Board to advise Richard Dixon Hughes.**	**HL7 Australia, IT-014 and others as appropriate**
HL7 Australia Nominee Representation, Funding, and Accountability	It is vital that HL7 Australia have a consistently funded nominee at the International Affiliates meetings and that accountability to HL7 Australia, DoHA, and Standards Australia be agreed and clear. This has been problematic recently. **Action: HL7 Australia, consistent with its membership support and governance requirements, ensure it has resources to independently, and consistently fund the HL7 Australia nominee delegate to Working Group meetings and effects this involvement with agreed accountabilities in place.**	**HL7 Australia, Standards Australia and DoHA**

7 AFFILIATE AGREEMENT AND RELATED ISSUES

DESCRIPTION

Matters relating to the relationship between HL7 International and its affiliates are addressed by two task forces formed under the aegis of the International Council:

1. Affiliate Agreement Task Force (AATF), which is responsible for coming up with an updated affiliate agreement acceptable to both HL7 International and its international affiliates; and

2. International Membership and Affiliation Task Force (IMATF), which is examining alternative membership models and their impact on the relationship between HL7 International, its international affiliates and various classes of HL7 membership around the world.

   This activity has taken on additional importance as one of the membership models under consideration as part of the proposed new HL7 business plan is unitary membership in which all HL7 members join HL7 International, which means a greatly diminished role for the affiliate organisations, if they continue to exist.

Michael van Campen (MvC) from Canada has been leading both task forces (as HL7 director elected by the affiliates) with assistance from Robert Stegwee (Co-chair of Affiliate Council, HQ Liaison and HL7 The Netherlands) and Catherine Chronaki from Greece (who is the other HL7 director elected by the affiliates but was an apology for this WGM). In addition to the affiliate chairs from HL7 Australia, Canada, Germany, The Netherlands, Switzerland, and UK, the CEO of HL7 (Chuck Jaffe), the Chair (Bob Dolin), the Executive Director (Mark McDougall) and the HL7 Honorary Treasurer (Hans Buitendijk) are participating in the work of the Task Forces.
David Rowlands, Chair of HL7 Australia, is a member of both task forces but was unable to attend this particular WGM. With the support of the Board of HL7 Australia, David Rowlands nominated Richard Dixon Hughes to represent HL7 Australia at the meetings of the AATF and IMATF being held in conjunction with the WGM. In so doing, the Board of HL7 Australia recognised that as Co-chair of the HL7 Advisory Council, Richard may have some conflicts of interest to manage (as do others including MvC) but, overall, would be in a good position to assist in progressing the work and the Australian interest.

PROGRESS AT THIS MEETING

AFFILIATE AGREEMENT TASK FORCE (AATF)

The affiliate agreements between HL7 International and its affiliates set out the rights and obligations of HL7 International and its affiliates and provide the legal basis under which affiliate organisations are able to operate as the HL7 affiliate in a territory, make use of HL7 International intellectual property and extend privileges of HL7 membership to their own members.
Current AATF activity is aimed at negotiating and agreeing a single common set of terms and conditions for the renewal of the affiliate agreement to commence in 2012 and run through 2013.
The major issues for Australia are the terms under which HL7 Australia may utilise HL7 intellectual property, distribute it to its members and allow it to be used in the production of local HL7 implementation guides and their publication as Australian Standards® under arrangements with Standards Australia.
The affiliate agreements previously in place were extended by one year up to the end of 2011, with the intention being that a revised agreement would be completed by mid-2011, ready for exchange in October/November to be in place for commencement on 1 January 2012 for the 2-year period 2012 through 2013.
Because of delays encountered by HL7 International in getting legal input and coordinating with other activities such as an update of the IP licensing arrangements, preparation of the revised agreement is running behind schedule. A new draft of the revised agreement as proposed by the lawyers for HL7 International was circulated to Affiliate chairs in mid-August. In preparing for these

meetings, the Board of HL7 Australia issued a communiqué outlining its key concerns about changes to the most recent draft of the affiliate agreement.
Richard Dixon Hughes attended the meetings of the AATF held on Q3 (Quarter 3) and Q4 Monday, 12th September, Q2 on Tuesday and Q2 on Thursday and the subsequent Affiliate Chairs' meeting representing HL7 Australia as a proxy for David Rowlands. Richard was unable to be in San Diego in time for the afternoon session of the AATF on Friday, 9th September (immediately before the WGM) but was given an update on progress and the opportunity to make any further input or comment on progress to that point.
Taking into consideration detailed comments put forward by some of the affiliates including UK, Canada, Australia and Germany (which also had support from Austria, the Czech Republic, Switzerland and some others), the meetings considered in detail the draft of the revised affiliate agreement after it had been re-drafted by lawyers for HL7 International. Key matters addressed during the WGM included:

1. Refinement of the wording in order to separate prefatory and explanatory material from the substantive legal provisions of the agreement, to improve its clarity and enforceability.

2. Recommended amendments to clarify that the agreement cannot be changed unilaterally by HL7 International changing its rules.

3. Restoring the rights of the affiliate organisation itself to use HL7 protocol specifications.

4. Substantive agreement that intellectual property arising from "Translation" of the HL7 Protocol Specifications (into other languages) would be treated separately from that arising from "Localization" (such as producing implementation guides). As requested by Australia, they are now addressed in separate sections with copyright in translations vesting in HL7 International and it being proposed that copyright in Localizations vest in the Affiliate (and not be "joint").

5. Obligations which operated unilaterally in favour of HL7 International were reviewed and, where appropriate, corresponding obligations were placed on HL7 International, particularly in relation to protection of each other's' intellectual property, disclaimer of warranty and indemnities.

6. The dispute resolution provisions were re-worked to be clearer and to better integrate with the draft terms proposed by the American Arbitration Association.

7. Additional administrative and reporting burdens on Affiliates being proposed under the agreement were reviewed and brought back to more closely reflect current reality.

Immediately after the WGM, Michael van Campen produced an updated version 9 of the draft agreement incorporating the recommended changes and circulated it to the members of the AATF and provided it to HL7 staff for further legal review.
The aim is still to try and get an agreement finalised in time to allow it to be executed to come into effect from 1st January 2012. This could still be achieved if everything goes smoothly and the deadlines in the following "happy path" schedule are achieved:

19 Sep	Submit to HL7 Staff / Legal [achieved]
19 Sep to 17 Oct	HL7 Staff / Legal review
17 Oct to 21 Nov	Affiliate Review and Vote to Approve
22 Nov	Submit final draft to HL7 Board for review
05 Dec	HL7 Board approval
06 to 31 Dec	Affiliate signature process
01 Jan 2012	New agreements commence

A response to the HL7 Australia communiqué was also received, indicating that all key issues had been addressed to the extent possible in the proposed v9 re-draft of the affiliate agreement.

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Affiliate Agreement Task Force (AATF) and renewal of Affiliate Agreement	The affiliate agreement that governs the arrangements between HL7 International and its affiliates (including HL7 Australia) is being updated for 2012 through 2013 to better reflect the contractual relationships between the parties and provide greater clarity around the use of HL7 International intellectual property. The changes are being negotiated through the AATF, of which David Rowlands is a member, with assistance from Richard Dixon Hughes and oversight by the HL7 Australia Board and with the aim of ensuring that existing rights such as member access to HL7 specifications and the ability to produce and publish Australian HL7 implementation guides as Australian Standards and other issues raised by HL7 receive favourable consideration and are incorporated into the draft agreement. **Action: HL7 Australia to continue with negotiation of a suitable affiliate agreement for 2012 through 2013 with the aim of facilitating the continued availability of HL7 materials in Australia under reasonable commercial terms and allowing the continued publication of HL7 Implementation Guides as Australian Standards.**	**HL7 Australia others as appropriate**

INTERNATIONAL MEMBERSHIP AND AFFILIATE SHIP TASK FORCE (IMATF)

PROGRESS AT THIS MEETING

Whilst the AATF centres on the arrangements that will apply over the next two years, the IMATF is considering the medium- and longer-term membership structure of HL7 and its affiliates, including the desire of HL7 International to become a more unitary organisation, whether there should continue to be affiliates and, if so, what role they should play. The IMATF has taken up some of the themes that arose in the One Member One Vote (OMOV) task force. The work of the IMATF still has some way to go but is particularly germane to current thinking surrounding the broader HL7 business model, the nature of HL7 membership and the use of HL7 intellectual property.
The IMATF met all day Saturday 10th September and during Q1 and Q2 on Wednesday, reporting back to the Affiliate Chairs' meeting on Thursday afternoon. Richard Dixon Hughes attended all meetings of the IMATF representing HL7 Australia as a proxy for David Rowlands.

Prior to the WGM, the IMATF had identified and fleshed out the implications of three principal models for the future, recognising that there are many variations of each. The three models and major implications (as clarified during discussions at the WGM) are:

1. National representation

   The basic feature of this model is that governance of HL7 as a global enterprise is organised through national representative bodies similar to that which operates in CEN (for the European region), ISO or IHTSDO. Individuals or organisations would belong to a national member body, with some arrangement (similar to that which operates in IHTSDO) to allow participation by those that come from a country that does not have a national body. Under this model, it is assumed that those in the USA would be represented by a national body. Variations include whether each country gets one vote or whether (national) membership fees and voting power for different countries could be scaled to reflect the strength of their economies and their contribution to the cost of running HL7 as a global organisation respectively. This model has been strongly advocated by some of the European membership.

2. Single membership

   This is a purely unitary model in which all individuals, organisations and others from around the world would join HL7 International as 'equal' members of the global organisation. In its purest form, the notion of affiliates (at least as independent organisations having separate memberships) would be phased out. The only form of membership for the purposes of receiving member benefits (including access to IP), payment of fees and participation in HL7 governance processes would be through HL7 International itself.
   Under this model, groups of members in some localities (countries, regions etc.) may have sufficient common interest to form either permanent or temporary groups to foster co-operation among themselves but these would have no official recognition, rights or role within the governance of HL7 International.
   Variations of this model include allowing for different fee scales depending on the strength of the economy in which a member operates.

3. Single membership with registration in one or more realms

   This option entails a unitary membership model in which all members belong to HL7 International but are registered to participate in the activities of one or more realm-based affiliates that have been recognised by HL7. This would particularly suit individuals or organisations operating in multiple territories and/or across national or regional boundaries. This model differs from single membership in that it assumes each member be registered with at least one Affiliate – and would likely require a US Affiliate to cater for the needs of US members.

After some discussion of the above, it was recognised that all have advantages and disadvantages in the eyes of many stakeholders and that, while far from perfect, retaining the status quo is also an option. So the following was added as a fourth option:

4. Status Quo

   As today, with individuals and organisations able to obtain various levels of member benefit by joining either an affiliate or HL7 International or both (and no US Affiliate).

For most models, where the affiliates continue as independently incorporated organisations, it was recognised that there are several different models for collection and distribution of membership revenues (including central collection, distributed collection, separate fees).

The principal items of business covered during the IMATF sessions at the WGM included:

1. Further clarification of the above four models.

2. The proposed HL7 business plan currently under consideration at the Board, which includes suggested new membership categories and a desire for a more unitary approach to membership and the management of HL7 intellectual property. The CEO provided additional information in confidence to both the IMATF and the Affiliate Chairs on the proposals currently being reviewed by the Board and participated in detailed discussion of the impacts and implications.

3. The Honorary Treasurer of HL7, Hans Buitendijk, was officially invited to join the IMATF.

4. Considerable discussion of the problems that would be faced by HL7 in some countries (particularly in Europe) if HL7 (as a US-based organisation) were to move to a unitary membership model without membership benefits being available through locally constituted representative bodies subject to domestic law, such as the existing Affiliates. The problems are understood to be both cultural and legal. As result of these discussions, the CEO indicated greater awareness and concern for the legal and cultural difficulties of moving to a unitary membership model without locally constituted representative bodies.
   The legal restrictions on some affiliate organisations sharing personal details with overseas organisations were noted as a current potential barrier to the maintenance of a unitary membership register enabling HL7 to better serve its global membership.

5. The need for HL7 to consistently communicate a stronger message about the overall contribution of international affiliates and their members to the HL7 global community.
   HL7 staffers often summarise the affiliates contribution as US$200,000 or only 5% of HL7 revenue of around US$4 million; however, this only focuses on affiliate membership fees funds rebated to HL7 International HQ. It neglects the total revenues raised by affiliates and the services, marketing and relationship-building provided directly by the affiliates out of their share of locally-derived revenues.
   An alternative formulation would recognise that for every $1 of revenue an affiliate pays to HL7 International, the affiliate raised $5, that not all HL7 HQ revenue is membership revenues and that when a member of an affiliate attends a WGM, this is included in HL7 International's revenue.

Compared with US$2 million in membership/licensing fees raised directly by HL7 International, affiliates raise around US$1 million or ⅓ of global membership revenues. Members of affiliates also contribute around 30% of WGM attendees. The total membership of HL7 across the globe is split approximately 50/50 with some 2,500 members belonging to affiliates and 2,500 belonging to HL7 International (ignoring those who belong to both or more than one affiliate).

The value of the affiliates in providing local representation, HL7 training and the marketing, promotion and distribution of HL7 products, and in leading the adaptation of HL7 to local needs is also not widely recognised in the way HL7 International reports on HL7 activities.

The IMATF noted the leadership of HL7 International needs to embrace these messages, if HL7 International is to be accepted by its wider membership as a truly global organisation.

6. The final session of the IMATF for the week was used to develop a set of evaluation criteria against which different membership of affiliation models could be compared. The criteria were developed in two separate groups with Michael van Campen being left with the task of preparing a draft consolidation. This resulted in a list of twenty factors to be further refined by the IMATF.

The Wednesday sessions of the IMATF were open for others to attend and several affiliate chairs and others participated including Ed Hammond (USA), Suptendra Sarbadhikari (India) and Phillip Scott (incoming UK chair).

Preliminary results of this work was shared through the Affiliate Chairs sessions of the International Council (with the CEO, Executive Director and Treasurer of HL7 all present) and will be taken forward through teleconferences of the IMATF in coming months. Richard Dixon Hughes made arrangements to ensure that both he and David Rowlands would be advised of the immediate outcomes of the weeks' activities so that he could check the outcomes and ensure an effective transition of Australian representation on the IMATF back to David Rowlands.

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
International Membership & Affiliation Task Force (IMATF)	The IMATF is considering the medium to longer-term membership structure of HL7 and its affiliates, including the desire of some in HL7 International to become a more unitary organisation, whether there should continue to be affiliates and, if so, what role they should play. These discussions overlap consideration by the HL7 Board of its forward business plan and potentially impact the role of HL7 Australia and the benefits currently received by its members and the Australian eHealth community. **Action: HL7 Australia to continue engagement on HL7 membership model through IMATF with view to ensuring Australian stakeholders can continue to obtain HL7 membership benefits cost-effectively and have their interests in HL7 represented locally and at the global level.**	**HL7 Australia others as appropriate**

8 HL7 BOARD OF DIRECTORS AND GOVERNANCE

DESCRIPTION

The HL7 Board is the principal governing body for HL7 International. It has four face-to-face meetings each year (at the three working group meetings and at the annual Board retreat) and holds regular teleconferences in the other months.

The Board comprises fourteen voting members - the Chair, Vice-chair, Treasurer, Secretary, seven directors at large (including three appointed by the CEO), two directors elected by Affiliates and the Chair of the Technical Steering Committee (TSC). The senior executive team (CEO, CTO end Executive Director) are non-voting members of the Board and the Advisory Committee external Co-chair is an invited non-voting participant.

The CEO report, CTO report and Treasurer's report are standing items on the Board agenda and general governance issues arising from these reports will also be discussed in this section.
As the Advisory Council external Co-chair, Richard Dixon Hughes participated in the Board meeting as a non-voting member of the Board. The Board meeting ran from approximately 15:30 to 22:00 hours on Tuesday, 13th September with a one hour dinner break.

PROGRESS AT THIS MEETING

GENERAL BUSINESS

In addition to topics covered in more depth later in this report, the following are among the more notable matters which were addressed by the Board at its face-to-face meeting.

Board appointments

The new appointments to the Board for two-year terms from 2012 will be Michael van Campen (MvC) (Honorary Treasurer), Becky Kush and Ed Tripp (Directors at large), Diego Kaminker (Director elected by affiliates – replacing MvC in this role).
Bill Braithwaite, Dennis Giokas and Hans Buitendijk will be leaving the Board and received the first of many thanks for their contributions. The CEO is yet to nominate someone to replace Dennis Giokas as one of his nominees on the Board.
Note: with MvC becoming Honorary Treasurer, the international affiliates will have a voice on the inner Executive Committee of the Board for the first time.

Strategic initiatives

The annual update cycle of the HL7 strategic initiatives concludes with their adoption by the Board for the following year at the annual plenary meeting. The most recent (August) draft of the 2012 Strategic Initiatives incorporates prior inputs and discussion and was put forward for adoption. There was some debate over the need for inclusion of product strategy.

International WGM 2013

A previous proposal to hold the international WGM in France in May 2012 was unable to be progressed due to difficulties finding an appropriate venue at the right price; however, the Board would like to proceed with a meeting in France, if it can be arranged at a reasonable

cost to HL7 and the delegates. A further proposal is now being prepared to hold an international WGM in France in May 2013, with either Bordeaux or EuroDisney (near Paris) being the likely venues. Previous research has indicated that such a meeting can only be run at a loss to HL7 International. The level of underwriting to be used in planning the event has been referred to the Finance Committee for guidance, which will depend on HL7's financial situation at the time.

The possibility of several European countries banding together to run a WGM was also discussed with Germany and The Netherlands possibly being prepared to consider subsidising a joint event at some point.

New affiliates

Bosnia and Herzegovina has been through the due diligence process and is ready to be admitted subject to confirmation of a minor issue concerning diversity of interests, International Council confirming the recommendation and the affiliate signing the affiliate agreement.

Mexico submitted a very comprehensive proposal on 9th September and is awaiting the Due Diligence Committee to translate some of the submissions and interview the petitioners before a recommendation is made. The application appears very strong and there is a possibility that it may be able to be progressed in time for Mexico to become an affiliate at the January WGM; however, given the previous history with affiliates in Mexico, care is being taken to ensure that the new arrangements are likely to sustain a satisfactory and continuing relationship.

The HL7 China affiliate is reported to be a bit behind in running its elections but is in contact with the Due Diligence Committee and matters are expected to be resolved in due course.

Education strategic plan

Abdul Malik Shakir gave an update on the education strategic plan project which was given on behalf of the Education Committee. The plan is now targeting a much broader reach, including recognising growing needs around the world (not just the US, and needs for education services beyond those provided by HL7 itself. Engagement in finalisation of the plan is encouraged and conference call times have been moved to facilitate world-wide participation.

A core recent activity has been the conduct of a survey of needs and activities. The plan identifies 85 actions, which can be summarised under the following seven key themes:

1. Stakeholder needs assessment – identifying the various communities that need training (including educators as well as implementers);
2. Collaborating with others in development and delivery of education – noting the need to train/educate over 10,000 people per annum in coming years;
3. Content development;
4. Delivery methods;

5. Quality assurance (ensuring that relevant and appropriate feedback is obtained and analysed, especially for new online methods, and that an increasing number of tutorial givers are trained in instructional techniques);
6. Content management (policies for versioning, distributions); and
7. Resource management (can we do our own webinars, podcasts etc.).

A priority for the Education Committee is to finalise the needs for support of expanded education activities in the 2012 budget for HL7 International.

In response to a question, Abdul Malik, confirmed that significant valuable input is being provided to the Education Committee from Australia particularly through Heather Grain's recent involvement.

eLearning update

eLearning is a growing success story. Two thousand, one hundred and ninety-nine students have completed the course to date. The first 2011 edition ran from March 2011 to July 2011. The second edition has no wait list for the first time ever as they can now admit more students per course, thanks to improvements in online technology. It is expected that eight hundred to nine hundred students will complete the program in 2011.

Engagement with the American College of Physicians (ACP) and the American EHR Partners program.

ACP is a professional body with a membership of one hundred and thirty-five thousand, over 90% of which are front-line family physicians in practices of five or less. It has had a long and supportive relationship with HL7 and its CEO up until earlier this year. Dr John Tooker, is a member of the Advisory Council.
Dr Thomson Kuhn addressed the Board on behalf of ACP and introduced the American EHR Partners program jointly developed by the ACP and Cientis Technologies, a Canadian research and consultancy firm. Points made by Dr Kuhn included the following:

- Most physicians don't know about technical eHealth standards, don't want to know and should not have to know about them,
- On the other hand, interoperability of EHR systems and information is becoming increasingly important to physicians and for this reason they need help to understand the relationship between standards and interoperable use of their EHR systems,
- It is also important to have means of identifying and making contact with the small proportion of physicians that have the interest and ability to use EHR systems and IT to lead improvements in clinical practice and care delivery,
- The American EHR Partners program provides an interactive online community of physicians supporting physicians in the selection, implementation and ongoing use of EHR systems in their practices,
- There are around ten thousand, five hundred clinicians and the program is supported by over a dozen clinical societies as well as industry bodies, including

AHIMA (American Health Information Management Association) and AAPC (Practice Coders),

- Features include newsletters; blogs; system evaluation and rating forums; the ability to search, display and compare appropriate EHR solutions; readiness tools and training tools,
- The site includes increasing amounts of information from broader collaboration in areas such as clinical quality reporting; chart coding; patient engagement; accountable care organisations (ACOs) and other new practice reimbursement models; point of care advice and decision support; population health management; the patient-centred home; and care coordination,
- HL7 was invited to become a "content partner",
- They are able and open to participation from overseas and are keen to enter into open source sharing of information,
- More information is available from http://www.americanEHRpartners.com and membership is free to users,
- The HL7 Board will consider the implications and potential benefits in terms of clinician engagement of participating as a content partner.

HRex and bundled IP rights for local health authorities

Following the success of a pilot project in California (Cal-x) for lab data exchange and mining of population health and biosurveillance information, Homeland Security (HS) and CMS have issued a letter of commendation and approved the Cal-x project being scaled up to a nation-wide implementation.

The new national program is known as HRex and went live on 29th August. This program will implement exchange of laboratory data between commercial and public agency labs and the three thousand, five hundred state and local health departments using communications based on HL7v2.5.1. A central repository will provide infrastructure to support bidirectional lab reporting between the Centers for Disease Control (CDC) and the various health departments.

As part of the arrangements, an agreement in principle has been reached with CMS for the various health departments to be licensed to use HL7 v2.5.1 for US$1000 p.a. apiece (totalling US$3.5M in annual revenue). A contractual agreement has yet to be finalised but when concluded should relieve some of the financial pressures on HL7.

Relationship with ONC and US Government agencies

There are now regular meetings between ONC and the HL7 leadership to ensure delivery of implementation guides, quality measures and other artefacts needed to support the ONC Standards & Interoperability (S&I) framework. It was observed that the relationship between ONC and HL7 leaders at the meeting was very positive, professional and collegiate, which should be of benefit to all.

It was noted that the additional US$2 billion in ARRA/HITECH funding being administered by the ONC will expire in October and that the office will be running on its annual budget of around US$ 70 million from that point onward, most of which will be consumed in salaries.

HL7 is working through and resolving issues with licensing of its IP in various US government agencies, with a new shrink-wrap licence being agreed with CDC (for specifications being

issued by them), which will also be adopted by the Agency for Health Research and Quality (AHRQ).

International outreach

The following international outreach activities on the part of HL7 were noted:

- Pakistan HIT Summit Nov 22-24. HL7 has been asked to deliver the keynote presentation at the national program on healthcare information and interoperability;
- European Healthcare 2011. HL7 will give a keynote presentation in Vienna on 21st September highlighting SDO collaboration, integration of HL7 specifications into global solutions and the impact of HL7 technology on pan-European exchange of clinical data;
- Peoples Republic of China. A keynote address will be delivered on 7th November to various government agencies supporting healthcare and clinical research. The focus will be on the use of HL7 for interoperability amongst bodies;
- Medical Informatics Europe (MIE). HL7 provided a half-day workshop at the annual meeting in Oslo in August and provided a range of other presentations;
- Canadian Healthcare IT Summit. HL7 will present on 28th September, addressing opportunities for tooling, data reuse, and education;
- EFMI Special Topics conference in Moscow, April 2012. HL7 has been invited to present and will focus on leveraging the HL7 experience;
- eLearning program in Russian – to be developed for use in the Russian Federation and other Russian-speaking countries; and
- Russia - Meetings with ministers of several agencies (Health, Communication, and President's Office) to promote RFPs for healthcare IT projects to include conformance with HL7 standards.

Pledge to support individuals in their health through IT

After consideration of a request to adopt the Health IT Pledge for non-Data Holders as promoted by the U.S. Office of the National Coordinator (ONC) as part of the US Government's support for eHealth in America, the Board unanimously agreed "to pledge to engage and empower individuals to be partners in their health through information technology" and encouraged HL7 members to take either the Pledge for Data Holders or the Pledge for non-Data Holders as appropriate.
An HL7 press release provides more details and may be found at:
http://www.hl7.org/documentcenter/public_temp_05240E46-1C23-BA17-0CD780D7BF328345/pressreleases/HL7_PRESS_20110914.pdf
More details about the pledges can be found on the ONC website at:
http://www.healthit.gov/pledge

HL7 Chair Emeritus

In honour of his long and distinguished service to HL7 International, the Board approved Ed Hammond being appointed the first Chair Emeritus (an honorary position, without separate voting rights).

HL7 FINANCIAL POSITION AND BUDGET

In recent years, there has been some decline in HL7 International revenues requiring belt-tightening measures including deferral of some investments in additional capability.

The 2011 HL7 International budget included estimates of revenue at $3.515 million (USD) and expenditure at $4.047 million for a deficit of approximately $0.5 million.

One of the key objectives of work being carried out on the HL7 business plan has been to ensure that HL7 is financially sustainable and has the financial resources to make required investments in technology and support services. Preliminary measures to stabilise the financial situation commenced in the 2011 year and included cuts to discretionary expenditure and measures to increase membership and reducing abuse of HL7 intellectual property rights by non-members.

These measures are proving effective and forecast outcome for 2011 is now expected to be a surplus of around $300K with the turn-around driven by higher revenues of $4.468 million, some 27% better than the original budget. The higher revenues are particularly due to an increase in membership and several better-than-expected education events. The Sydney 2011 ISEMWGM was factored into the budget on the basis that it would break even for HL7 International, which was achieved.

The increase in membership is a direct consequence of HL7 collaborating with key industry bodies to be more proactive in following up non-member organisations that market products based on HL7 protocol specifications. When these organisations are reminded that they need to be members of HL7 in order to use HL7 intellectual property legitimately, most sign up and pay their dues promptly. The campaign continues while a revised longer-term business plan is finalised.

Assuming similar revenue streams and expense burn rate, key elements of the preliminary 2012 budget for HL7 International is as follows (USD):

Revenue:	$4,530,000
Expenditure:	$4,199,143
Net operating income:	$330,857
Year-end cash:	$4,442,974
Projected year-end reserves (mths):	12.7

One of the key messages for Australia is that HL7 International will continue being more active in managing the distribution and use of its intellectual property while its principal revenue stream remains tied to use of its IP through membership and that, while some changes are being considered, this situation is not expected to change significantly in the next year or two. Australian interests will need to factor this into their plans and ensure that adequate provisions continue to be made for access to and use of HL7 International's intellectual property.

HL7 BUSINESS PLAN

The CEO, executive team and external consultant, Virginia Riehl, have progressed a revised business plan for HL7 International to the point where a detailed discussion draft has been circulated to the HL7 Board for its consideration.

The full details of the proposed business plan and underlying financial projections remain confidential to the HL7 Board until the Board has had time to consider it and agree to its being progressed to the next stage. The CEO presented a broad outline of the key features of the proposed plan and the process for its adoption to the general session of the International Council. The proposals being put to the Board were also presented to and discussed at meetings of affiliate chairs on a confidential basis.

Development of the plan has taken into account inputs from varied sources, including: the Advisory Council, the Board and its Business Model Task Force (whose role is now complete) and the wider HL7 stakeholder community, including national Affiliates. Key elements as presented at the open meeting of the International Council include:

- Increased revenue through growth in membership including both growth in current categories and the introduction of new categories for more direct engagement with clinicians;
- Continuing to protect HL7 IP appropriately by simplifying and widely publicising IP policies and strongly encouraging users of HL7 IP to become members or pay appropriate fees for access and use;
- Novel packaging of IP and membership rights including more directly addressing the particular needs of provincial/state and national programs;
- Increased educational offerings delivered at more levels through more channels in ways that better address the needs of potential users;
- More professional support to assist in the administration of HL7 Work Groups and facilitate the more rapid development of better quality HL7 specifications and standards;
- Continuing the development of tooling beyond the needs for standards development – simplifying implementation and facilitating greater uniformity of implementation;
- Improved branding and marketing with a focus on identifying and meeting customer needs; and
- A desire to move toward internationalisation that achieves “one member one vote” and implements an equitable dues structure across all realms.

It is proposed that further investigation to be conducted into 2012, including independent market research, to assess the feasibility of, and potential approaches to, changes in the following areas:

- A more unified membership structure for HL7 as a global organisation that works toward “one member one vote” and an equitable dues structure across all realms, considering: What needs to change? And what needs to stay the same?

  This aspect of the updated business plan will need to take on board the views of the affiliates (which represent half of HL7's global membership) and the work being carried out by the IMATF on alternative membership models.
- Potential separation of membership and intellectual property rights. What is the likely impact on membership, participation and revenue?
- Revamped membership fee structure: Will stakeholders support the process and the financial implications? What are the price-volume trade-offs?

- Free-of-charge licensing for use of HL7 specifications. If this is an ideal end-state, how does HL7 get there and continue to fund itself?

The timetable suggested by the CEO for decision-making and implementation of the proposed business plan following its presentation to the Board at the September 2011 meeting would be:

- Board Approval: Target Oct 2011 (approval in principle)
- By the end of the first quarter of 2012: completion of independent market research – including assessing the market acceptance (including among commercial vendors) for more sweeping changes that would separate IP rights from membership (including possible increases in fees paid to HL7), the impact on membership revenue, and the implementation requirements
- Refinement and update of the plan over the next six to twelve months to reflect the outcome of market research and consultation with HL7 stakeholders (including affiliates)
- Implementation: to be incremental over the period 2011 to 2013; guided by the feedback from further investigation & market research; supported by time-delimited decision points and feedback; and flexible (driven by the revenue cycle).

Core elements of the proposed HL7 business plan include an increase in HL7 membership, more bundled offerings and enforcement of IP policy and these aspects have already commenced – along with a 5% increase in rates for various classes of membership from January 2011. These measures have largely been responsible for a turn-around in the projected results for 2011.

Hopefully, if paying memberships can be significantly increased in both the US and around the world, this may allow the rates to be scaled back so that HL7 membership becomes more affordable to a much larger community.

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
HL7 Board – proposed new business plan	Building on previous considerations including work by a Business Plan Task Force, the HL7 CEO has put forward a proposed new business plan. This plan potentially impacts the role of HL7 Australia and the benefits currently received by its members and the Australian eHealth community. **Action: HL7 Australia to participate in review and comment on proposed changes in the HL7 Business Plan with a view to ensuring Australian stakeholders can continue to obtain HL7 membership benefits cost-effectively and have their interests in HL7 represented locally and at the global level.**	**HL7 Australia others as appropriate**
HL7 Business Model & Business Plan	Overall, there is a good relationship and a high level of mutual respect between the Australian HL7 community and HL7 International; however, as HL7 International updates its business model and seeks to become a more globally relevant organisation with a global membership, Australians need to ensure that the HL7 leadership understand Australian interests and the need for a value proposition for use of HL7 products and services that makes sense in Australia. It is particularly important to ensure that Australian stakeholders are consulted as part of the independent market research for the HL7 Business Plan and provide feedback on the proposed changes. **Action: HL7 Australia to participate in review and comment on changes in the proposed HL7 Business Plan and seek to have Australians included in any stakeholder feedback and market research undertaken to support implementation of the plan.**	**HL7 Australia others as appropriate**
Protection and use of HL7 intellectual property	The stability of HL7 International's financial position is likely to continue to depend on organisations paying a reasonable price for use of its intellectual property (IP), at least for the next few years. Without other sources of revenue, ongoing protection of its IP therefore remains a priority for HL7 International, and this needs to be respected where HL7 IP is used in Australia. **Action: HL7 Australia, Standards Australia and NEHTA to ensure that effective measures are in place to protect HL7 International's IP when distributed and used within Australia.**	**HL7 Australia,** **Standards Australia & IT-014** **NEHTA**

9 FRESH LOOK TASK FORCE

DESCRIPTION

The "Fresh Look" Task Force (TF) was formed in March 2011 to carry forward some of the work of the former v2/v3/CDA Task Force. Dr Stan Huff was appointed chair of the TF with power to appoint the members. The initial goal was to focus on potential future needs for standardised representation of shared clinical models and their application in information interchange and the TF was hand-picked to include experts in these fields from both within and outside HL7. One of the primary reasons for this is that the HL7 V3 standard is widely thought to be too complex and to have failed to meet the needs of the community of interest.

This TF was formed and soon afterwards its members decided to pursue a Clinical Information Modelling Initiative (CIMI) as an exercise separate from the "Fresh Look" commission within HL7. The results of the CIMI activity were not reported to the HL7 Board**.**

As a result, the activities of the Fresh Look Task Force have divided into two separate streams:

1. The Fresh Look Task Force, which is operating under the auspices of the HL7 board, is to look at how HL7 can move forward and how it can best meet the needs of its members and user base.

2. The Fresh Look Clinical Information Modelling Initiative is not under the auspices of the HL7 board and has a wide group of international participants. The task for this group is to examine a wide variety of different methods for representing clinical information models and to agree on a common way forward for the international community.

The activities of each of these two separate streams will now be discussed.

FRESH LOOK TF – REVISED ROLE

The Fresh Look TF has now recommended that the "Fresh Look" activity within HL7 becomes an on-going innovation support function (rather than being a one-time thing that produces a set of recommendations and then disbands) with a revised scope that would include the following:

Envisioning the future - Envision the future situation and then make a plan and roadmap to get there, considering:

- What are the forces that shape the future? (such as: government policies; needs of the research community – SHARP, CTSA, CER, SMART; the move to patient centred care and the patient controlled electronic medical record);
- What does HL7 need to do to in order to create the future? and
- What are the resources that can help create the future?

Nurturing innovation - Use of "Fresh Look" as a means of triaging new ideas and initiatives. This would involve creating criteria for making recommendations (including comparing how ideas fit with the HL7 strategic initiatives and the "Fresh Look" vision of the future) and making recommendations for change to the Board and TSC based on robust use cases. As an incentive, challenge prizes may be offered as a means of stimulating new ideas.

Supporting implementation - A key element needs to be a focus on improving implementation of standards and not just their creation. Some suggested approaches for doing this include:

- HL7 having processes that include implementation is an inevitable outcome (such as those used by OMG);
- Implementation facilitation and guidance - support for local to standard mapping; terminology mapping; and maps from other standards to HL7 standards; and

- "Just in time" configuration of payload contents (messages or services).

Aligning policy and practice - Considering changes to management processes such as:

- Researching internal behaviours and culture, how recommendations are made to the Board, how technical and policy decisions are made;
- New internal policy such as HL7 balloting requirements and then contracting for production of the standards;
- Bringing in work being done in the affiliates that would be of global value; and
- Requiring that people must be implementing systems as they create the standard.

Improving communication

- Continuing discussion of issues in open forums;
- Developing and encouraging different modes of communication through HL7 channels; and
- Using Web-based tools to solicit input.

The TF has recommended that the following be specifically excluded from the scope of the Fresh Look TF:

- Resolution of V2/V3/CDA Task Force issues and
- Relationship to Clinical Information Modelling, including Grahame Grieve's recommendations on Resources for Health (which is already being progressed in TSC and relevant WGs) and use of CIC for expert clinical input to HL7 modelling processes.

In order to progress these recommendations, the TF recommended that the change of scope be communicated to the general HL7 membership and that an open forum and one-day meeting of the task force be convened for the January 2012 WGM.

Discussion of these proposals (which were then approved by the Board) included consideration of the following:

- The need for appropriate constitution and membership of the ongoing "Fresh Look" function, noting that its scope has been redefined to exclude clinical modelling, which was the original basis for the selection of its members.
- The need for a connection to be re-established between HL7 and the now independent CIMI function so that HL7 is able to be informed of its deliberations and to consider and respond appropriately to its findings.

PROGRESS AT THIS MEETING

FRESH LOOK - CLINICAL INFORMATION MODELLING INITIATIVE

The Fresh Look Clinical Modelling meeting occurred on Sunday afternoon from 1pm and was very well attended by an international group. There was representation from Australia, Singapore, UK, USA, Canada, the Netherlands and others. Within the representation, there were also people from the US Veterans Affairs and Department of Defence, as well as vendors and a number of national programs. A total of about thirty people were present in person and by teleconference. There was no doubt that this topic was of great interest to a number of jurisdictions and vendors as was evidenced by the large turnout and lively debate.

The group spent some time discussing a proposed name, before settling on CIMI (Clinical Information Modelling Initiative.)

At the meeting there were discussions around three main topics:

1. **Data types including HL7 and ISO data types**
   The discussion revolved around the fitness for purpose of these standards. It was generally agreed, that the ISO data types were not really fit for purpose and that some changes would be needed to make them fit for use with clinical models. Suggestions were using a particular profile of the data types, modifying the standard to make it better for implementation, or using a different set of data types such as the openEHR data types or a set that Graham Grieve and Thomas Beale had been working on which were similar to the openEHR data types.

2. **Reference Models**
   There was a preliminary discussion of reference models including openEHR and CEN 13606. Interestingly, the HL7 V3 RIM was not considered a candidate for this process. Reference models were discussed in terms of the need for a consistent and reliable approach to creating models that were able to be computable and used to generate other artefacts using automated approaches.

3. **Single Modelling Formalism**
   The task force has a plan for selecting a single formalism going forward. There are a wide range of possibilities for a modelling formalism, however currently they have been narrowed down to the following possibilities:
   - UML models
   - openEHR Archetypes
   - CEN 13606 Archetypes

   Other formalisms such as Intermountain Health CML and the UK LRA project (currently in suspension) are not being considered at this time.

The meeting is going to be reconvened on the weekend before the IHTSDO meeting where some of the formalisms will be presented (Sydney, 8th and 9th October 2011).

Overlap between the Clinical Information Modelling Initiative and Detailed Clinical Models

There is considerable overlap between the DCM initiative and the CIMI initiative. Indeed, the two are trying to achieve the same result and the UML technology that has been used as a default within HL7 is one of the technologies that is being considered by CIMI. The CIMI has a larger and more international membership and is looking at a wide range of models. Australia should watch this closely and consider adopting the CIMI approved approach for clinical modelling as its national approach.

The Fresh Look Task Force met on Monday afternoon for two quarters. The first quarter was open to all participants, while the second was closed to invited participants only.
The main topic on the agenda for the first quarter was a presentation by Graham Grieve of his proposed 'Resources for Healthcare' approach which achieved a lot of interest from many parts of the HL7 community. Resources for Healthcare (RFH) defines a set of "resources" that represent granular clinical concepts. The resources can be managed in isolation, or aggregated into complex documents. This flexibility offers coherent solutions for a range of interoperability problems.
The simple direct definitions of the resources are based on thorough requirements gathering, formal analysis and extensive cross-mapping to other relevant standards. A workflow management layer provides support for designing, procuring, and integrating solutions.

Technically, RFH is designed for the web; the resources are based on simple XML, with an http-based RESTful protocol where each resource has predictable URL. Where possible open internet standards are being used for data representation. More information about this approach is available at the link shown below: http://www.healthintersections.com.au/rfh/introduction.htm

While the resources for healthcare approach are in very early stages of discussion, it generated a great deal of interest at this working group meeting. It is likely that RFH will have more work put into it over the next months and years and may represent a way forward for HL7 as a new approach.

The second quarter invitation only session had representation from the HL7 Board, Canada Health Infoway, UK Connecting for Health, IHTSDO and others. Australia is not officially represented on this task force, however neither are a lot of other countries. Australia's interests are represented by Dr Sam Heard, whose proxy at this meeting was Dr Hugh Leslie. During the meeting there was a discussion about how the task force should operate. It was clear that the task force was not equipped to decide about what the future should be, however it should be able to provide a place where innovative ideas can be heard, discussed and then passed to the wider community. There was wide ranging discussion about how to make this happen but no decisions were made.

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Fresh Look Task Force	This group has the potential to steer delivery of new products which leverage HL7's organisational and technical strengths while addressing major model, interaction, and content-based limitations in Clinical Communications, Decision Support, and workflows. **Action: HL7 Australia, and IT-014 should consider how best to be updated on progress and encouraged to contribute any Australia specific issues. Oversight should be established with a relevant IT-014 committee.**	**IT-014** **HL7 Australia**

10 TECHNICAL GOVERNANCE MATTERS

DESCRIPTION

This section addresses general issues relating to overall governance of the HL7 technical program as reported in presentations by the CTO and chair of the TSC in meetings of the Board, International Council and general sessions:

PROGRESS AT THIS MEETING

The following are among the matters of technical governance of interest to Australia:

- The Open Health Tools (OHT) group is now proposing to implement an open clinical artefact repository in close collaboration with HL7. As this was the most costly component of the proposed HL7 tooling, HL7 will no longer undertake this as an in-house project but will collaborate with OHT in developing a repository that will meet the shared needs of HL7 and the OHT implementation community.
- HL7 funding for tooling. The CTO is hopeful that HL7's improved financial position will enable some of the suspended tooling work to proceed and proposals are being prepared.
- Services Aware Interoperability Framework (SAIF) CD is now ready for balloting
- SAIF Implementation Guide will not be ready to identify a new Behaviour Framework until the current SAIF and OO project is much further along
- OMG / HL7 methodology alignment continues
- HL7 Tooling Plan with be aligned with Board Approved Strategic Initiatives
- HL7 Implementation: Develop standards that are easier to implement and more responsive to customer needs

Details of CTO PowerPoint presentations naming specific HL7 tooling proposals and proposed priorities are available on request through the IT-014 Secretariat at Standards Australia..

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Technical Governance Matters	**No actions recommended.**	

11 ARCHITECTURAL REVIEW BOARD (ARB)

DESCRIPTION

The Architecture Review Board has been resourcing the Service-aware Interoperability Framework (SAIF) for several years as a key building block for HL7 realising an Enterprise Architecture to guide the development of HL7 artefacts. SAIF is also a core interoperability approach for many external organisations, providing a common method of structuring specifications such that they can be used collaboratively in different solution settings.
At the Sydney WGM, the ARB agreed to create an initial version of the SAIF Book available for informative ballot at the HL7 Orlando meeting in May 2011. There are many HL7 projects piloting SAIF and beginning to exercise the content of the SAIF work and will result in a more consistent process for independent HL7 artefacts to be externally orchestrated in different solution contexts.

PROGRESS AT THIS MEETING

Prior to this Working Group Meeting, it was decided to put off the normative ballot of the SAIF book following on from the successful informative ballot in May 2011. The informative ballot resolution resulted in significant content changes which were subsequently only completed at this WGM. The most significant changes include:

- The Enterprise Conformance and Compliance Framework (ECCF) has had a change in title to Enterprise Conformity and Consistency Framework (ECCF). This change is seen to more accurately represent the focus of ECCF that is more than conformance and compliance (now captured under conformity) as it includes traceability and compatibility (consistency). This change probably more reflects inaccurate understanding of compliance but does make some of the broader applications of ECCF more explicit.

- At the May HL7 WGM, it was agreed to split SAIF into the SAIF Canonical Description (CD) and Implementation Guide (IG). The CD includes a set of abstract models (called languages) that describe the concepts supported within the four frameworks: Governance Framework (GF), Enterprise Conformity and Consistency Framework (ECCF), Information Framework (IF), and Behaviour Framework (BF). This implicitly provides a set of requirements that are the basis for an IG. An IG provides a set of concrete modelling grammars and associated artefact templates that meet the obligations set out more generically in the CD. HL7 will, as part of its enterprise architecture programme, define its own IG complete with artefact templates and specific grammar choices. It is assumed that

others will develop IG's based upon their own grammar selections and artefact requirements. The common reference point will be the CD but the greater the overlap between IG grammars and artefacts, the greater utility of interoperability between IG's.

- The Governance Framework (GF) is the least contentious part of SAIF and alongside the ECCF provides the most agreeable foundation from an HL7 perspective. Each in its own right is about governance of organisations and artefacts such that aligned interoperability outcomes can be produced. Little significant change has followed balloting but there still remains work to do in HL7 adopting an ECCF-based conformity assessment process.

- The Information Framework (IF) and Behaviour Framework (BF) have been the most contentious part of SAIF as they have the most potential impact on the content of HL7. On one hand, many consider their efforts inadequate to cover all existing requirements of static and dynamic content descriptions but on the other hand are too prescriptive to allow for different modelling methodologies to co-exist alongside HL7-related efforts. Cecil Lynch is the primary author of the IF and has made significant changes to his original draft to capture a more abstract canonical model for information allowing for a mapping into current and future HL7 information models as well as to those outside the realm of HL7 such as OpenEHR and Snomed CT.

- The Behaviour Framework has invoked much debate. It proposed a new behaviour model that covered both CD and IG modelling elements. It was both castigated for too little detail and too much detail. One of the drivers for extracting the canonical content into a separate document was to provide for an easier introduction into all the SAIF frameworks and also to step away from prescribing new concrete modelling approaches when others may want to reuse existing approaches/grammars. This restructure of the BF continued at the San Diego meeting with further extraction of IG material from the CD material.

- A further effort on the SAIF CD was around a revamped set of concept maps that have become the basis for SAIF training material. The goal is to articulate the concepts and relationships constituting the basis of the SAIF CD in single framework maps. Through the ongoing distillation process, we are getting much closer to this goal with simplicity overriding completeness.

- The aim is to ballot the normative SAIF CD at the January WGM. This will be based upon the new editorial work as well as new compliance criteria required for validating Implementation Guides against the SAIF CD. NEHTA have made a contribution to this based upon our own work around the National eHealth Architecture Framework and the National eHealth Solution Framework.

- Work continues across various working groups to imbed SAIF modelling approaches into HL7 artefacts. The HSSP Project has begun a rewrite of their Service Functional Model (SFM) Guide to express requirement in SAIF concepts and structure. However the majority of the SAIF artefact template specification is happening under a Modelling and Methodology (MnM) project specifically aimed at delivering the start of the HL7 Implementation Guide.

http://www.hl7.org/Special/committees/arb/index.cfm

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Architectural Review Board	**No actions recommended.**	**N/A**

12 CLINICAL DECISION SUPPORT (CDS)

DESCRIPTION

The CDS WG develops communication standards (including documents, services, messages), information models (including Virtual Medical Record- vMR), support tools, an expression language and knowledge representation formalisms around Clinical Decision Support. This is both patient-centric for alerts, reminders and care optimisation as well as population-based for quality assurance and surveillance. The WG identifies the controlled vocabularies and develops the feeder and response communications for interactions with CDS systems. It works closely with the Arden Syntax WG (overlapping chairs) which develops a specific knowledge formalism now implemented in deployed systems. The WG also collaborates closely with HL7 clinically focussed groups whose stakeholders use CDS and which also develop standards useable by, or closely aligned with those of, CDS. These include Patient Care, Orders and Observations, Clinical Genomics, and CDA/Structured Documents (documents and messages for Referral, Patient Care Provision, Lab Orders and Results, Guidelines and Protocols which form bases of standardised feeders, outputs, and control of CDS systems). The group has also developed a CDS Services standard in collaboration with HL7 SOA and the OMG HSSP project. The WG membership mainly comprises vendors with working applications and clinicians associated with academia or industry. There is currently no V3 facilitator.

With its end-points of care optimisation, quality and safety, CDS is arguably the raison d'être of Health IT and of prime importance to the Australian community. It is however not well-aligned with our local standards work groupings. Deployments tend to be ad-hoc without standardized criteria for reliable, safe interoperation. They are however widely used in clinical practice especially Primary Care.

PROGRESS AT THIS MEETING

http://wiki.hl7.org/index.php?title=Clinical_Decision_Support_Workgroup

Status of Current Principal Standards

Arden Syntax version 2.8 passed normative ballot in May 2011. Version 2.9 will include fuzzy logic and enhanced interfacing to other languages, including GELLO through Arden's "Curly Braces"

which will provide a level of RIM interfacing; it will be worked on for January 2012. Arden's current data model is not RIM-based.

The DAM for the Virtual Medical Record, vMR is a Draft Standard for Trial Use (DSTU) and its September ballot was reconciled at this meeting. It is intended to be enhanced as Release 2 for the January 2012 ballot.

The Gello (OCL-derived) Expression Language ballot was also reconciled at this meeting and enhancement for a further ballot is targeted for Jan 2012.

Context Aware Information Retrieval or Info Button is a balloted normative standard and addresses content but needs development of a Services component. This standard has strength and weakness in simplicity, ease of use and implementation.

HL7 Decision Support Service (DSS) Standard --normative HL7 standard passed ballot in May 2011.

HL7 Decision Support Service (DSS) Service Functional Model (SFM) specifies business requirements and functional capabilities of DSSs and has been in DSTU since December 2006.
Order sets Draft Standard was balloted and reconciled in 2008, but yet to be incorporated into a current document and published as DSTU although groups want to use this now.

Virtual Medical Record Project (vMR):

The vMR uses only the CDS-essential EHR abstractly specified data. It is thus independent of implementation technologies including HL7 V2, V3 messaging and V3-CDA. It encourages CDS at the point of care by reducing costs and response turnaround time. It eliminates the need for EHR vendors to maintain proprietary CDS structures and messages. It is of great value to emerging clinically focussed applications addressing patient outcomes and community needs.

vMR is being further developed with more Implementation Guides (IGs) and Template specifications for standard data models: CCD, Care Plan of PC, and for priority tasks of CDS eg. drug –drug interactions, vaccine advice, family history risk analysis and genomics. Transformations are being developed between standard models and it is moving to more alignment with HL7 work.

CDS and Public Health Emergency Response PHER TCs continued work on immunisation decision support. We reviewed one member's production, Arden rule-based solution, which executes a background immunisation check and alert whenever a patient presents to Outpatients for any reason. We reviewed work so far by CDC who will implement immunisation support in a formalism which they are in the process of specifying and selecting. Initial use case will be Hepatitis A immunisation. They are most likely to select Gello or Arden as they are committed to HL7 standards. We considered a more abstract and general specification implementable as GELLO, Arden, or a new superseding representation.

Work is proceeding on interfacing between the CDS standards with Arden-Gello-and VMR. Andrew McIntyre from Australia presented candidate work which his team has been developing where Gello strings are used in the Curly Braces of Arden. Gello has capability for converting data types

and units as well as bringing RIM interfacing capability. There is potential to similarly develop interfaces with other standards including ISO and openEHR based EHRs.

David Rowed led a discussion around the well-recognised major problem of accessing data and hooking into the workflows of existing EHR-based applications via “Integration Points”. David outlined the Patient Care Services project being scoped from Australia with SOA support which addresses this. Several members of the WG are keen to be involved. David has been tasked to circulate more details prior to reconsideration of CDS committee involvement in January.

CDS Context Aware Knowledge System or “Info Button” is being applied in the “CliniGuide” project development within the University of Utah with discussion led by Guilherme Del Fiol, CDS co-chair. This was worked through at the joint meeting with Structured Documents and will be used to retrieve medication lists and problem lists from EHR-based systems with integrated access to treatment guidelines and patient education materials. The project proposes to use a variation of the CCD standard as basis for the exchange. The simplicity and limitations of Info Button in this use are its focus on a single core clinical concept and context limited to the clinical task at hand. In this proposal CCD becomes the knowledge request payload. Only a subset of CCD aligning with VMR and relevant to knowledge request and retrieval would be required. The recognised Infobutton service-based enhancement needs could be addressed in this work and would lead to DSTU Profile developed in association with SOA.

CCD does not provide an adequate Family History Model and like V3 in general, although appropriate for inter application messaging, is considered unsafe for practical CDS implementations: it is too complex (too hard to set attributes etc.). Nor is CCD good for Rules --it needs simplification, although Green CDA improves on this.

The requirements are fundamentally different: Run-time vMR is transient, instantiated only while rules run, whereas CCD is persistent and intended for sharing care etc. vMR is the basis for writing rules and the intent in this current work is to go from CCD -> { vMR + detritus} and run the rules.

CDS currently doesn’t have a V3 facilitator. The WG is addressing this now.

The Structured Documents – based Patient Education Project is developing a standard way of structuring the record of education given during an encounter for storage in the patient’s EHR which will also provide a medico legal audit trail of that aspect of care. This is being linked with the Info Button Standard and will be compliant with US Meaningful Use.

A reference implementation of these HL7 CDS standards is being developed in the Open CDS project led by CDS co-chair, Dr Kensaku Kawamoto. This project has over twenty collaborating organisations from industry, academia and health service providers. Internally, it uses the HL7 vMR which is built on the RIM. Data mappers work between the vMR and CCD as well as to other standard representations. The project is also building around open tools for terminology (including SNOMED) support (Apelon), knowledge and rule authoring and domain specific language (DSL) creation.

This project provides an excellent insight into HL7 CDS standards and tools as well as the related standards it employs. It is an excellent starting point for Australian groups progressing from ad hoc approaches to mature standardised decision support applications and should be promoted here.

The project site is: www.opencds.org

At a joint meeting with Orders and Observations the WG looked at representing clinical data in HL7 version 2 for input and output of the vMR and its inclusion in the next balloted IG. This is the same need which was addressed when enhancing the REF message as part of the IT-014-06-06 work for HL7 version 2.6 which led to our relationship segments, mood codes, and instance identifiers being brought into Version 2. Andrew McIntyre presented a method similar to that he has proposed as a candidate in the IT-014-06-06 work on Archetyped Data in our HL7 Version 2 Technical Paper. This uses the sub id field of OBX messages to group segments for serialisation deserialisation of hierarchical data. David Rowed pointed out that the Australian team had encountered resistance to using this sub-id approach when proposing its enhancements and therefore followed the relationship segment approach. The co-chair of OO, Rob Hausman, was concerned that V2 was working well in laboratory messaging and questioned whether another approach to its payloads was appropriate. David pointed out the inadequacies of V2 for rich clinical data and Australian work to address this. Rob felt it was important that his WG be a co-sponsor of this work and David indicated Patient Care should similarly be. CDS accepted this wider involvement and Patient Care WG later accepted the responsibility as part of its Version 2 work (which is largely done by Australia), asking David Rowed to manage this.

It is most important that we do not allow a situation where there are multiple ways of handling this clinical data in V2 need. Australia has a big investment in using V2 in this way for collaborative care messaging.

Summary of Gaps and Needs underpinning Recommendations

- Interoperability with Deployed Applications and EHRs

The committee realises the ever-present difficulty of interfacing into the data and hooking into the workflows of deployed systems. The Patient Care Services project being scoped from Australia with SOA support addresses this and members of the WG are keen to be involved prior to review in January.

- Lack of agreed approach to Knowledge Representation

There is no single agreed formalism for knowledge representation but the WG is open to accelerating work in this direction.

- Need for harmonised CDS cConcepts

There is no HL7 agreement on key definitions around CDS concepts, most notably “Levels” of CDS. We should look to ISO (where Australia has taken the lead via TS 14668 CDS specifications) and adopt uniform terminology.

- Overlapping Deployment Options

There are no clear guides available for selecting CDS standards appropriate for different application areas.

- Multiple Explicit and Implicit Models and Methodologies

There is no unified model, methodology nor implementation path which ties together the multiple directions (vMR, Arden, GELLO,) which CDS is taking or has taken (Guideline Interchange Format has beendropped). Patch-like attempts are being made to interface these, but a unifying approach for the next generation of CDS is needed.

- Representation of Clinical Data in CDS HL7 V2 input / output

There is need to agree on the method of clinical representation in HL7 V2 messages as these, or derivatives, are used as inputs and outputs from CDS systems. Australia has led the way with this via the Referral message enhancements driven from IT-014-06-06. Meaningful Use in US has V2 as one of its acceptable platforms, and CDS will be part of the third stage Meaningful Use. The V2 clinical data representation which takes in Archetypes in V2 as well as issues around document payloads has proven difficult with many unresolved issues. We must resist the development of multiple methods of representing clinical data in V2.

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Clinical Decision Support Standards	Clinical Decision Support is widely used in clinical practice and systems in Australia (e.g. prescribing software, RACGP Red book, GP sidebar add-on, National Health Call Centre, College of Pathology Guidelines) but is not standards-based and there are no compliance criteria to ensure safety, reliability, and accessibility of interfaces. Many guidelines are in textual form that are not machine processable and are unable to leverage off existing EHRs and productivity tools. **Recommendation and Action: Formation of CDS Standards WG in Standards Australia with close linkage and cross representation from other WGs, vendors and knowledge providers (especially Drug and Pathology Knowledge providers and Therapeutic Guidelines). Discussion required at IT-014.**	**IT-014** **RACGP as leads**
Virtual Medical Record vMR Project	vMR reduces costs, turnaround time at point of care, frees vendors of difficult design and maintenance; it enhances quality and competition in available CDS delivery and focuses directly on Patient and Community outcomes and safety. Its technology independence ensures general applicability and lasting investment value. **Recommendation and Action: Find a Standards Australia home for this together with other CDS needs. Set-up a project to link this in with Australian initiatives.**	**IT-014 leading MSIA, Professional Groups, HL7 Australia**
Multiplicity of CDS WGs standards	Australia support CDS WG's progress on its next generation which should have a uniform model and methodology. **Action: CDS Delegates to take this to future meetings.**	**HL7 Australia, IT-014 via directions to future Delegates**
Multiplicity of CDS WGs standards	With vMR, Gello and Arden as CDS standards and HL7 Version 2 and CDA used in input and output to CDS systems, it is not clear which standards are best suited for which tasks. **Action: CDS Delegates, and collaborating CDS workers in Australia to work with the WG to do comparative analyses and deliver guidelines for use of different approaches.**	**IT-014, CDS Community in Australia**

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Development of CDS Standards	Australia does not generally take part in HL7 ballots of CDS standards. **Recommendation: Australia take part more inclusively in CDS ballots.** **Action: Standards Australia circulate ballot notifications throughout the IT-014 community and recommend balloting.**	**IT-014**
Development of CDS Standards	Australian involvement at HL7 CDS has been ad hoc and piecemeal, usually by clinician delegates with prime responsibilities across Patient Care, Structured Documents, SOA and Community Based Health. This limits Australia's ability to progress in this key direction. **Recommendation: Australia includes Clinical Decision Support as an ongoing area of prime responsibility for its HL7 delegation.** **Action: Assignment of CDS for comprehensive cover by HL7 delegations.**	**IT-014, HL7 Delegates**
Interfacing CDS with Applications	Clinical Applications are mostly closed systems with CDS supplied by the vendor resulting in severe limitations on scope and optimisation of CDS package utilisation, as well as impeding innovation, development, competition and commerce by industry and expert groups. **Recommendation: Progressing initiatives to develop standards for service based interfacing, including the Australian-driven Patient Care Services Project, and engaging knowledge vendors and DSS vendors in requirements specification. "Integration Points" be identified.** **Action: The three groups convene a meeting to develop a strategy for stakeholder engagement and proceed with the requirements gathering phase.**	**MSIA, HL7 Australia, IT-014**
Priority of CDS	There is lack of appreciation of the prime importance of Clinical Decision Support by policymakers. It needs to be understood as the final pathway integrating all the accepted standards initiatives including EHR, communications, terminology, structured data, knowledge and evidence for the benefit of optimal patient care, outcomes and safety together with environmental and population health. **Recommendation: Promotion to government funding and policy implementers of CDS development with a view to supporting a standards WG and taking steps to require appropriate deployments in funded projects.** **Action: Seek Engagement of key funders and policy makers.**	**IT-014, RACGP, College of Pathologists**

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
CDS and HL7 V2 Referral Messaging	CDS input and output, like our Referral and Discharge HL7 V2 messaging, requires rich clinical structured data in its payload. This has been difficult and is ongoing work which has been led by Australia. We have a large investment and stakeholder dependence on V2 and cannot allow proliferation of methods to develop as CDS goes down a parallel V2 path in the same problem space. **Recommendation: Australia work with CDS , Patient Care and OO to ensure that we reach a single solution for structured clinical data in version 2, that it satisfies our requirements and is consistent with our Discharge and Referral messages.** **Action: IT-014-06-06 take a watching brief on the CDS V2 work and engage as needed.**	**IT-014, IT-014-06-06**

13 CLINICAL INTEROPERABILITY COUNCIL (CIC)

DESCRIPTION

This Council provides the standards development framework, organisational processes and forums to collaborate with the clinical community to define content, flow and other domain requirements necessary to the development of robust health data standards. The Council will provide mechanism for clinical domains to develop common approaches to standards-related activities and form consensus on issues of interest among multiple groups. This Council will be unique to Health Level Seven in that the focus is on the clinical content, not the technology of the standards.

PROGRESS AT THIS MEETING

http://www.hl7.org/Special/committees/cic/index.cfm
Wiki: http://wiki.hl7.org/index.php?title=CIC
CIC continued its work on a number of Domain Analysis Models (DAMS). These are the Cardiovascular DAM, Emergency services DAM, and the Anaesthesia DAM. While these DAMs are realm specific for the USA, it is likely that some of the work is translatable to Australia. There is still no computable way to take information developed in a DAM and use it in information systems. These are still only human readable documents. There was some discussion about how to use DCMs to represent the clinical information components of the DAM. This approach if used correctly would enable the DAMs to contain computable information models for reuse.

CLINICAL STATEMENT

The Clinical Statement Pattern had gone through DSTU ballot in the September 2011 ballot cycle. All ballot comments were reconciled before and during the September WGM. It can be considered “passed the DSTU” ballot stage.

It was debated whether the Clinical Statement Pattern should be considered IMDP (information model design pattern). IDMP is considered "official, MnM approved nuggets of modelling"
It was agreed that the entire CS pattern in its current form would not fit the "definition of" IMDP, but parts thereof.

A future topic for consideration including:
Whether CS Pattern should progress to normative status – it was agreed that this would be a challenge. The level of "completeness" of the CS Pattern would need to be assessed prior to this decision and to DSTU expires (in 2 years).

It was also agreed that the CS Pattern would need to have some enforcement/conformance function for it to have a valuable "end state" of DSTU and progress to the next level.
Also that impact assessment of the CS Pattern on other domains would be required.

Other important works to come include:

- Harmonization with Patient Care – Care Provision Model; and
- CDA and pharmacy models.

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Clinical Interoperability Council	**No actions recommended.**	**N/A**

14 COMMUNITY BASED COLLABORATIVE CARE

DESCRIPTION

This WG was set up by Australia to address communication needs coming to IT-014-06-06 from Department of Human Services (Victoria) and NSW Health covering their HL7 V2 work on community based projects (including Rapid and CHIME). This included messaging in Mental Health, Aged Care, Home Nursing, Allied Health, as well Social and Community Support. This is more than ever of high importance to Australia's delivery of cost-effective, multi-disciplinary management of complex and chronic disease and related social welfare. Advocating it was provocative and originally divisive at HL7 but on request Australia provided the organisation with a gap analysis which led to the formation of the Special Interest Group (SIG) under Patient Care's sponsorship. The WG develops standards for health promotion, disease prevention, assisted living, home health, long term custodial care, hospice, community health and day treatment centres. Under our leadership it has successfully delivered new message definitions for Collaborative Care. It has also maintained relevant sections of the Version 2 specification, delivered behavioural modelling of cross-facility interactions between care providers and services in context of independent living together with residential aged care assessment and transfer.

Most recently it provided the business framework for the Human Services Directory Project which has passed ballot as a normative (although intentionally DSTU) standard under SOA and which is being deployed across Australia. The WG has become more focussed on privacy, security and consent directives much of which the care-focussed members of our delegation feel could be more appropriately done in the Security WG.

PROGRESS AT THIS MEETING

Security and CBCC had several joint meetings during the working meeting. The topics covered during this time were consent directives (e-consent), refactoring confidentiality codes, and the advance notice of proposed rulemaking (ANPRM) for 'Metadata Standards to Support Nationwide Electronic Health Information Exchange' in the US realm.

Max Walker (Australia), Co-Chair, was unable to attend this WG meeting. Max has provided strong leadership of the group in working to keep it on course for our community based service needs in the face of competing pressures to distract it away from our priorities for support of care service delivery.

The group shares responsibility with Patient Care for Version 2 Referral and Collaborative Care Health messages, the work being principally done by Australia. . There has been editorial review work between meetings on the WG's Chapters 11 and 12 in relation to problems raised by inconsistencies appearing in other referenced chapters. There are also problems identified in Australia by IHE and IT-014-06-06 which need solutions. These relate to medication history in Referral and Discharge messages but no V2 work was done on any of this at the CBCC meetings. This needs to be addressed by Australia.

Consent Directives (e-consent)

Consent directives relate to patient consent that is captured electronically and stored for re-use in a consent repository. The facilities for management must include cases of withdrawn consent, revoked consent, transmission to information requesters and audit logging. There was an information and educational session by Continua Health Alliance who gave a presentation on the empowerment through interoperable e-consent management. Continua Health Alliance manages some three hundred and fifty healthcare provider companies looking at interoperable personal telehealth (e.g. fitness). They have identified a number of interfaces and have integrated e-consent into the use of these devices for monitoring and contributing to a patient electronic health record. The devices that are assigned as personal area network (PAN) devices include blood pressure monitors and fitness devices, other local area network (LAN) devices such as mobile fitness monitors that interface to an Application Hosting Device (AHD) (such as a phone or computer) which then transmit to a wide area network (WAN) device. The consent enabler uses the HL7 CDA R2 Consent Directive and IXE XDR Profile. The presentation included a demonstration of the vTrack Service Portal. The consent articulation via a patient portal includes consent rules which capture the semantic consent. Policy can be changed at any time. When accepted the C*onsent Directive Authorization* is created in XML.

In relation to the application of consent directives in Australia, since filtering mechanisms and algorithms are required to apply privacy consent directive rules describing the consumer's preferences, this may include restricted access to certain categories of health information (e.g.,

all HIV related information). A privacy consent directive may also require that personally identified health information is "masked" to protect the patient's sensitive information. Currently there are no regulations around consent directives although there are international standards for use through IHE, OASIS and continued development via HL7. Australia needs to ensure that its intended use of e-consent is consistent with international work (such as IHE profiles) to enable interoperability across jurisdictional and international boundaries. This recommendation is consistent with the aim of “improving Australian health information systems by facilitating a standards-based approach to development and implementation, and achieving interoperability between systems” (as specified in the implications for Australia guidelines of the HL7 Delegate Template Report_Explanation Guide.doc).

Refactoring Confidentiality Codes

The discussions on confidentiality codes are important because the use of such codes is fundamental to the consistency in handling information privacy between organisations. This is in strict association with the objective for the work group meeting of “improving Australian health information systems by facilitating a standards-based approach to development and implementation, and achieving interoperability between systems” (as specified in the implications for Australia guidelines of the HL7 Delegate Template Report_Explanation Guide.doc.
The discussion on the confidentiality codes has been ongoing over several HL7 meetings. The points of discussion have revolved around the current purpose of the confidentiality codes and their use. This includes whether they should relate to security and privacy or patient safety. This working meeting was used extensively to attempt to thrash out the issues and included presentations on the current use cases.

The current problem is that the *confidentiality code* has become a mix of privacy policy codes including sensitivity of information and how it should be handled, and metadata tags (data about data content) used to convey information on the sender and receiver responsibilities to prevent unauthorized use or disclosure. This will result in incorrect and misunderstood application of the code particularly in relation to the placement of the code in the transportation wrapper as well as the document header. Potentially, this may result in breaching protected information by disclosing the sensitive nature of that information to unauthorized receivers.

Refactoring *confidentiality codes* will fit seamlessly into the Composite Security and Privacy DAM with minimal changes. In addition, it aims to address blending internal Privacy Policies with Role and User base Access and interoperable Confidentiality Codes; defines new *interoperable* Confidentiality Codes where receiver responsibilities for the information being exchanged are specified; provides a limited set of codes that convey general information handling rules; and convey sensitivity levels without disclosing why the information is or is not sensitive. This must be linked to the organisational privacy policy including jurisdictional privacy policies. It is proposed also that the code indicates the consent directives which specify disclosures that are *more* restrictive than generally applicable Jurisdictional Health Privacy Policies, and Disclosure Authorisations which specify disclosures *less* restrictive than generally applicable Jurisdictional Health Privacy Policies.

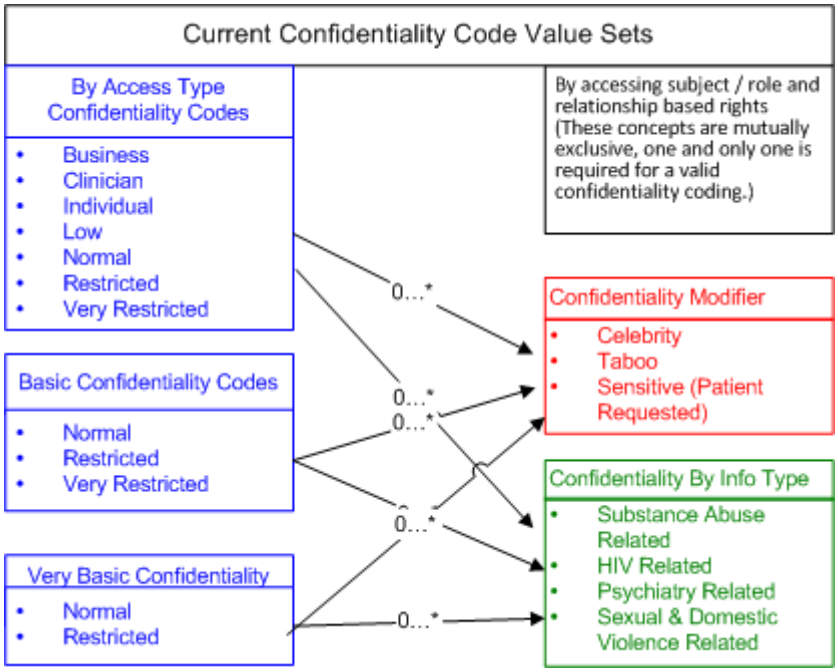

Figure 2. Current Confidentiality Code Value Sets

This is also true of other healthcare messaging standards such as DICOM and IHE XD* metadata about documents. Commonly it is used to hold the sensitivity classification of an object. This is a way that a sender can inform a receiver of how to handle the data in their access controls. This is a way that a publisher of documents can indicate the sensitivity classification of a document. With the current value set, as shown in Figure 2, the codes have several different but linked meanings.

Use Case: France

France uses the code to document the confidentiality level of the document. In late December 2010, the national shared record <DMP> for patient care coordination became functional. The document paradigm is specified in the national interoperability framework, where all documents are CDA R2 and are all indexed in XDS metadata. There are two portals for information retrieval; one for patients and one for healthcare providers. More information on this can be found at www.dmp.gouv.fr. The confidentiality code is at a document level and not at the wrapper level. This condition is driven by French legislation and regulation in regards to patient rights requirements. The patient can choose to have a DMP or not and can view the whole DMP. Also, the patient can provide their own content to the DMP, can administrate the record and can designate the preferred doctor. To facilitate situations where viewing of the record may either compromise patient safety or be detrimental to the patient, the confidentiality code is used to control the release of the information to the patient. Two examples of this are given below:

> *Use Case 1*: Document is temporarily invisible to patient. For instance, where an anatomic pathology report diagnoses cancer. In this case the metadata flag indicates that the patient cannot view this result and has to wait for the doctor to consult with patient. The XDS metadata 'confidentialityCode' allows multiple values. 1st value derived from the CDA header (N, R, V). 2nd value is added with the meaning 'doc invisible to the pat'. Doc is

unchanged. After consultation with doctor the XDS metadata "confidentialityCode' is updated to remove the 2nd value.

Use Case 2: The document is masked by the patient from healthcare professionals other than the preferred doctor. The patient masks a document in the DMP. A 2nd value added to XDA metadata with meaning 'document masked to healthcare professionals'. The document remains unchanged, but stays visible in the DMP to the document author as well as by the designated preferred physician. The queries to the XDA registry filter this document to all other healthcare professionals.

France added the affinity domain codes and is using this as a de-facto workflow trigger – which is proving successful.

There was significant discrepancy in views regarding the use of the confidentially code and its purpose. In HL7 and the RIM the term is 'confidentiality' and from a security perspective this is inconsistent and should be labelled *accesscontrol code.* The outcomes from the meeting in regard to this matter were a widening of view and lack of consensus on the coding. The security view was firmly that the codes needed to reflect the classification of the information and not to stipulate how the information should be handled. The handling should be derived from the equivalent of the classification with the security and privacy policy associated with it.

For instance:

Low (L) - Low sensitivity,
Normal (N) - Normal clinical data to be handled by normal 'good health care practice' rules
Restricted (R) - Restricted clinical data, restricted to those having a care relationship
Taboo (T) - Information not to be discussed with the patient.

Ultimately what are required are codes that can be interpreted and applied automatically to documents and information by computational methods and not through human intervention. Thus the code sets as defined in HL7 should be generic classifications and other codes sets can be refined based on the use within specific affinity domains. This means that additional metadata tagging of information may be required to provide runtime information to enact access control decisions against detailed security and privacy policy, including enforcement of access restrictions defined by the classification, and other criteria such as where a document should be shared in specific ways.

Australia should provide input to this discussion in relation to how this is being implemented in Australia. This would provide a useful insight into the Australian use case for HL7.

Advance notice of proposed rulemaking (ANPRM)

The advance notice of proposed rulemaking (ANPRM) for 'Metadata Standards to Support Nationwide Electronic Health Information Exchange' in the US realm was presented. Feedback is sought on patient identity, provenance; and privacy, in addition to additional metadata categories, metadata elements, or metadata syntax. The feedback of the group will be used to

formulate the HL7 response to the Office of the National Coordinator for Health Information Technology, Department of Health and Human Services to advise the President Obama. Although centred in the US realm, the issue of metadata in patient information exchange is relevant to all realms and jurisdictions.

The proposal states that metadata should be with any patient information exchanged, but does not specify what that metadata should be. Some US States are already defining what this metadata should be on their interoperable data exchanges. For instance, Connecticut is defining for this under the Affinity Domain Policy at http://www.ct.gov/dph/cwp/view.asp?a=3936&q=462960&dphNav_GID=1993.

The vocabulary used in Connecticut is based on the ISO standards.

The major point is that the metadata model should be describing the object (e.g. Element, Message, Document), not trying to duplicate the Privacy or Security layers. Privacy and Security policy and enforcement will leverage all of the metadata provided. Currently, there is a lack of standards for encoding privacy and security policy in an interoperable and computable form. As such because of this vocabulary such as sensitivity (called confidentialityCode by HL7) is used.

The enforcement of such policy is then done at multiple points along the exchange including at the data custodian point, infrastructure exchange points, and data consumer end point. This type of federated security architecture is robust and can be enhanced incrementally. In IHE implementations when more than one policy affects an object then a combinatory policy that considers precedent, jurisdiction and safety must be used at the organisational level. These combinatory policy along with the various privacy and security policies are the core; these must be defined before we attempt to create a privacy policy encoding standard. Work in this space is actively being pursued by HL7 and other related organisations such as OASIS (e.g. XSPA). This work is leveraging the lessons learned through more stepping stone standards such as IHE BPPC, and the more advanced HL7 CDA Consent Template DSTU.

The relevance to Australia is in regard to the metadata requirements specifically for information (as in the ANPRM), where the patient obtains a summary care record from a health care provider's electronic health record system and requests for it to be transmitted to their personal health record (PCEHR). It is assumed that this is already defined (or will be) in the composition of the PCEHR message transfer format. This recommendation is in alignment with the objective of "Improving Australian capacity to implement health informatics standards and eHealth systems by expanding local knowledge and expertise based on international best practice" (as specified in the implications for Australia guidelines of the HL7 Delegate Template Report_Explanation Guide.doc).

Further information on this and previous meetings can be obtained from http://wiki.hl7.org/index.php?title=Community-Based_Collaborative_Care

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Consent directives	Currently there are no regulations around consent directives although there are international standards for use through IHE, OASIS and continued development via HL7. Australia needs to ensure that its intended use of e-consent is consistent with international work (such as IHE profiles) to enable interoperability across jurisdictional and international boundaries. **Action: Ensure that work in the area of consent directives are consistent with international standards, or can define international standards where these are not yet in place.**	**IT-014, NEHTA**
Confidentiality codes	Australia should input to this discussion in relation to how confidentiality codes are being implemented in Australia. This would provide a useful insight into the Australian use case for HL7. **Action: NEHTA should provide IT-014 with information on how the confidentiality codes are being implemented currently and how they are proposed to be used in the PCEHR and e-health information exchange. This would inform and contribute to the international discussion which is important for future cross boundary information exchange.**	**IT-014, NEHTA**
Metadata definitions for patient information transfer	The US currently has an advance notice of proposed rulemaking (ANPRM) for 'Metadata Standards' to Support Nationwide Electronic Health Information Exchange. The relevance to Australia is in regard to the metadata requirements specifically for information (as in the ANPRM), where the patient obtains a summary care record from a health care provider's electronic health record system and requests for it to be transmitted to their personal health record (PCEHR). It is assumed that this is already defined (or will be) in the composition of the PCEHR message transfer format. **Action: Review whether or not the outcomes from this ANPRM have relevance for Australia and the PCEHR in relation to the standardisation of metadata for patient information exchange.**	**IT-014, NEHTA**
Community Based Health – focus of the group	Community Based Collaborative Care WG was set up by Australia to address the need of mainly state jurisdictionally-provided services covering allied health, mental health, community nursing, aged care, and social support services. It has done exceptional work in Aged and Residential Care messaging and in developing the Human Services Directory SOA/HSSP standards deployed in Australia. It has been difficult for us to keep the focus and to maintain our jurisdictional involvement commensurate with our needs. The group has become focussed on privacy and security/consent directives which might be better addressed in the Security WG. This is diverting the work away from our needs. **Recommendation: Australia makes a serious effort to have this WG again address our needs and takes steps at HL7 to review the best location for the security work. Alternatively we move to bring the Community Health Provision work back to Patient Care (its original sponsoring group) with the appointment of an additional co-chair from our jurisdictional community health sector.** **Action: Key stakeholders in Australia meet to review our needs and strategies in this area and aim to ensure ongoing involvement in these standards.**	**Standards Australia, NSW and Victorian Dept of Health, IT-014-06-06 co-chairs**

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Referral Message representation of Medication History	The Version 2 REF message managed by CBCC cannot properly represent Medication History **Recommendation: IT-014-06-06 work program be extended to re-install HL 7 V2 in Patient Care Messaging (recently dropped from the work program) and that this together with other needs for clinical content be addressed by IT-014-06-06 in collaboration with IT-014-06-04, with view to bringing proposals to Patient Care and CBCC WGs.** **Action: IT-014 be requested to put HL7 V2 in Patient Care Messaging back onto the work program for IT-014-06-06.**	**Standards Australia, IT14,** **IT-014-06-06,** **014-06-04**

15 CONFORMANCE AND GUIDANCE FOR IMPLEMENTATION AND TESTING (CGIT)

DESCRIPTION

The Conformance and Guidance for Implementation and Testing Work Group supports all conformance activities of users of the HL7 standards. This includes the localisation of HL7 standards to suit specific real-world situations, the creation of implementation guides, and the mechanism to specify, interpret, and test conformance to HL7 standards. This Committee was renamed at the May meeting and was formerly known as the Implementation and Conformance workgroup. This change in name reflects a renewed emphasis on supporting implementations that are conformant with HL7 Standards.

PROGRESS AT THIS MEETING

The latest committee documents, minutes and notes can be found at
http://wiki.hl7.org/index.php?title=Implementation_and_Conformance

Due to other Committee commitments relatively little of this committee's work program was able to be covered. Three issues especially relevant to Australia were targeted.

HL7 Version 2.9 Proposals for conformance/compliance

Version 2.8 of HL7 is currently in the process of publication having completed all balloting. The next version (2.9) is now at the "request for proposals" stage.

The committee agree to support the following initial proposals:

1. Develop a Best Practice Guide for V2 implementation especially in relation to conformance requirements and statements. This would take the form of a document and Template for writing HL7 V2 profiles. The output would be informative (non-normative).

2. There is a need to harmonise definitions of conditionals e.g. mandatory but empty as defined in the V2.8 standard. The definition of these which forms part of the datatypes

description in the standard (Chapter 2A) is now less specific than that in the conformance section (Chapter 2B). Conditionals describe the requirements for flexibility when data is mandatory or missing and explicit statements on C(XE) datatypes in Chapter 2A when data is missing are required. (proposal 6714)

This has only become an issue following changes in optionality of coded data elements introduced in version 2.71 (US realm specific) which was included in V2.8

The relevant conditional datatypes are:

- C(X) – conditional on trigger type – not used in some specified trigger events
- C(RE) – conditionally required but may be empty
- C(R) – conditionally required

It is possible to have C(R/RE) – an example is “start date” and “end date” fields (e.g. for medication). C(R/RE) would mean at least one must be valued (required) and the other is required (sender/receiver must support it) but may be empty. Associated conditional predicates the need to be specified to explicitly state fields that are “linked” in this manner.

Core Principles for terminology binding and associated conformance requirements

This issue was discussed at a joint meeting with the Vocabulary Committee based on a document prepared by them.

See: http://wiki.hl7.org/index.php?title=Binding_Syntax

This document is a human readable representation of the terminology binding rules that are in the HL7 MIF.

Details in section 5.3 and 5.4 need input from the conformance committee.

This document was balloted in May 2011 but attracted negative votes and needs work on (a) the definition of binding and (b) the syntax for binding.

The document also needs to be updated to reflect the changes that have come about with the introduction of the new version of the MIF and general behaviour related to conformance (conformance rules) needs to be incorporated.

It was agreed this document is to be updated by the Conformance Committee during post working group teleconferences and returned to the Vocabulary Committee.

The Implementation guide needs to be available in multiple languages – the initial plan is German, Spanish and French. It cannot be done by simple translation as the BNF changes in the target language reflecting the language syntax. Members were identified who are native language speakers to take this forward. It is planned to present the completed document at the next HL7 International Council meeting.

It was noted that there is an intention to align the terminology syntax in Version 2 with that for Version 3. There is a need for volunteers from the version 2 community to take this forward with a goal of including a harmonised common binding syntax and conformance

requirements in HL7 V2.9. Most of the additional support required has already been incorporated in v2.7 and v2.8 but a "completeness survey" needs to be undertaken and a Version 2 section added to the "Core principles for terminology binding" document.

Terminology mapping and conformance requirements

Some agreed principles:

- A mapped term must never represent a greater level of detail than available in the original code even though there may be known context that would allow to make it possible.

- Conformance testing – A Receiver application needs to store and be able to display the received code(s) as well as any codes to which it has been mapped. Conformance testing should ensure that is the case.

Issues:

- Is it adequate to test correct implementation of a large value set with a set of messages/documents containing a random subset of the allowed value set plus some terms from outside the value set?

The Committee agreed this was practical and reasonable.

- What should be the behaviour of a receiving system when a valid code from a terminology is received but which is outside of the defined mandatory value set for a given data element?

The Committee felt this was context dependent and should be specified by the conformance profile.

- What should be the behaviour if a more detailed terminology term is received that is mapped on receipt to a less specific term. This mapping will lead to a loss of information if the original code is not persisted. Should this raise an error/warning? Is this context dependent or can general rules be agreed?

It was agreed that for receivers of terminology the steps should be:

1. Always persist (store) what is received
2. Perform any required translation/map to local representation/codes
3. Display local code display text
4. Provide capability to show the original code(s) and text as well as translated code(s). This capability should preferably be part of the User Interface (UI) but may be implemented solely as a database lookup that can be used for conformance testing and verification.

Raising of an error/warning was considered optional.

The USA National Institute of Standards and Technology (NIST) which is permitted only to do inspection testing, without access to software code, will be able to implement these conformance testing processes using data supplied from database queries and the software User Interface.

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Terminology Conformance Principles	Principles to be used when testing terminology conformance. **Action: Ensure the newly formed Australian Terminology Conformance Working group established by the CCAG is aware of the agreed terminology conformance principles and practice.**	**IT-014-02**
Proposals phase for HL7 V2.9	HL7 is currently gathering proposals for the next version of HL7 (2.9). **Action: Ensure Standards Committees and vendors are aware of the opportunity to put forward new V2 proposals at the next HL7 WGM and any new proposals are communicated to the delegates.**	**HL7 Australia, IT-014, MSIA**

16 DETAILED CLINICAL MODELS (DCM)

DESCRIPTION

Modelling of clinical information and processes is endemic to many of the activities carried out by many HL7 Work Groups and is of particular interest to Patient Care WG, Clinical Statement WG, Clinical Interoperability Council, Modelling and Methodology (MnM), Structured Documents WG.

A Project Summary for Detailed Clinical Models can be found by following this link:
http://www.hl7.org/special/committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=320

It is important to note that the Detailed Clinical Models project is not a working group or committee in its own right but is an activity currently owned by the Patient Care WG as well as having input from MnM and Structured Documents.

PROGRESS AT THIS MEETING

Wiki: http://wiki.hl7.org/index.php?title=Detailed_Clinical_Models

It is important that this group was trying to identify and track longer-term developments relevant to the strategic direction of HL7 and the broader health informatics community and, in particular, the practical measures that HL7 should take to progress the work and recommendations of the former V2/V3/V4 Taskforce (of which Richard Dixon Hughes was a member) and how this relates to the

various proposals for simpler implementation than full HL7v3 messaging including the work of the Clinical Information Modelling Initiative (CIMI) being led by Stan Huff, Grahame Grieve's work on Resources for Health (RFH), openEHR approaches, hData (Mitre Corp), HL7 SAIF, and ISO 21090 Harmonised data types for information interchange.

Discussions were held with the convener and several members of the CIMI (which is no longer reporting on its activities to the HL7 Board as part of "Fresh Look"). It is understood that work is focussed on datatypes, reference models and methodology and seeking an agreement on the best representational technology to use for defining and sharing clinical models. The four candidates being evaluated are understood to be OWL, *open*EHR, ISO 13606 and UML.

The CIMI Fresh Look group took up much of the discussion about detailed clinical models at this WGM. There is still much discussion about how to represent DCMs internally within HL7, but little consensus. At a joint meeting with the MnM working group, there was a lot of discussion about the granularity of a DCM and whether or not clinical elements are independent. There is still no documented way of representing a DCM and the discussion with MnM went around some possible HL7 centric ways of doing so including 'SAIF artefact definitions'. MnM encouraged Patient Care to join this effort. No decisions were made or minuted for this meeting. Joint meetings with CIC WG discussed how DAMs and DCMs intersect and it was decided that more work needed to be done in this area.

William Goossen demonstrated the Netherland's UML style guide for DCMs at a high level, however it needs more technical analysis to understand how it might work. At first glance, it looks to be far too simplistic to be able to represent models of any complexity.

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Clinical Modelling – strategic directions	Grahame Grieve and representatives of Ocean Informatics are both invited members of the Clinical Information Modelling Initiative (CIMI), which was formed within HL7 but is presently operating independently of HL7. There is also growing interest in the potential application of the Resources for Health (RFH) philosophy developed by Grahame both inside HL7 and in the wider health informatics community. Significant advances and changes are possible. **Action: IT-014 (through IT-014-09 and IT-014-06), HL7 Australia and NEHTA CTI/Standards to track, monitor and, where possible, participate in influencing and defining a well-structured approach to future standardisation of clinical models and their implementation in messages, documents and processes.**	**IT-014-09** **IT-014-06** **HL7 Australia** **NEHTA (CTI Standards)** **Grahame Grieve**

17 EDUCATION AND MARKETING

DESCRIPTION

The Education and Marketing committees met jointly during the meeting and have been reported together in this section.

The Education Committee is responsible for ensuring the quality and availability of education and learning deliverables provided by HL7 and about HL7, internationally, and to nurture a community of HL7 educators to enable this. It encourages affiliate educational development consistent with realms' needs and requirements. Particularly relevant to Australia is that the Education Committee manages the education program Work Group meetings, but not educational activities and events of the Affiliates.

PROGRESS AT THIS MEETING

Committee Overview, Minutes & Documents:
http://www.hl7.org./Special/committees/marketing/minutes.cfm
Wiki: http://wiki.hl7.org/index.php?title=Marketing_Committee
Documents: http://www.hl7.org/Special/committees/education/index.cfm
Wiki: http://wiki.hl7.org/index.php?title=Education_Committee (used infrequently)

Marketing

This is a Board appointed committee of volunteers with some level of affinity with marketing, though little real knowledge of the area. Board may decide to fund the engagement of a marketing firm to assist with marketing. This is an issue however, as previous work of this type has not been particularly useful and failed to identify the unique selling points of HL7 nor the value proposition for engagement very clearly. There is no Australian member of this group, though observation and input from Heather Grain has been welcomed.

Recent activities include and focus upon:

- The Ambassador program
- University outreach
- Marketing plan development, 2011/2012 update

Communication aspects include development of:

- Action plans, deal with prioritised/selected issues
- Need to define our products and USPs (Unique Selling Points), this issue was not considered by the group until raised by Heather Grain. The omission of this marketing thinking is of concern as marketing requires clear understanding of products, stakeholders, and USPs in order to identify value propositions to 'sell to the market'.
- Product categories

The US based ongoing attendees level is decreasing. The international attendance has been increasing very slowly recently.

Education

Education strategic plan will produce a strategic plan for education related activities throughout the entire world-wide HL7 international enterprise. The strategic plan is to address all forms of HL7 Educational activities regardless of the delivery mechanism.

Stakeholder identification and needs assessment for educational products has to be undertaken.

The Education Strategy initial comments have generated significant discussion within the community. The meeting identified priority directions:

- Delivery method – through webinars and podcasts and alternative venues.
- Collaboration: Delivery enablers - Leveraging external resources and educational infrastructure, including enablers and inhibitor review
- Stakeholder needs assessment - Identifying and be able to respond to the needs of stakeholder groups – employer priorities, community priorities
- Quality: Ensure quality in education products and activities.

Specific issues of priority:

- Identification of the relationship between membership and access to materials for teaching either by HL7 Australia, or by other educational organisations is not clear.
- IP payment issues are also not clear (i.e. student access to HL7 materials with the new membership model). It was established that any organisational member may provide access to materials for their students.
- The quality of educational deliverables is in review with the intent (though not well understood in the community) to move to a more competency based model in order to improve quality and more clearly delineate learning outcomes.

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue/Action/Recommendations	Recommended for action by
Education Plan for Australia	Identification of educational strategy for HI7 in Australia is needed. This plan should include quality provisions. It should also include priority educational needs to build the workforce and support national initiatives. **Action: Develop an education strategy for both HL7 provided education and education through suitable educational organisations.**	**HL7 Australia, NEHTA, DOHA**

18 ELECTRONIC HEALTH RECORDS (EHR)

DESCRIPTION

The goal of the Electronic Health Record (EHR) Fresh Look Task Force is to support the HL7 mission of developing standards for EHR interoperability. The Fresh Look Task Force will contribute to this goal by creating and promoting appropriate and necessary standards which include:

- Functional Requirements for Electronic Health Records (EHR) and systems (EHRS);
- Functional Requirements for Personal Health Records (PHR) and systems (PHRS);
- Definition of a high-level framework to support the interoperability requirements and life cycles; and
- Identification of existing and emerging information requirements and other HL7 artefacts.

PROGRESS AT THIS MEETING

Committee Overview, Minutes & Documents:
http://www.hl7.org/Special/committees/ehr/index.cfm

Wiki: http://wiki.hl7.org/index.php?title=EHR

The main activity of the EHR WG at this meeting was progressing ballot reconciliations to finalise the ballot package for Release 2 of the Electronic Health Record Systems Functional Model (EHR-S FM), which is a joint project involving HL7, ISO and CEN through the Joint Initiative Council (JIC). The current revision 1.1 was published jointly as ISO 10781, which will be updated though joint ballot of R2 in HL7, ISO and CEN.

A secondary objective is updating the Personal Health Record Systems Functional Model (PHR-S FM) from an HL7 DSTU to a full ANSI/HL7 normative standard. This is also planned to be a joint publication with ISO and CEN but work on this is being held up by most of the resources available to the WG being committed to finalisation of the EHR-S FM R2.
There were a number of other presentations including:

- Reviews of work on cardiovascular data sets at Duke University;
- Extensions of the EHR-S FM to population and public health; and
- Health Quality Management Framework DSTU – based on work by Gora Datta (Cal2Cal), Krystal Kallem (AHIMA) and Deloitte.

EHR Systems Functional Model (EHR-S FM)

The project is aiming to have a ballot package available for EHR-S FM Release 2 by 1st December 2011 to include the following components:

- Read-Me Guide
- Overview Chapter
- Conformance Chapter
- Functional Model Chapters (as approved for ballot)
  - Overarching
  - Care Provision
  - Care Provision Support
  - Public Health Support
  - Administrative Support
  - Records Infrastructure
  - Trust Infrastructure
- Glossary and Verb Hierarchy
- Previous Ballot Reconciliation Spreadsheets – for Reference
  - HL7 R2 Comment Only Ballot – DC, S Chapters – as balloted April 2011
  - ISO 10781 R2 NWIP Ballot Comments – as balloted February 2011
  - ISO/CEN 10781 R1.1 FDIS Ballot Comments – as balloted October 2009
  - ISO 10781 R1.1 DIS Ballot Comments – as balloted April 2009
- Map – R1.1 to R2 – Function Level

The document has been significantly restructured with the previous three functional model chapters being replaced by seven in Release 2.

The tasks and timelines (as at 15 September) for achieving this and progressing it to joint ballot as a full international standard are as follows:

	When/Target	EHRS FM Release 2
2011	Jul - Sep	• Comment Reconciliation • Continued Chapter Updates and Re-organization
	12-15 Sep	EHR WG Meeting – San Diego, California
	1 Dec	Ballot Draft Ready
2012	16-19 Jan	EHR WG Meeting – San Antonio, Texas
	1 Feb	ISO, CEN, CDISC, IHTSDO Joint DIS Ballot Opens
	1 Apr	HL7 Ballot Opens
	1 May	Joint Ballot Closes
	14-17 May	EHR WG Meeting – Vancouver, BC, Canada Ballot Reconciliation Begins
	Summer/Fall	Joint Re-Ballot

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
EHR Systems Functional Model Release 2 (EHR-S FM R2)	Since Australia last had significant involvement in producing release 1.0 and the subsequent international standard release 1.1 of EHR-S FM (ISO 10781), the document has been extensively revised and restructured based on implementation experience, primarily in the US with some in Canada and Europe. Australian delegates have provided some input on WG teleconferences and through working on reconciliation at HL7 WGMs. However, this involvement has been limited and has highlighted the need for the resulting output to be thoroughly reviewed in Australia, once released for ballot. This work is tracked by IT-014-09. The model provides a framework for functional assessment of EHR systems widely used in systems certification and assurance. **Action: IT-014-09 to continue monitoring development of EHR-S FM R2, contributing where possible, but with a view to ensuring that there is strong Australian engagement.**	**IT-014-09**
PHR Systems Functional Model (PHR-S FM)	In the process of progressing from DSTU to a full ANSI/HL7 normative specification, this HL7 specification is also set to become an international standard providing a functional framework for specifying the characteristics of shared personal health record systems. It is potentially applicable to conformant PCEHR repositories but is still some way from completion. **Action: There are no specific actions for Australia at this time other than to monitor and have oversight of progress.**	**IT-014-09**

PROGRESS AT THIS MEETING (Joint EHR and Security)

The joint meeting with Security and EHR opened with a presentation on "What means SOA for the EHRS-FM" by Bernd Blobel. The HL7 strategic initiative and customer expectations are driving the need for high quality standards that are easily implementable. This includes how we develop standards and implement them, and having them understood and implementable by customers. Where possible for this, automated solutions are preferable. (A discussion of the basis of standards that are applicable in the application of security to SOA was given). The reliability of standards needs consideration because of the many different types of standards that apply to the health area. These include technical reports, technical standards, international standards, narrative specifications, semi-formal and formal specifications, and platform independent and dependent recommendations. Therefore, there is a need to understand the standards in order to future proof the work of HL7. Good modelling factors include the stakeholders' specifying what to model and how this is specified (e.g. how do they want to use the EHR). This focuses on the business view of healthcare and not the computing perspective. It is still somewhat unclear if the EHR functional model is limited to what needs to be done, or it has the capacity to include technology independence and define more how things should be done.

Without understanding the system structure from the multiple structural elements then the multiple architectural issues cannot fit into an SOA framework. The level of granularity in the EHR domain as it relates to the cross domain, for instance to Security, needs to include the limitations and constraints, and is not yet well defined. It is also unclear whether or not these limitations and constraints will be part of the model or may be met by the developers or at a higher level. One solutions space for this is to apply the Security-Privacy DAM, which is represented by ontology of policies. They provide a relationship logical construct and does not specify on how to implement the solutions. Also, it does not provide the technical solution, however it does provide the interrelationships (not technology specific) as the DAM is generic and IT independent. In association with the SOA framework that provides the components to run the services. This is the business view and includes the IT aspects as part of SOA, as it SOA's role even though platform independent.

From the electronic health record-functional model (EHR-FM) perspective, the security and solutions will be influenced by the jurisdictions – i.e. there will be additional aspects to the SOA perspective. For EHR working group, the issues are developing a set of phrases to establish conformance of what is required for the security. This is also driven by policy. The skill set required is not available in the EHR working group to go forward to annunciating these requirements. Figure 3 gives a potential mapping of the security services that will be required for the EHR-FM. This is taken from the existing implementation in Canada.

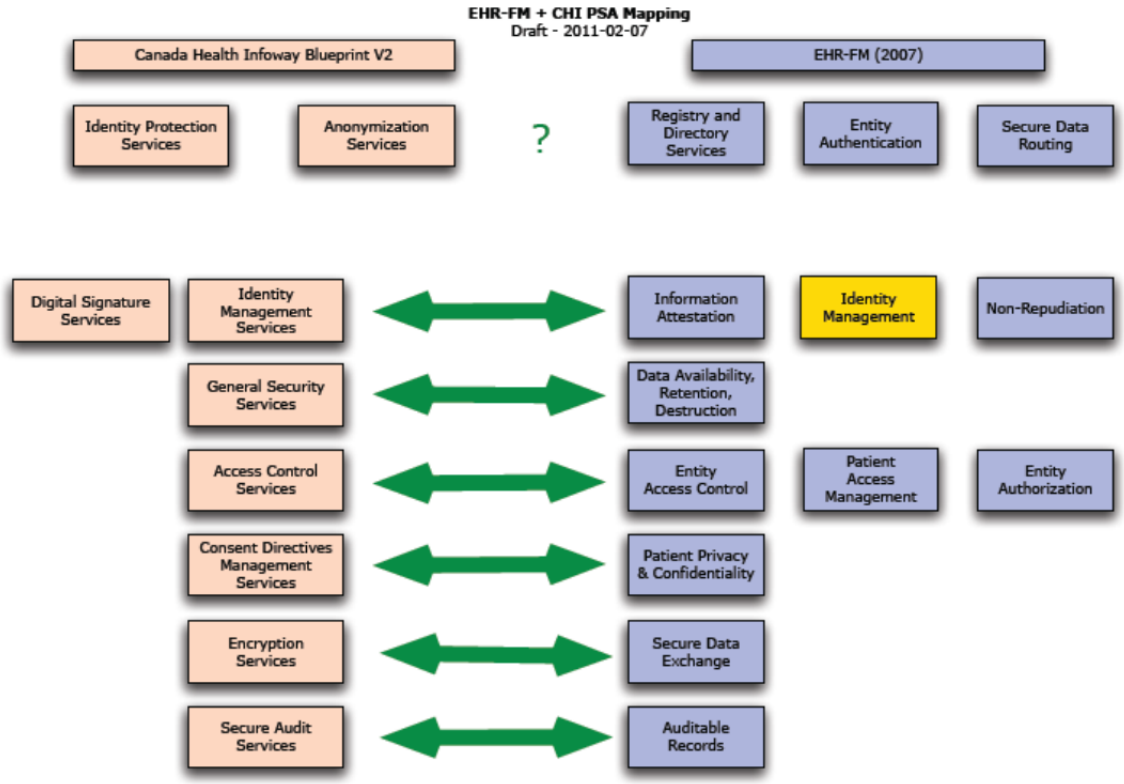

Figure 3 –A mapping of the proposed security services integration in the EHR functional model.

With the knowledge of the current NESAF which is a risk based approach, the HL7 model (Security and Privacy DAM as implemented by the EHR workgroup) is significantly more specific and provides the mechanism for a robust and defensible method for security and privacy. It is particularly relevant to the integration of NESAF to the development of systems that will support and deliver the services of the Australian e-health system. It is recommended that IT-014 should review the HL7 security and privacy work as a perspective to strengthen and inform the NESAF. This should include a review of how the HL7 EHR-FM is defining the security requirements and how these are enunciated. The meets the criteria for the HL7 delegation in regards to a focus on "improving Australian capacity to implement health informatics standards and eHealth systems by expanding local knowledge and expertise based on international best practice" (as specified in the implications for Australia guidelines of the HL7 Delegate Template Report_Explanation Guide.doc).

Further information on this and previous meetings can be obtained from
http://wiki.hl7.org/index.php?title=EHR

Recommendations arising from the meeting

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Application of security models to e-health implementations	With the knowledge of the current NESAF which is a risk based approach, the HL7 model (Security and Privacy DAM as implemented by the EHR workgroup) is significantly more specific and provides the mechanism for a robust and defensible method for security and privacy. It is particularly relevant to the integration of NESAF to the development of systems that will support and deliver the services of the Australian e-health system. **Action: IT-14 should review the HL7 security and privacy work as a perspective to strengthen and inform the NESAF. This should include a review of how the HL7 EHR-FM is defining the security requirements and how these are enunciated.**	**IT-014**

19 JOINT INITIATIVE COUNCIL (JIC)

DESCRIPTION

The JIC is not an HL7 committee; rather it is a group of SDO leaders which oversees projects to avoid duplication and improve harmonisation as well as initiating joint projects. John Quinn (HL7 CTO) is the principal representative of HL7 at the JIC, although the CEO, Chuck Jaffe also attends some of the meetings.

Membership of the JIC includes CEN, HL7, OMG, ISO, IHTSDO, GSC and CDISC. The last meeting of the JIC was in Kuopio, Finland in May in conjunction with the ISO/TC215 meeting.

The HL7 TSC hosts a session at the commencement of each HL7 working group meeting that provides a forum for discussion of JIC activities and supports harmonisation of SDO project work.

PROGRESS AT THIS MEETING

As there has not been an ISO/TC215 meeting since the last HL7 meeting. An update of the current state of the projects was given on each of the topics below:

1. IHE (Keith Boon – IHE/HL7 official liaison) – Joint work with HL7 is progressing on CDA implementation guides for imaging reports. These supplement the previous cardiology reports implementation guide. In addition HL7 and IHE are developing a USA National implementation guide for CCD. The two groups are developing joint specifications for exchange of summary documents needed for transition of care such as referral and discharge based on the existing IHE profiles. Additional input and cooperation has been received from IHTSDO in developing this work.

2. The next eighteen month development cycle for IHE profiles has commenced and the "call for proposals" for IT infrastructure has just closed. IHE will be announcing shortly the areas in which profile will be developed in the coming cycle.

3. A work item on a Patient Care Coordination profile is continuing from the previous cycle. This was initiated and is being led by IHE Australia represented by Jon Hilton. The profile will be developed using the HL7 standards for referral and the recently completed IHE workflow infrastructure profile.

4. The next IHE Connectathon will be in Chicago (January 9-13, 2012) followed by the European Connectathon in May in Bern, Switzerland.

5. IHE/GSC have established a cooperative process with HL7 to work on patient identification standards.

6. LOINC – HL7 continues to cooperate with the Regenstrieff institute in an effort to identify most common laboratory tests and results and to publish corresponding LOINC codes. Part of this project involves cooperating with IHTSDO to restart the Terminfo project for terminology models and explore the relationship between LOINC and SNOMED.

7. The relationship agreement between the Regenstrieff Institute (LOINC) and IHTSDO is being redrafted.

8. ISO/TC215 – The Health Informatics Managers Association of America (HIMAA) has been appointed as the new secretariat (Lisa Spellman). The next ISO/TC215 meeting will be held Oct 18-21 in Chicago. The May 2012 ISO/TC215 meeting will be held back to back with HL7 meeting in Vancouver.

9. The joint OMG/HL7 conference in Washington in July 2011 was well attended. CTS2 passed the OMG Architecture Board review and has now been published as an OMG standard (available for free download).

20 HEALTH CARE DEVICES

DESCRIPTION

The Health Care Devices working group facilitates the integration of health care device information at the enterprise level by:

- Establishing standardised version 2.x and version 3 content to support health care device interoperability at the enterprise level;
- Harmonising device data models between HL7 and other organisations including ISO/IEEE 11073;
- Harmonising and coordinating device terminology usage within HL7 components;
- Support revision and harmonisation of the Clinical and Laboratory Standards Institute (CLSI) Point of Care Test (POCT) and laboratory automation standards; and
- General coordination and harmonisation between HL7 and other national and international organisations involved in health care device informatics and interoperability.

PROGRESS AT THIS MEETING

HL7 Device Project status

1. Anaesthesia Devices – This project involves development of CDA representation of device data using the IEEE 11073 device data model.
   This project is being progressed by the USA Veteran's Administration (VA) by applying DCMs to devices. The initial scope is just ventilator devices and associated procedures such as intubation/extubation. Informative ballots of the Domain Analysis Models (DAMs) X 2 have already been completed. It is proposed to complete a further informative ballot at the next cycle if VA resources become available (postponed due to lack of resources last cycle).

2. IHE Patient Care Devices – see webinar available at: www.ihe.net
   The IHE Patient Care Devices (PCD) committee co-sponsors the USA HIMMS and the American Association of Medical Informatics (AAMI).
   The call for proposal for IHE PCD for cycle seven has just closed (this is the commencement of the IHE eighteen month development cycle). Ten new work proposals have been received – see IHE web site.

NIST Tooling for Device conformance testing

The USA National Institute for Standards and Technology (NIST) has been working jointly with the IHE PCD Committee to develop test tools for use during product development and for testing at IHE Connectathons.
NIST are moving to isolated testing for IHE cycle six (current) to be used at the Connectathons next year and will be available for the USA, Europe and potentially Australian Connectathons.

The NIST tooling supports the HL7 version 2 messaging used by all devices. Previously this has been instance testing only but a new capability will provide isolated testing this cycle. Peer to peer testing will be developed during the next IHE cycle. The tooling is available on the web or as part of the IHE Connectathon test harness.

1. Instance testing – A message is received from the device and a report is generated. The tooling allows selection of an IHE actor and transaction type and initiation of the message feed. Evaluation of the message occurs at multiple levels (i) the HL7 standard message structural level (ii) The IHE Technical Framework level constraints (iii) the vocabulary level using the Rosetta terminology. The tooling will currently strip transport elements such as the Soap envelope, automatically, if present.

2. Isolated testing (new capability) – The device is tested against a test system including triggers and workflow.
   The system under test may send or receive messages. Messages are validated "on the fly" as for instance testing but with checking of acknowledgements. Multiple actors and test cases are supported. These can be selected using the NIST User interface. The system shows a description of the test case, then sends/receives a message and processes the response (acknowledgement). By user option, the results can be recorded to a database for logging and review.
   The system will be going live on the web in early October for pre-Connectathon testing for the Chicago Connectathon in January.
   Currently, the interface only supports the HL7 Minimal Lower Layer Protocol (MLLP) for message transport. Validation of the web service wrapper will be developed in future releases.

3. Peer to peer testing – this is not yet underway but is planned for the next IHE cycle in eighteen months' time.
   Note this is in contrast to the IHE Australia testing for the Secure Message Delivery (SMD) Standard developed in conjunction with the Australian Health Messaging laboratory. This tests the web transport (SMD) compliance and provides isolated testing of the HL7 message, though for a limited range of non-device related HL7 transactions.

4. Rosetta vocabulary conformance testing – John Carguilo
   A new system has been developed by NIST called the Rosetta Terminology Mapping Management System (RTMMS) to manage the device terminology (Rosetta) and perform validation of the terms within messages.
   A web application has been developed that allows vendors and reviewers to access the Rosetta tables in conformance with the IHE Rosetta Terminology Mapping (RTM) profile. The application saves the data to an XML format defined by the IHE RTM profile. Required subsets can be defined and filtering of terms implemented based on semantic regular expressions. The application uses the IEEE11073 Nomenclature database for term codes.

Administrative (SDO) users can register new or mapped terms whilst vendors can only view terms i.e. there is differential access based on login.

Issues with the IEEE Intellectual Property licensing are in the process of resolution.
NIST will be hosting RTMMS and the underlying Rosetta databases. RTMMS supports versioning and users can access previous versions that have been deprecated. The Rosetta data is generated in real time.

Future work plan:

- restructuring the underlying database to improve management capabilities;
- support for synonyms for terms;
- SNOMED and LOINC support (when the mapping of those terminologies to Rosetta is completed); and
- Advanced search capability.

Pharmacy administrative messages for infusion pumps

There is a trial IHE Profile, the Device Event Communication (DEC) profile which was developed from use case that arose during the development of the published intravenous infusion pump IHE profile (PIV). However, it became clear that an extension was needed to the HL7 V2 standard to implement this capability and this has in turn led to an HL7 V2.9 proposal for a generalised device status report trigger (R42) to be called an "Unsolicited Event Device Observation Message Trigger".

Triggers R40 and R41 already exist for an alert from a device which requires a clinician response. R42 is similar but has different implications for regulation and patient safety as it is not intended to require a clinician response. However, like R40 and R41, R42 is a low bandwidth, high availability trigger and is intended to communicate administrative events. The DEC profile defines a set of these common events – initially those arising from infusion pumps such as Start/Stop/Keep Vein Open Mode/Pulse infusion etc.

The R42 trigger will be used with the unsolicited observation result message type (ORU) which is managed by the Orders and Observation Committee. A joint meeting with the Orders and Observations Committee during this WGM approved the proposal and it will now go forward for incorporation into the HL7 V2.9 standard.

The IHE Patient Care Devices Committee will formally harmonise and integrate their workflow and message exchange with the HL7 Pharmacy Committee at a joint meeting to be held in Paris on Oct 5 and 6.

Committee: http://wiki.hl7.org/index.php?title=Health_Care_Devices_(DEV)_WG

Agenda: http://wiki.hl7.org/index.php?title=DEV_WGM_Agenda_September_2011

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue/Action/Recommendations	Recommended for action by
Devices - Updated NIST Testing Tools	NIST is rolling out new tools. **Action: Communicate the availability and functionality of this tooling to Australian Healthcare device manufacturers**	**DoHA,** **IHE Australia, NATA**

21 HUMAN GENOME ANALYSIS AND HEALTHCARE – SUMMARY OF A DISCUSSION WITH KAISER PERMANENTE

Over lunch a discussion occurred about Kaiser Permanente's strategy for future healthcare with Jamie Ferguson, the Vice-President for Health IT Strategy and Policy, Kaiser Permanente (KP). The discussion is summarised below.
KP is a non-profit organisation that provides health maintenance insurance for more than twenty million people in the USA and is currently implementing genetic analysis as part of their patient-related EHR system.

They have a cohort of 150,000 patients age 65 plus resident in Southern California who have provided informed consent to having a complete DNA sequence performed and stored as part of their KP health record. They have been given undertakings that their insurance status and treatment will not be adversely affected by consenting to this.

Each complete DNA sequence currently takes 5 days to complete and generates 2-3 Terabytes of data. It is anticipated that new DNA sequencing machines based on fibre optic technology will be introduced in 2-3 years which will be capable of a full human DNA sequence in 3-4 hours with an associated fall in cost by a factor of ten.

KP are developing a set of clinical decision support rules based on the presence of specified DNA sequence patterns. Currently there are more than 300 rules and they anticipate there will eventually be 20-30,000 rules. The rules are used to recommend patient specific preventative health regimes as well as recommend individualised treatments for established diagnoses.

Whilst the program has been running for less than two years, more than 50,000 DNA sequences have been completed and stored. The biggest success so far has been in recommending optimal cancer chemotherapy regimes based on a patient's enzyme profile (derived from their DNA sequence) that is known to affect chemotherapy agent activity. This has allowed chemotherapy agents and doses to be individualised so as to reduce side effects and optimise effectiveness. A publication documenting the benefits achieved is in preparation.

The theoretical potential of such an approach has been discussed since the first human DNA sequence was performed. It appears this is now becoming a reality.
This program represents a massive investment – estimated at approaching US$500 million dollars.

The issues that this initiative raises are:

- How do you manage a database that contains 4 Terabytes (4,000 Gigabytes) of data per patient? Localised GP and Specialist systems will be unable to manage such large volumes of data.
- How should a set of 20-30,000 clinical decision rules be validated, maintained and utilised? The KP process is to have a single centralised decision support engine and a team of clinicians and IT engineers who are dedicated to this enterprise.
- KP have the clear view that the cost savings that will flow from prevented morbidity and mortality will repay the investment many times. They believe that this approach is the only way to effectively address and possibly reverse the rapidly increasing cost of health care.

22 INTERNATIONAL COUNCIL

DESCRIPTION

Previously called the Affiliates Council this meeting considers international advances and issues of the HL7 organisations around the world.

The International Council provides a forum for the HL7 International Affiliates (like HL7 Australia) and other interested HL7 members to discuss and communicate issues regarding the international development, adoption, application and implementation of the HL7 standard.

The International Council recommends to the Board of Directors actions and policies on behalf of the International Affiliates and advises the Technical Steering Committee and Board of Directors on matters relating to areas of standardisation that are relevant to the International Affiliates.

PROGRESS AT THIS MEETING

The meeting started with the CEO report from Charles Jaffe with the highlights from HL7 in 2011. This included the expansion of the epSOS project and its broadening governance. (epSOS – European Patients - Smart Open Services is the main European electronic Health **in**teroperability project co-funded by the European Commission and the partners). In addition, there has been growth in interest in HL7 by Russia and China, and maturation and scaling of Cal-X (communication between the Health department and CDC) for laboratory reporting for all public and private labs in the US.
Diego Kaminker (HL7 Argentina) replaces Michael Van Campen (HL7 Canada) as an International Affiliate Director effective January 2012.

epSOS

In alignment with the objective of HL7 attendance by the Standards Australia delegation to *"promoting free trade and its benefits to health ICT (by lowering the cost of integrating and implementing local health information systems, many of which are imported, and by reducing costs to Australian exporters) – both these outcomes require Australian requirements to be embedded into global standards so that they can be adopted in Australia, rather than having different*

standards across domestic and international markets" (as specified in the implications for Australia guidelines of the HL7 Delegate Template Report_Explanation Guide.doc).

The epSOS project is a key initiative for Europe in e-health, and as such is a project that Australia needs to look at closely in terms of both the infrastructure and the processes that are facilitating this cross-jurisdictional venture. The epSOS project is expanding rapidly and being implemented. This is based on the IHE profiles, whilst some flexibility within a jurisdiction is possible. This is rapidly being adopted as a de facto standard for Europe and for the proposed US system. The recommendation is that a review of the current status and architecture implemented in epSOS should be considered to inform design and more importantly implementation of e-prescribing and cross jurisdiction prescription transfer.

Other reports and projects

A key message from the CEO was the review of progress with the 2011 Business Plan. A main focus is to increase revenue through membership growth and new membership opportunities, and to increase the educational portfolio as well as protecting the IP of HL7, which is seen as important to revenue generation and protection. Expenditures will be focussed on tooling development and not just publishing, and professional management and support for workgroups of HL7 including increasing staff. A new company for marketing and branding is being engaged. The reach of HL7 is also incorporated into the plan for expenditure. The current business plan has been submitted to the HL7 Board and the target for approval is October 2011. It is envisaged that the implementation of the plan will be incremental over 2011-2013. This implementation includes feedback and discussion with members.

John Quinn gave the CTO report. The current tooling vision and core principles for tooling has passed ballot. The Model Interchange Format (MIF) is at version 2.2.0. SAIF CD is now ready for balloting. A key factor of the current vision is to share with and co-develop with Open Health Tools. This includes an expanded scope of tooling in the new Strategic Initiative, whose objective is to make HL7 tooling easier to use. Currently the requirements for CDA implementation guides, EHRS Functional Model Profile and IHTSDO's Workbench are needed.

Current tooling vision

Currently there are interdependencies of tooling between SAIF, the HL7 Modelling Interoperability Framework (MIF) and OMG/SOA methodology.
The MIF is in the process of moving from V2.1.6 to V2.2.0 which will have significant impacts on current software tools and future tooling development. To meet these challenges HL7 will:

- Expand the scope and emphasis on tooling in the HL7 Strategic Initiatives;
- Co-develop tooling with OHT; and
- Establish a central shared artefact repository and terminology server based on the CTS2 standard.

Tooling will be used to address strategic needs as well as to develop standards that are easier to implement and more responsive to customer needs.

Tooling is in the requirements gathering phase. The requirements already identified include:

- an enhanced IHTSDO terminology workbench;
- CDA implementation guides;
- enhanced templates designer software; and
- a tooling dashboard to visually track tooling progress (this is a new project).

The international council affiliates' liaison report was not available. It was noted that HL7 was having difficulty contacting HL7 China as they were not responding to email. Stephen Chu offered the Asia Pacific Informatics Association may be able to assist with this.

HL7 Board appointed the Fresh Look Task Force in Jan 2011 in Sydney, as reported on by Stan Huff. Its mission is to look at reviewing what HL7 can do more efficiently in developing interoperability solutions. The Clinical Information Modelling Initiative, a separate group, formed from this group. The Fresh Look Task Force was to meet during this work meeting. Australian members include Grahame Grieve and Richard Dixon Hughes.

Richard Dixon Hughes provided the Joint Initiative Council (JIC) update. At the last ISO/TC215 meeting a decision was made that the face-to-face meetings are now open for attendance.

John Ritter provided the International Mentoring Committee update. The international mentoring committee is designed to support the affiliates and promote recruitment. Recently, Mexico has re-joined membership. Future proposed activities include promoting the project scope statement and proposing a tutorial on "Maximizing your involvement with HL7". The goal is to enable people to mentor their organisations, communities or realms. A tutorial will be developed as part of this project.

Affiliate Due Diligence Committee update was provided by Michael van Campen. New application from Mexico to re-affiliate, whose membership was previously terminated in 2010. Additional petitions in progress have been received from HL7 Bosnia-Hersegovina. Further, there is interest but no formal applications yet from Bangladesh, Costa Rica, Slovenia, Sri Lanka, Hungary, Poland and Bulgaria. Since the last meeting there have been no terminations.

Other activities that were reported on were from Yu-Ting Yeh (General Secretary of HL7 Taiwan) who reported on the 10th Asia-Pacific HL7 Conference on Health Information Standards, where there were one hundred and forty-seven attendees to the conference on the 26-28th August, 2011. Robert Stegwee reported on behalf of the European Office. Recently, Marketing ran a workshop at Medical Informatics Europe (MIE) 2011 to demonstrate how standards influence and solve issues of interoperability. International Council Technical Steering Committee (TSC) Representative Report Jay Zimmerman reported on the meeting held prior to this working meeting and the status of the SAIF Canonical Description (CD). The EHR Workgroup reported on the Functional Release Model 2 update from ISO, CEN, CDISC, IHTSDO Joint DIS Ballot. This is progressing and will be discussed at this meeting. Michael van Campen noted that the next International (non-US) WGM location will be in Vancouver (May 13-18, 2012). At present there are discussions on hosting the 2013 WGM in France.

Michael van Campen provided the Affiliate Agreement Task Force update. The affiliate agreement was extended for a year to the end of 2011. The agreement has been under review by the Task Force, and will be ready for feedback by HL7 staff and legal by 15th September, 2011 and to general HL7 comment by 15th November, 2011. As part of this task force in conjunction with the International Membership and Affiliate Task Force (IMATF), Michael reported that the task force will focus on a new affiliate membership model. The task force has articulated a set of principles for the membership model. Options analysis is the next stage for the task force.

Rene Spronk reported on behalf of the Marketing Committee, an HL7 Board appointed committee. It is envisaged that the HL7 Board will decide to engage a marketing firm in the near future. The Marketing plan is being structured to be a template that can be localised by each individual country. Strategic aspects have been added in relation to the products that HL7 own. The products are: standards, support, education, community and accessories. Lastly, the International Education Plan was discussed by Abdul Malik Shakir. It has been recognised that the current education offerings are very US centric and this is being reviewed. This review was initiated in 2010 and a roadmap of activities is close to finalisation but still requires more affiliate member input.

Council Overview, Minutes & Documents:
www.HL7.org/Special/committees/international/index.cfm

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Australian support for IHIC 2012 in Singapore	HL7 Singapore sought support from HL7 Australia in its bid to hold IHIC 2012 in Singapore on 20-21 September and is looking to Australia to come in as a co-sponsor particularly to provide assistance with organisation and ensuring there is good promotion, support, speakers/faculty etc. **Action: HL7 Australia to assist HL7 Singapore with promotion, support and raising sponsorship for IHIC 2012, assisting with organisation as required and working with IT-014 and NEHTA to maximise potential Australian interest and benefit to Australia.**	**HL7 Australia in collaboration with IT-014, NEHTA and HL7 Singapore**

23 HL7 ROUND THE WORLD UPDATES

AROUND THE WORLD

Argentina: Membership is now at twenty and slowly increasing. Ongoing and important involvement is in the project to implement V2 with the government. E-learning has been a major focus with Spanish and English editions of HL7 education guides. Over four hundred students from thirty-five countries have taken the e-learning courses. This has been a highly successful e-learning model. Face-to-face courses have also been undertaken.

Australia: Membership is at an all-time high with one hundred and eighty-six voter equivalents (eighty-two actual members). Recent activities included one day forum on 'Implementing CDA in a v2.x world'. There has been significant support for national programs development through Standards Australia and with an accelerated format moving towards the national development of PCEHR AU$467M program for July 2012 and the AU$620M telehealth program.

Austria: No report

Canada: Canada has over five-hundred and fifty members in the Infoway Standards Collaborative IHTSDO, HL7, IHE, ISO and three-hundred and forty-eight HL7 members. The activities which have been focused on since the last meeting are terminology, progressing specifications for CR and Pharmacy, increasing interest in CDA and doc based approaches.

Czech Republic: The Czech membership comprises nine organisations and five individuals. Currently the Czech Republic is collaborating with Germany and Austria. They are looking to the 2013 Prague European Federation of Medical Informatics (EFMI) STC. There are issues to be resolved regarding the IP license according to Czech law with HL7 and member organisations.

France: DP Dossier Pharmaceutique – deployment has been extremely successful with 86% of the 22000 community pharmacies now connected. http://esante.gouv.fr/ . In addition, the beta testing STS = "Service de Terminologie Standard". Also, there is a new project - Interop'Sante=HPrim + HL7 France + IHE France.

Germany: The membership in Germany is now two hundred and fifty with 2/3 of these organisational members. Germany is looking at the extension of the German eHealth standards collaboration collectively known as eHealth Interoperability Forum. Since the last meeting, Germany hosted an HL7+IHE meeting. They have also furthered the implementation guides for diagnosis guides, nursing guides, Pathology report, cancer registry report, and maternity child report. A large educational program is underway with universities and other countries.

India: Actively involved in the introduction of HL7 standards through the Ministry of Health and Family Welfare, mentoring Bangladesh to become an affiliate and assisting Sri Lanka (where establishing a not for profit organisation is very difficult).

Italy: Italy has thrity-one member organisations and seventeen individuals. The current work plan is an open ballot on CDA2 Patient Summary, Patient Administrations (published), ordering and scheduling. Other plans include educational activities with e-learning courses with Italian tutors, as well as basic education information days.

Japan: In 2011 Japan began Conformance Testing of HL7 CDA. SS-MIX (Standardized Structured - Medical Information Exchange) became a national standard and is based on CDA and HL7 V2.5. Of the 1200 EMR systems in Japan, already 725 are using SS-MIX. A second project is the Sentinel Project for safety of pharmaceuticals. This project collects data related to the safety of pharmaceuticals in EMR systems.

Korea: Korea now has thirty-five members including the new member organisations Samsung, LG electronics and GE Healthcare. In 2011, Korea hosted two HL7 symposiums. Future activities will include certificate exams, and a symposium focussing on the case studies on implementation and adoption of HL7.

New Zealand: The state of healthcare is changing a lot of pressure to get health records up and running. IHE profiles are being adopted increasingly. There is an e-learning pilot course running. A GP to GP CDA pilot will take place this year, with four main primary care vendors in collaboration. E-prescribing is being implemented using CDA.

Norway: Norway was approved as an affiliate in April, 2010. The focus since joining has been on establishing organisational infrastructure and training sessions to market HL7. Currently there are fifteen member organisations. In 2011 activities have included establishing a technical steering committee, a workgroup for patient administration and a workgroup for CDA to work on national guidelines. Technically they have published V3 implementation guide, introduced change proposals for patient administration and working on a national guide for CDA. Training was undertaken for members in pharmacy, and HL7 Norway promoted themselves using a stand at MIE 2011. Planned activities are a new workgroup in pharmacy and laboratory. On a national basis, ‘e-resept’ (digital prescriptions), national medication project, national patient summary and personal health portal for citizens are planned. In addition, two-three training sessions will be held a year in implementing HL7 V3.

Romania: In 2011, Romania initiated a HL7 pilot for clinic and laboratory information systems interoperability document adapted to Romania. Also, they ran their first HL7 e-learning course with twenty-three participants, of which nineteen completed the course. The plans for 2011-2012 are to create a new e-learning course, promote certification examinations in HL7 and further develop the interoperability document.

Russia: The Russian HL7 affiliate was established in 2009. They have undertaken teaching clinicians the basics of HL7 standards. In 2011, an acute care project using V3.0 messaging was implemented. Discharge summary exchange project (using CDA) is being used in over thirty hospitals in Moscow. Translations of HL7 documents being undertaken. There is also a trail of SNOMED CT. Education being undertaken in CDA, V3.

Singapore: The AGM was held recently and a new executive team elected. Membership has a new students group with public tertiary institutions. They are actively promoting use of standards using LIM model (V2 & XML). The recent achievements include creating awareness and promoting community driven events, educating the public and more engagement with affiliates in the region. In 2010, HL7 Singapore financially broke even. The current issues for Singapore are: developing the membership base, committee overload still an issue, standards adoption particularly with migration, and vendors commitment to standards is still an issue as they are delivery focused. Future focus is on more cost effective trainers to come to Singapore.

Spain: HL7 Spain held two working meetings in 2011. There were two hundred and fourteen attendees for training and certification and the pass rate for this was certifications awarded in 2011 = sixty-nine making a total of two hundred and eighty-two since 2005. In regards to collaborations, there are several in place with Spanish universities and the strong academic links is proving fruitful. Currently, they are working on several projects, including mirroring models and the HL7 Practitioners Guide to UML.

Switzerland: No membership updates. IHE & HL7 for laboratory communications was launched this year.

Taiwan: As reported in main report.

The Netherlands: The structure of the healthcare management for e-health is changing in the Netherlands. Sector associations are going to take over the management and governance of HIE infrastructure, as obligatory by political environment. This has brought discussion on Standards collaboration with IHE, HL7, NEN (Dutch Standards Institute) as the Ministry of Health position is still unclear. They have maintained a standards focus, working more closer with IHE (pharmacy and patient care coordination between domains). HL7 is an active participant in epSOS. The 'String of Pearls' initiative, where university medical centres are looking at linking shared medical data for research is progressing well. The V2 implementation guide has been renewed and is now a Dutch Std NEN 7504:2011. The V3 Core Component Implementation Guide is to be balloted soon. Various public events were and are being held in 2011.

Turkey: No report.

UK: (Philip Scott) : HL7 UK has one hundred and fifty-three members but has seen a decline in personal membership. The NHS England Interoperability ToolKit (ITK) project has been progressing. The scope of this project is looking at local interactions and spine mini-services. The Department of Health is seeking NHS Information Standards Board endorsement. HL7 UK is looking to work more closely with IHE. Academic Outreach has seen an Introduction to HL7 and CDA modules offered at seven higher education institutions. Commercial sponsorship is still being sought with a view to cost neutral but seems a possible income source. Targeting informatics post-graduate programs has been a good advertising medium for the HL7 community. This year, the road shows were commercially sponsored for regional events. V3/CDA simplification paper was presented at MIE 2011 in Norway about this.

Uruguay: No report.

USA: (Jamie Ferguson) Stage 2 for meaningful use stage 2 in EHR's moved from 2013 to delay to 2014. A number of areas of existing measures and minimum benchmarks have been increased from stage 1, for example a new requirement is that surgical progress notes for 30% of patients are now required. The standards activities have included recommendations new for meta data standards and coded values for sensitive content.

Further information on this and previous meetings can be obtained from
http://wiki.hl7.org/index.php?title=International_Council

24 MODELLING AND METHODOLOGY (MNM)

DESCRIPTION

MnM has overall responsibility for the methodology used to develop future HL7 standards and also acts as a clearing house for inter-committee design issues.

PROGRESS AT THIS MEETING

MnM met with patient care. A distinct lack of consensus within patient care was noted; patient care is to define and agree to the artefact definitions they are creating.
MnM also discussed the RFH proposal at length. A few weeks prior to the meeting, Grahame Grieve made a proposal called "Resources For Health" (RFH). This is "v3 re-imagined": a different take on how to assemble the pieces of the v3 standard in a way that is focused on the implementers and is much easier to understand.

For the RFH proposal, see http://www.healthintersections.com.au/?p=502 and http://www.healthintersections.com.au/?p=510.

The proposal created a huge amount of interest amongst the meeting attendees; many people assured Australian delegates that the proposal was "the talk of the meeting". The following committees devoted at least a quarter to considering the RFH proposal:

- How the ontology aspects will work?
- Fresh Look Taskforce
- Implementation Technology Specification
- Healthcare Devices
- RIM based application architecture
- Structured Documents

MnM devoted between 3 and four quarters to the RFH proposal, and committed to creating a project focused on completing the RFH proposal for HL7.

The discussion covered many technical and social aspects of the RFH proposal including:

- How the ontology aspects will work?
- How the governance over HL7 development processes would work?
- How the RESTful aspects relate to other possible choices for exchanging resources?
- How extensibility it is governed?
- How the proposal relates to other HL7 work, particularly hData?
- What the proposal means for other standards organisations?

These are all important questions for developing RFH for the next meeting in San Antonio.

Most importantly, there were very few critics of the overall shape of the RFH proposal. The community as a whole was very much in favour of the ideas that RFH represented. One key commenter referred to the support as “overwhelming”.

Committee Overview, Minutes & Documents:
http://www.hl7.org/Special/committees/mnm/index.cfm
Wiki: http://wiki.hl7.org/index.php?title=Modelling_and_Methodology

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Modelling and Methodology	**Action: Australia should track the development of RFH closely and see how it aligns with other work that is proceeding.**	**IT-014**

25 PATIENT CARE WORK GROUP

DESCRIPTION

The Patient Care Technical Committee (TC) was formed as a Special Interest Group (SIG) in 1993. A small group of individuals were brought together with the objective of assessing the current HL7 specification and bringing forward recommendations for extensions to support a variety of activities related to direct patient care. Over a series of meetings and discussions the conclusion was reached that the current HL7 model did not adequately support the needs of the patient care community, particularly in the areas of patient goals, problems, care plans/critical paths, assessments, and histories and physicals. The group developed, as a SIG, a set of new segments and messages, and the decision was made in the fall of 1995 to establish Patient Care as a Technical Committee. A new chapter (twelve) was produced and approved as part of HL7 Version 2.3.

Today The Patient Care Fresh Look Task Force defines the requirements and solutions for communicating information regarding the creation, management, execution and the quality of care provision.

PROGRESS AT THIS MEETING

Co-chair elections were held. At the time of writing this report there is confusion as to the co-chair situation, post meeting-ballot. Both Klaus Veil and Hugh Leslie from Australia contested this while the status of Kevin Coonan (USA) a considered-interim co-chair filling a teleconference-created fifth co-chair position, is disputed. There were some voting irregularities in terms of eligibility to vote. This should be resolved within the next few weeks. Australians put their names forward as individuals without prior confirmation through IT-014, though support may have been provided if asked.

Care Plan Project:

This was passed as DSTU several years ago then went dormant. It was resurrected several meetings ago at Patient Care and has project leads from Australia (Stephen Chu) as well as from USA and Canada.

It is important to Australia as its subject health processes form a key part of Medicare funded primary care and flow-ons into allied health, community nursing, and mental health. The processes underpin the shared responsibilities of Collaborative Care both at information content and behavioural or dynamic levels, and inform IT-014-06-06 work on Collaborative Care Communications.

The WG is currently working on storyboards in high priority domains. These are:

- Chronic Care
- Acute Care
- Home Care
- Perinatology
- Paediatrics
- Allergy/Intolerance
- Staying healthy

The Primary Care storyboard model delivered early in the project by Australian input had fallen off the list, supposedly having been subsumed into chronic disease. David Rowed argued that Primary Care was the main initiator and manager of government funded Care Plans in Australia with flow-on through Nursing, Allied and Mental Health as well as community-based jurisdictional services. The group agreed to this and David has been asked to develop the Primary Care storyboard.

The approach had been to develop Storyboards considered in terms of pre-condition, description, and post-condition around encounters with updates to EHR and the Care Plan at each point.

The Perinatology storyboard was worked on at the meeting. [It stops at birth but should go into the early post-natal period.]

The process illustrated general needs for the Care Plan project's future directions which were agreed:

- Bring it more into line with ISO concepts especially System of concepts to support continuity of care — Part 1: Basic concepts and terminologies (Contsys). Need for a unified approach, noting variations like:
    - Issue (ISO) vs Condition (HL7)
    - Single Provider Episode of Care focus of HL7 vs Collaborating Teams in Issue Thread representation (ISO)
- The Collaborative care interactions and message needs will also be made explicit at each stage
- Better guides for implementers
- Identify clinical validation groups(physician, nurse,) and countries for each Storyboard and where possible, a care co-ordinator and manager
- Agree on a process to finalise and publish.

The main topics covered were:

- **Allergies and Adverse reactions**

  This topic is about harmonising a number of different models that are in use or are being considered in various parts of the world. Leading up to the working group meeting there were presentations of models from the US, Canada, and Australia as well as discussions about how these things should be represented. This WG meeting had a lot of participation and it was decided that some use cases and story boards needed to be developed to further the work. This is important work that Australia needs to continue to be involved with as it represents a first step into creating a truly international and standardised approach to representing clinical content.

  The allergy/intolerance and adverse reaction topic has attracted significant interests from groups of many countries including Australia, Canada, Europe/UK and US. Models developed by groups of these countries were reviewed and intensely discussed during conference calls prior to the September WG meeting. Australia is one of the leading nations in this project. The Clinical Decision Support (CDS) WG has taken keen interest in the allergy and adverse reaction model and is beginning to engage in this project. Continual advancement of this project together with CDS is highly important for Australia and NEHTA's eHealth benefit realisation that acknowledges decision support as one of the critical success factor for eHealth.
  The Dietetics group also actively engages in and contributes to this project.

- **Harmonisation of the patient administration encounter model**

  Patient Care and Patient Administration are attempting to compare, contrast and harmonise the two different models of patient encounter that are used in different RMIMs. It is noted,

that if a DCM approach to building content were in use, then this issue would likely never have arisen.

- **Discussion and agreement on current projects**

  Patient Care WG spent one quarter on discussing the current projects and seeing where they were up to and how they were being managed. This served to consolidate the projects currently in process and where they were up to. This list is available at the working group website as detailed below.

- **Detailed Clinical Models**

  The CIMI Fresh Look group took up much of the discussion about detailed clinical models at this WGM. There is still much discussion about how to represent DCMs internally within HL7, but little consensus. At a joint meeting with the MnM working group, there was a lot of discussion about the granularity of a DCM and whether or not clinical elements are independent or not. There is still no documented way of representing a DCM and the discussion with MnM went around some possible HL7 centric ways of doing so including 'SAIF artefact definitions'. MnM encouraged Patient Care to join this effort. No decisions were made or minuted for this meeting.
  Joint meetings with CIC WG discussed how DAMs and DCMs intersect and it was decided that more work needed to be done in this area.
  William Goossen demonstrated Netherland's UML style guide for DCMs at a high level, however it needs more technical analysis to understand how it might work. At first glance, it looks to be far too simplistic to be able to represent any models of any complexity.

  The DCM work continues to attract controversy and serious debates. A small number (six) of DCMs including pressure area care DCM had progressed through informative ballot in the absence of approved methodology and quality criteria. Australia has continued to engage in this debate and is also providing leadership in the development of formal methodology and quality criteria to govern DCM development.

- **Review of story board approach and validation**

  A number of story boards around care planning have been developed for Perinatology, Home care, Chronic care, Paediatric and Allergy/Intolerance, Stay Healthy, Acute Care and Primary Care. These story boards are in various stages of completion and are being validated by small numbers of clinicians in various places in Canada. It is likely that validation by small numbers of clinicians only will lead to problems with acceptance by the wider community.

- **Joint meeting with CIC**

  Patient Care met jointly with CIC to discuss joint projects. These projects include a number of important DAMs which have passed or about to pass ballot. These are the Cardiovascular DAM, Emergency services DAM, and the Anaesthesia DAM. While these DAMs are realm specific for the USA, it is likely that some of the work is translatable to Australia. There is still no computable way to take information developed in a DAM and use it in information systems. These are still only human readable documents. There was some discussion about how to use DCMs to represent the clinical information components

of the DAM. This approach if used correctly would enable the DAMs to contain computable information models for reuse.

- **Joint meeting with HER**

  This meeting discussed both the Public Health Functional Profile and the Diabetes data strategy. The Public Health Functional Profile is a US realm specific functional profile relating to the EHR-FM. There has been criticism of the Public Health model in that its name suggests that it covers all of public health when indeed it only covers vital records, cancer and early hearing. It was suggested that these be published as parts of a wider Public Health Functional profile that is yet to be developed. The Diabetes data strategy project reported some results at this WGM. The project gathered a large number of data elements from many places and then worked out the overlap. After modelling them, there was found to be a 'sea of change' and although DAMs are being developed, it was found to be very complex. This project also reported that using Excel wasn't a good idea and wasn't good for versioning. There was also an important discussion about how to link information models to the EHR functional model but no decisions were made.

Committee Overview, Minutes & Documents:
www.hl7.org/Special/committees/patientcare/index.cfm
Committee Wiki: http://wiki.hl7.org/index.php?title=Patient_Care_WG

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue/Action/Recommendations	Recommended for action by
Patient Care WG **General**	The Patient Care WG is key to all clinical communication standards to be used in Australia and has been the WG through which we have taken change requests covering Referral, Collaborative Care and Community Health. It is the group most closely paralleling IT14-6-6. It covers a wide area and has a huge workload. Our needs could easily be neglected in this resource competitive environment. **Recommendation: Australian delegates maintain high priority on being active in, and reporting on, this WG. Multiple delegates need to have this in their areas of responsibility. Australia should maintain leadership through holding 1-2 co-chair positions. This should keep our requirements paramount.** **Action: Delegate nominations continue being sought to cover this area and it to be included in responsibilities for multiple delegates. Australia to support its filling of 1-2 co-chair positions.**	**IT-014**
Care Plan	Care Planning is a critical process in Collaborative Care and has requirements for Collaborative Care Communications. It is significantly funded via Medicare and General Practice co-ordinating across Allied and Mental Health. **Action: Collaborative Care messages and CDA documents be tested against current IGs which should be enhanced to accommodate Care Plan content, where relevant, interactions and trigger events if found necessary. More widespread involvement in the PC Care Planning projects be sought from our clinical communities.**	**NEHTA, IT-014-06-06, IT-014, RACGP, Allied Health**

26 PHARMACY

DESCRIPTION

This group helps to assure that the HL7 messages and models concerning medication related information - including prescribing, dispensing, and administering medication - address all of the requirements of the many stakeholders and variations in different countries.

PROGRESS AT THIS MEETING

Status update on EPSOS

EPSOS is the EEC project for electronic exchange of prescriptions amongst EEC countries. This project now includes prescriptions and healthcare summary (patient summary record) exchange across 23 countries.

There have been 17 new countries who have had their requirements finalised in the last 18 months in conjunction with the HL7 Pharmacy Committee who are developing the CDA content for EPSOS.

Each country has an EPSOS National connection point (NCP). Each country does their own implementation using either existing infrastructure or an IHE XDS implementation with Pharmacy content and workflow.

The IHE implementations participate in a projectathon which is a dedicated mini-Connectathon. The next will be in conjunction with the European Connectathon in Bern (May, 2012).

IHE Pharmacy update:

(a) The supply chain white paper and medication documentation is in progress (see below).

(b) Some change proposals for the community pharmacy have been received but the specification is stable.

(c) There is a proposal to add pharmacy administration messages for infusion pumps to the IHE profile. This proposal is being taken forward jointly with the IHE PCC committee and was agreed by the Health Devices joint meeting at this WGM.

The IHE Pharmacy Whitepaper on Medication Documentation 2010-2011

There are many terms used in different countries for a medication summary such as Medication Record, Medication Profile or Medication Reconciliation. The term medication Documentation will be adopted as a term covering all of these. It is information presented to the user to allow judgment and decision making about the patient's medication.

In the Netherlands wherever there is a partition of health care, Medication Documentation (called a medication profile in the Netherlands) must be passed on along with allergies and some laboratory results. They are considering implementing one of three architectures (a) a "relay process" where

data is passed from one practitioner site to the next; (b) a central repository; or (c) a central indexing system with data retained in local repositories.

IHE has a profile in development to do this gathering of the medication data (the Patient Care Co-ordination profile) but the current IHE white paper is attempting to address presentation and process. Input from external stakeholders is being sought for the Medication Documentation Whitepaper

There is a section in the USA Clinical Care Document (CCD) that implements this functionality. IHE has already developed the QED (Query for existing data) profile which may also be able to be used to implement this functionality.

IHE is looking for standards to move this goal forward.

There will be an out of cycle joint meeting in Paris between IHE pharmacy and HL7 pharmacy (Oct 5-7). The White paper will be one input and HL7 Pharmacy will be contributing content specifications. The UK will contribute information from a current IHTSDO co-chair Ph.D conducting research in this area.

Other topics to be included in the Whitepaper and discussed at the Paris joint meeting will be Pharmacy workflow and substance substitution.

The new IHE XDW profile –

This profile enables workflow to be recorded in a CDA document – a virtual workflow sheet. It will support pharmacy workflows and in particular ETP within the EPSOS project. This profile is currently completing review of the comments received at the recent European Connectathon with the goal for the profile to be finalised, published and available at the Chicago Connectathon.

HL7 Pharmacy are to consider endorsing this after the joint meeting in October.
ISO Dose Syntax New Work Item Proposal (NWIP) – this is a proposal to develop the business requirements for representation of medication dose syntax. Modelling for this has already been completed by HL7 Pharmacy.

A number of projects/work items from the HL7, IHE Pharmacy and ISO are particularly significant to Australia: the European pharmacy profiles (covering prescription and dispensing with medication administration yet to be developed), the IHE Medication Profile, and the ISO Dose Syntax business requirement proposal.

The European (IHE) pharmacy profiles are currently being piloted in 17 EU nations. Of particular interest/relevant to Australia is the adoption of CDA in the IHE pharmacy profiles. While the use of CDA for prescription is in generally being accepted by the HL7 community, the endorsement of IHE to use a document-centric technology (XDW) to manage prescription-dispensing workflows continues to attract serious debates. The XDW technical specification was rejected in the first public comment. It was rewritten and second round public comment closed in August 2011. If it passes second round public comments, the technical specification will likely to be tested at the European IHE Connectathon (April/May 2012). Australia is making significant contributions to the very vigorous discussions on this topic.

IHE Pharmacy has commenced work on developing a whitepaper on defining the scope for querying relevant medication data repositories/sources to procure relevant medication data and profiling (i.e. application of relevant filtering criteria) techniques for building up a medication profile to support medication reconciliation and review by clinicians. It will help shape the development of "proof-of-concept" prototypes based on knowledge gained through the whitepaper development. This work is critically important to the medication profile work currently being proposed by the NEHTA Medication Management Team. Australian delegate has been invited to participate in the development of this whitepaper and will be a key member of the leadership team in this piece of work.

IHE Pharmacy Group also proposed that a profile to be developed to manage data flow (in particularly) the flow and acknowledgement of medical device (e.g. infusion pump) flow to clinical decision support system and clinical information systems. This will result in new messages to be defined. It was agreed that a whitepaper should be developed to more clearly articulate the scope and requirements as well as to help reaching consensus. Both the medication profile and medical device data flow topics will be discussed further at the IHE Pharmacy Face2Face meeting in Paris in early October.

The ISO Dose Syntax business requirements proposal was initiated to identify a set of business/clinical requirements needed to guide the development of Dose Syntax modelling. UK NHS had previously commissioned the development of Dose Syntax model. This model remains as UK internal artefact. The ISO proposal is intended to identify the requirements from international perspectives and used to determine whether the UK model requires to be modified or extended. If it is eventually decided that the UK model is to be endorsed with or without enhancement, an implementation guide will need to be developed. It is anticipated all works will require 2 years to complete. The requirements and model are very relevant to Australia and will complement the AMT model. Australian delegate is working closely with UK representatives on this topic/proposal both to contribute to the work and to ensure that Australian requirements are incorporated.

The Nutrition Order DAM has been subjected to informative ballot. The scope covers diet and special orders, including infant formula, tube feeding. It was determined that more work would be required on the informative model which will progress with the aim for the model to be reballoted in January 2012 ballot cycle. Important concept such as allergy/intolerance and adverse reaction only has a placeholder in the current informative model. The Dietetic group is working closely with Patient Care on this topic and hope to incorporate the model that comes out of Patient Care WG works (possibly as CMET).

HL7 v2.7 project proposal: At a joint Pharmacy OO session, it was proposed that works would be required on a set of product logistic messages to tack requests, delivery and communicate receipt of (pharmaceutical, blood, surgical consumable) products as part of the inventory management and inventory tracking workflow management.
After some discussions, agreement was reached to develop a common set of domain independent messages that can be adopted and adapted for domain specific requirements.
An issue was raised during the discussion: Legislations in most countries enshrines the principle that medicines are not considered as common commence products. Hence it was agreed that the groups should consider very carefully how a common set of domain independent messages can be

adopted for use in medication messages without violating the legal principle. One approach is to have pharmacy specific segment in the message.
Composite Order Model:

The OO/Pharmacy groups were at final stage of finalising the composite order model
The composite order model is considered a super model covering pharmacy and all other orders including lab, procedure, observations, etc.

The composite order is now evolved into a template which makes sure that the common pieces make sense to all domains and can be extended to include domain specific pieces. The debate or discussion is still ongoing on how to deal with the domain specific "edges".

Committee Overview, Minutes & Documents:
http://www.hl7.org/Special/committees/medication/index.cfm

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
epSOS trans-European electronic prescription exchange project	The epSOS project is expanding rapidly and being implemented. This is based on the IHE profiles, whilst some flexibility within a jurisdiction is possible. This is rapidly being adopted as a de facto standard for Europe and for the proposed US system. **Action: A review of the current status and architecture implemented in epSOS should be considered to inform design and more importantly implementation of e-prescribing and cross jurisdiction (public/private) prescription transfer.**	**NEHTA,** **IT-014-06-04**

RIM Based Application Architecture Work Group (RIMBAA)

DESCRIPTION

The mission of the RIM Based Application Architecture (RIMBAA) Fresh Look Task Force is to facilitate the adoption and implementation of the HL7 version 3 RIM. The focus lies particularly on the use of the RIM for application and database design; and to a lesser degree on the implementation of serializations for the purpose of interoperability (e.g. messages, services, documents).

PROGRESS AT THIS MEETING

The RIMBAA committee is presently functioning mainly as an exchange point for how to use and leverage the RIM in application design. This meeting the committee focused on the plans for VMR and the RFH proposal. There is no specific progress to report.

http://www.hl7.org/Special/committees/java/index.cfm
Wiki: http://wiki.hl7.org/index.php?title=RIMBAA

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
RIMBAA	No action recommended.	N/A

27 SECURITY WORKING GROUP

DESCRIPTION

This group supports the HL7 mission to create and promote its standards by publishing standards for trustworthy communication among all applications and services in HL7's scope. The Security WG also will lead the convergence and harmonization of standards for identity and access management among healthcare standards development organisations.

PROGRESS AT THIS MEETING

The items discussed in this section are those that were raised in the Security workgroup meeting and not the meeting with other HL7 workgroups which are listed specifically under those workgroups in this document. This section contains an update on the progress of ISO standards, other security standards organisations updates, international reports, and a discussion of the status of the security ontology project.

The security agenda at this working meeting was primarily concerned with the joint meetings with CBCC, SOA and EHR. Except for an update on the various national and international standards and projects, the security workgroup spent most of its time working on the projects from the joint workgroups. In order to facilitate the aim of "negotiating the harmonisation of ISO, HL7 and CEN Standards to achieve progressive inter-SDO eHealth standards harmonisation with the long-term goal of a unified set of global health informatics standards" (as specified in the implications for Australia guidelines of the HL7 Delegate Template Report_Explanation Guide.doc), an update on the ISO meeting and progression of various standards since May, 2011 (Finland meeting) was provided.

The ISO updates are summarised below:

- ANSI support to TC215 has ended and the new secretariat is AHIMA (under Lisa Spellman). Next meeting is in Chicago in October 2011.
- ISO 14265 Classification of purposes for processing personal health information - published as a technical specification (TS). It should be looked at in the context of the security workgroup data modelling.
- ISO 21091 Health informatics: Directory Services, healthcare providers, subjects of care and other entities. On track to become an IS. Ballot is now closed and the comments are to be resolved at next ISO in October, 2011 in Chicago.
- 27789 Audit trails - updating the document from comments received currently. The intent of this is focussing on DICOM for it core specification and specialising in EHR only.

Clinical auditing is being looked at a potential new work item, but as yet no one has offered to take this on.

- 14441 Security and Privacy Requirements for security system testing conformance testing. The intention is that this could be used internationally but is being driven by Brazil. Vendor certification done in one country. Not yet a committee draft. It should be noted that part 2 points to the HL7 EHR Functional Model.
- Draft Technical Report 16114 Security aspects of electronic health record migration. Expected draft in Oct.
- 28857 (16864 new number)- Guidelines on data protection in trans border flows of personal health information. Also the CEN document with the same purpose which is up for revision – so there is a proposal work item to harmonise these two. The issue is that a standard cannot replace a legal document. Support the development of policy (guidance on the creation of policy) across jurisdictions rather than a technical specification. Work item still requires named experts – follow up with Standards Australia as to what's happening with this.
- Revision of ISO21549-1 Health cards (as after 5 years) 8 part standard all needed revision. Most up for review and comment being collated and resolved. Part 2 Common Objects, Part 3 Limited Clinical Data, Part 4 Extended Clinical Data sent out for ballot.
- DIS 22600 "Health informatics privilege management and access control." (Parts 1&2 up for systematic review – included 3rd part to be consistent so into one ballot for an International Standard)
- NWIP for WG4/WG7 Risk management – Guidance for safety in health software. This proved to be a contentious topic at the ISO meeting as it is actually not about the safety in healthcare devices. This NWIP is distinct from TS 25238 "Classification of Safety risks from healthcare software" from the healthcare devices ISO WG7.
- ISO Privacy Steering Committee still active.

Other standard organisations update

- IHE Document Encryption (DEN) has a new supplement in trial implementation for document encryption. Includes all mechanisms for information in transit and at rest. Document can be found at http://www.ihe.net/Technical_Framework/upload/IHE_ITI_Suppl_DEN_Rev11_TI_2011-0819.pdf. In addition a webinar on this can be accessed at http://www.ihe.net/Events/webinars2011.cfm
- ANSI INCITS – the RBAC updated with added constraints from external environment and RBAC Policy enhanced Standard is in final comment resolution. The Next Generation Access Control is more flexible to include policies beyond RBAC
- OASIS
    - XACML has had further advancements to the standard (v3) to include obligations and changes demanded by workflow.
    - Electronic Identity Credential Trust Elevation Identity Methods (EITTEM). Proofing for this has been completed with knowledge based challenges. Collaboration of lower proofed identities to produce a newer identity of higher proof introduced. These changes are in relation to the US White House initiative and NIST documents.

- SAML – RESTful transport support. This has not progressed further although US Veterans Affairs has expressed interest. If it is to be worked on then additional interest is required.
- Developing Privacy reference model – This is using the HITSP use cases. These have been deconstructed but as yet there is no deliverable outcome.

International reports

Australia

The NESAF update was described and progression of PCEHR privacy legislation summarised. (National eHealth Transitional Authority – www.nehta.gov.au). The second revision is different to the focus of the first draft. There has been a move towards a totally risk based solution with no technical specifications. In the current scenario, access control is on a whole document as using CDA.

European projects

European patients Smart Open Services (EpSOS) and CALLIOPE. These projects involve forty-seven eHealth beneficiaries and twenty-three member countries. The Calliope project covers governance and political issues, with the Ministries of Health the main contributors, IHE-Europe representing ICT industry team, and Competence Centers working with local organisations. The aim is to provide concrete cross border services that ensure safe, secure and efficient medical treatment for citizens when travelling across Europe. Currently, pilot sites for ePrescription and/or patient summary scenarios are being implemented. All transmission is via epSOS backbone that handles all the security issues, access control, encryption, identification, using National Switch Points with no direct access between healthcare providers. The following formats are catered for: SNOMED-CT,ICD-10,EDQM, ATC, LOINC, HL7, IHE, ISO, ISCQ, UCUM. The proposed epSOS is also a test bed for European electronic health records but does not yet address payment details. The value sets have been harmonised between countries and agreement on what these are established. The functionality is centred on the patient possession of a Smart Card
eHealth Governance Initiative (eHGI). The project is to enable a unified governance environment across the European Union (EU). The current policy framework that supports epSOS focuses on the technical solution only. Therefore this initiative is looking at the overarching epSOS project in terms of data protection using policies.

Germany

German Institute of Standards: This is now a coordination centre for IT Security. Its purpose is for bodies to protect themselves from cyber-attacks. This is not restricted to health but is inclusive of the financial industry, and others.

Japan

Japan is using SAML with a third party model. This is being driven by the Japanese Healthcare office. Each region has trust relationships which include doctor ID, and healthcare role (Japanese defined roles). The trust is dependent on each healthcare PKI and it is used for Single Sign On within a region. It is currently in trial only at this point, with limited use in two regions.

Spain

There was nothing new to report since last meeting. The e-health system does not have patient controls and patients can only view data. They are currently piloting their interaction with epSOS.

USA

The focus for the update was web service end-points. For instance, Query Health is using a web based query model to query all health silos, http://wiki.siframework.org/Query-Health.

Security Ontology Project

The security ontology project was overviewed again and this specifically relates to Australia for "improving Australian health information systems by facilitating a standards-based approach to development and implementation, and achieving interoperability between systems." (as specified in the implications for Australia guidelines of the HL7 Delegate Template Report_Explanation Guide.doc). The security work group agreed that there is a need to simplify this for explanation to those unfamiliar with security and those models need to stick with their layer of abstraction. The group suggested that we need to move to some actionable deliverable as continued presentations on the ontology are not advancing the standard. Figure 4 shows a conceptual and simplified overview of the security ontology.

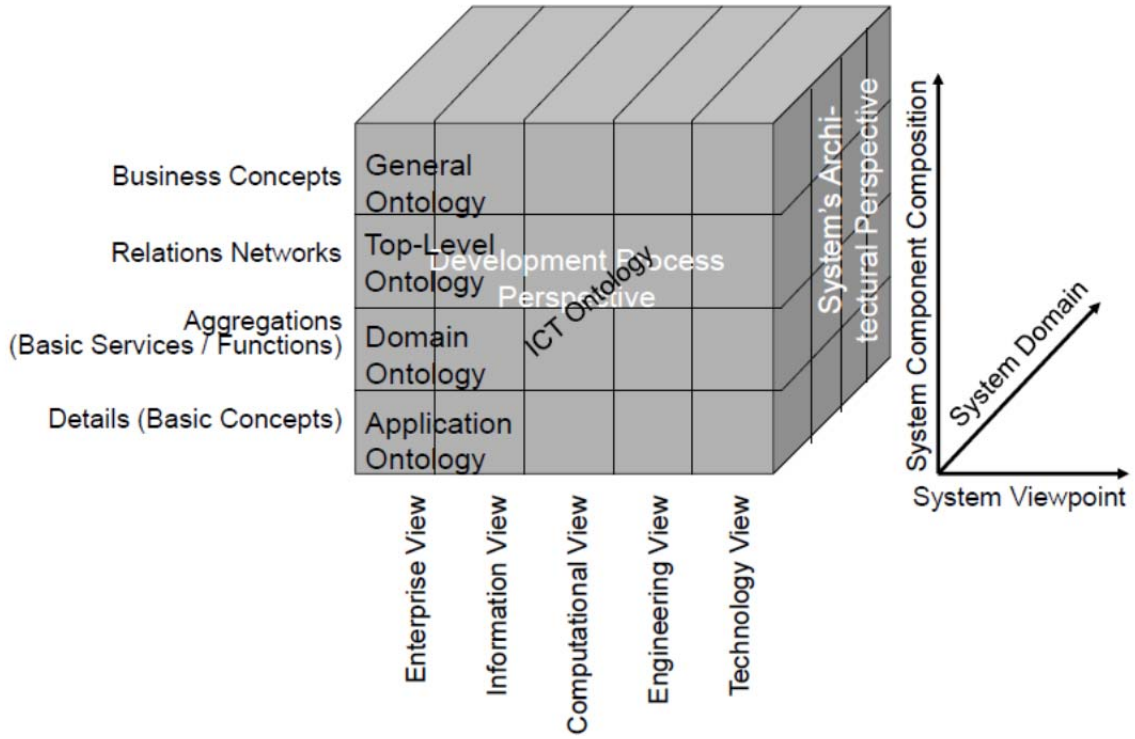

Figure 4. HL7 conceptual view of the security ontology architecture.

There has been a hiatus in the development of the project and it is now some way behind schedule. Confirmation of incorporation of last ballot comments and proper publication of comment response is required. This facilitated a discussion on more formal sectioned discussions via weekly teleconference and the times for this were amended to suit the Australian and Asia-Pacific representatives better. It is unlikely that the ontology is going to be ready for a January ballot. It was therefore motioned to be presented at the May 2012 ballot. The current project (OWL) form, document form, and comment disposition spread sheet will be circulated by Tony Wieda.

Committee Overview, Minutes & Documents:
http://www.hl7.org/Special/committees/secure/index.cfm
Wiki: http://wiki.hl7.org/index.php?title=Security

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue/Action/Recommendations	Recommended for action by
Harmonisation of ISO and HL7	From ISO updates apparent that security voting and nomination of national experts is not regularly occurring and this is impacting ISO's ability to further new work items. During this meeting this was followed up with Standards Australia. **Action: Review list of experts in security that can be offered for ISO new work item proposals.**	**IT-14, Standards Australia**
Use of existing health information databases (silos)	The US Query Health model for interrogating and querying silos of information is being adopted by several states. **Action: Review the Query Health model to see if it has relevance to Australian and the use of existing health information databases, and its potential for use in any national programs.**	**IT-014, NEHTA**
Security Ontology	The security ontology is very robust and detailed. It covers many aspects of security, privacy and access control that apply to the whole transfer of information for e-health. **Action: The HL7 Security Ontology is trialled for its potential application to aspects of the Australian e-health initiative and in particular to inform work on the NESAF.**	**NEHTA**

28 SERVICES ORIENTED ARCHITECTURE (SOA)

DESCRIPTION

The Services Oriented Architecture (SOA) WG supports the HL7 mission to promote and create standards by identifying common architectural "services" and their behaviours and establishing an industry position on the form these services take. The SOA WG produces Service Functional Models (SFMs) which will be balloted HL7 standards declaring the functions and information appropriate to them.

These services will promote the interoperability of healthcare systems, including but not limited to EHR systems for inter-product, intra-organisation, inter-organisation, regional, and national efforts.

The SOA WG works jointly with the Object Management Group (OMG) Healthcare Domain Task Force through the Healthcare Services Specification Project (HSSP) to develop healthcare middleware standards addressing interoperability challenges. Under the HSSP the OMG take HL7 balloted SFM's and continue the standards development process by issuing RFP's to the industry to implement a SFM. As an outcome of this process the OMG is able to produce normative technical specifications for the SFM's that are bound to specific technologies, transport protocols and technical conformance criteria.

Not all SOA WG projects pass through the HSSP process, some groups may choose to develop technical specifications within HL7 or adopt existing industry standards that meet the SFM requirements and are already a widely adopted standard.

A core component of the SOA WG is the Services Functional Model (SFM) and a standard boiler plate template of a SFM is available on the wiki (http://hssp.wikispaces.com/sfm). There is currently an active work project looking to refresh this SFM to incorporate more recent architectural changes to HL7. A full list of projects can be found on the HSSP wiki, however some key projects that have been initiated to date include:

- CTS2 (Common Terminology Services 2) -covered in Vocabulary section.
- DSS (Decision Support Service):
- HCPDS (Healthcare Community Services and Provider Directory Service)
- IXS (Identity Cross-Reference Service)
- PASS (Privacy, Access and Security Services) (covered in Security section)
- RLUS (Retrieve, Locate and Update Service)
- SOA Services Ontology

PROGRESS AT THIS MEETING

At the joint meeting of Security and SOA there was a recap of the past work and a discussion on potential future projects. It was decided after some discussion that at the moment there were few areas identified and until other groups requested the assistance of the SEC-SOA collaborative that the group may not need to meet in the near future. The future and use of Privacy, Access and Security Services (PASS) Alpha Project resulted in the resolution that the Security workgroup would look at creating a security best practice document for the SOA workgroup and leverage the ongoing work within IHE to extend audit profile to include access control.

Privacy, Audit, Security Service (PASS)

This project has not progressed since the last meeting due to resource limitations. Whilst it was commenced as a SAIF alpha initiative that phase is now completed.

At a joint meeting with the Security Committee there was extensive discussion on how to extend IHE's security profile (XUA) which is primarily focussed on audit, not access control, and the potential for PASS to be adopted/adapted for this role.

This is work that will be taken forward at IHE but should lead to a whitepaper (possibly jointly with IHE) on security best practice in SOA.

Patient Care Services Project

This project is in the early planning stages and being led by Dr David Rowed on behalf of the Patient Care Committee. There is a need for further engagement from clinicians and vendors which has not been possible as Dr Rowed has not been able to attend the last two meetings.

Independent Registries Project

This project was proposed at the last WGM. It initially attracted support from the USA Office of the National Coordinator (ONC) and Canada Infoway. However, it has now been placed on hold as the ONC is proposing a less ambitious approach with a simple endpoint location service (ELS). The Committee agreed to look at the Standards Australia technical report on ELS which incorporates an ELS service as specified by NEHTA and an active directory alternative proposal from Microsoft.

Record Location Update Service (RLUS)

The documentation for this service has been updated. It now includes a business model and conceptual model as well as two profile examples for CDA and a Medicare (USA) record.

Italy is planning a RESTFUL implementation of RLUS (see hData below) but this has not led to any changes to the Service Functional Model (SFM). Some minor revisions to the text are required (formal peer review by teleconference) and then the revised specification will be submitted for ballot for the January 2012 cycle as a normative full standards (currently DSTU).The updated document is available on the wiki.

hData Project

For information and FAQ on hData see: http://www.projecthdata.org/faq.html

The hData service consists of two closely related elements the hData Record Format and the RESTFUL transport application programming interface (API) which is a simplified service implementation specification that can be used as an alternative implementation path for most Service Oriented specifications.

Record Format

The hData record format has just completed DSTU ballot achieving quorum (84%) and ballot success. Four sets of comments were received during the ballot. Reconciliation and disposal of the comments was completed during this WGM permitting the specification to be submitted for publication as a DSTU.

RESTFUL transport API

This specification had been submitted to OMG as a fast-track project one week before the HL7 WGM. Formal acceptance by OMG was achieved at a joint meeting with the OMG executive and a letter of formal acceptance was received by the SOA Committee. The Request for Comment (RFC) document to be sent to OMG members soliciting expressions of interest in implementing this service was drafted and is ready for submission.

hData was accepted by OMG to be fast tracked as an alternate PSM for the RLUS PIM

Healthcare and Community Services provider Directory (HCSPD) Project

This project has been led by Max Walker from DHS Victoria and is based on the Human Services Directory being implemented in Victoria and the ACT.

The Request for proposal (RFP) was issued by OMG in January 2011. The closing date was set at that time as September 16, 2011. Only one company, DCA Australia, had submitted a "Letter of Intent" (LOI). However, OMG requires at least two (and preferably three or more) submitters to respond to the RFP with an LOI.

The following plan was developed by the Committee, in consultation with the OMG executive:

- EPSOS (The European international electronic transfer of prescriptions (ETP) initiative involving twenty-seven countries) was to be approached. HCSPD would address a number of issues within the EPSOS implementation but would need to be harmonised with the IHE Provider profile.
- Associated issues are that IHE (which is the technology implementation platform for EPSOS) is not an OMG member. A membership swap and resolution of IP issues are to be explored by the EPSOS leadership and OMG leadership with a view to the EPSOS consortium becoming a submitter for HCSPD.
- The USA ONC is to be approached for seed funding. Preliminary discussions indicated such an approach may lead to a favourable outcome. A USA vendor undertook to look at HCSPD submission if seed funding became available.

Both groups agreed to complete consideration within four weeks. OMG agreed to extend the LOI deadline to end of October.

Completion of the OMG process is planned by June 2012

PHAST Implementation of CTS2 (Ana Esterlich)

Phast is a French non-profit organisation developing standards in France for Health care. They use multiple terminologies - LOINC, HL7 vocab, SNOMED (French), Pathlex etc. and are very active in IHE Pharmacy and the EPSOS project. Previously they were using proprietary means to manage terminologies

Initial CTS2 implementation started with the CTS2 Query Profile (read only). The product is called "Standard Terminology Services" (STS). STS provides value-set lookup for government mandated value sets for Cardiology, Discharge Summary, Anatomic Pathology, Laboratory reports and Oncology. It also provides up to date versions of LOINC and associated terminologies such as UCUM (for units).

CTS2 provides a common read-access interface to all terminologies used by PHAST which are stored in an SQL database. The SQL database implements the CTS2 SFM and the HL7 RIM using the ISO data types. This approach has the advantage that it allows specification of bindings to domains and relationships between values sets, the concept domain and templates.

Currently only CTS2 read functions are implemented but it is planned that the "write/update" functions of CTS2 will be implemented later. In the meantime the SQL database is loaded and updated using proprietary interfaces.

WSDL and web service interfaces for the PHAST CTS2 implementation are available on the web at: http://extension.phast.fr/CTS2/RLO_CTS2_Main.aspx
PHAST have built a console test tool with a User Interface (UI) to test each web service. The console is available for download from the Phast wiki and can be installed on any workstation.

Decision Support Service (DSS)

This service specification is being finalised at OMG and should be published on the OMG website shortly. The specification has already passed HL7 Normative ballot.
The Open source implementation community is taking this specification forward with publicly available source code supplied by the Mayo Clinic to the OPEN CDS group. Full implementation code is available on the web at www.opencds.org along with a bulletin board and implementation community for support.
An "Open day" is being planned in December 2011, to take place in Los Angeles, to publicise CTS2 and DSS source code availability and the publicly available open source implementations.

Proposals for new SOA Committee work items

- A White paper on Service orchestration best practice and service catalogues.
  This would provide best practice guidance on assessing what services are required in a domain (service catalogue) and recommended methodologies (e.g. SOAML) and practices to effectively use a set of services to solve complex health IT problems (service orchestration)
- An Interdependent registry specification
  This project would develop a service specification to provide a common interoperable registry capability for both clinical and non-clinical domains.
- Medication profile retrieval using RLUS (see Medications and SOA below)

Conference planning

The Committee commenced planning for the annual OMG/HSSP conference to take place in Chicago Apr-May, 2012 and identified the themes of service orchestration (how services can work together to provide a flexible solution) and non-health implementations of CTS2 and DSS.

Medications and SOA

During this HL7 WGM, a series of informal discussions unfolded regarding the abstract nature of the SOA specifications and that it would be tremendously valuable to demonstrate how these abstract services could be applied to a domain need (e.g. ancillary, clinical specialty). Additionally, SOA has just completed ballot of the hDATA Record Format Specification. Finally, there are a number of efforts underway to define (or refine) all HL7 artifacts as they relate to the Services-Aware Interoperability Framework (SAIF).

What transpired was a proposed project that will be defined in the coming weeks. There is agreement in principle from the ArB, the Pharmacy Workgroup, and the SOA Workgroup to

create for ballot a Medications hDATA Content Profile, to be done in collaboration with the Pharmacy WG.

The new project scope document will be developed over the next few weeks via teleconference. The project scope will be formally reviewed and approved both by SOA and Pharmacy WGs before submission to the TSC for approval.

Further information on this and previous meetings can be obtained from
http://wiki.hl7.org/index.php?title=Service_Oriented_Architecture.
The Agenda for the week and minutes of the meeting are available at:
http://hssp.wikispaces.com/event-2011-09-HL7-SanDiego

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue/Action/Recommendations	Recommended for action by
hData DSTU	hData HL7 draft standard for trial use needs to be considered for inclusion in the Australian international work program as it may be relevant to national infrastructure initiatives **Action: Examine the relevance of hData HL7 DSTU for future simplified Service specifications**	**NEHTA**
CTS2 implementations	A National Terminology Service would reduce resource investment required to distribute, use and maintain eHealth terminologies. It would also facilitate term and termset searching and provide an underpinning for conformance testing of terminology There are now two open source implementations for a Common Terminology Service. One is a "toolbox approach" that allows rapid development of CTS2 compliant software and the other is the French (Phast) implementation as a "read-only" terminology source. **Action: Assess benefits of implementing and deploying a standards based Terminology Service. The CTS2 implementations would enable a rapid, low-cost, standards based roll-out in Australia.**	**IT-014, DoHA, NEHTA, MSIA**
DSS Implementation	The decision support service has now been implemented by the Mayo clinic and the code is available as open source. **Action: Ensure that groups considering decision support are aware of this highly functional, standards based, low-cost implementation pathway for Decision support.**	**NPS, NEHTA, MSIA, DoHA, AMA, RACGP**
HCSPD service	Database Consultants Australia (DCA) is submitting an OMG implementation of the Human Services Directory. This is the first time an Australian company has taken part in this part of the HSSP process. **Action: Provide support as required to facilitate DCAs involvement**	**IT-014, DoHA**

Topic	Issue/Action/Recommendations	Recommended for action by
Patient Care Services Project	There is a need to be able to extract data from clinical systems, to identify Integration Points and to enable optimal achievement of overall functional requirements by orchestration of interacting services from multiple vendor and knowledge services. Australian work by DoHA, RACGP and Industry has laid the foundation for this and a SOA / SAIF-compliant set of standards needs to be delivered. Mobilising the diverse and potentially conflicting parties is challenging progress. There is no obvious group for advancing this in the Australian standards community. It is supported by groups doing Clinical Decision Support and considered to underpin advanced stages of Meaningful Use. **Recommendation: Identify or create a place to look at this work in the Australian Standards Community.** **Action: Discuss at IT-014, call meeting of key stakeholders from software industry, knowledge vendors, MSIA, IHE.**	**Standards Australia, HL7 Australia, IT-014, MSIA, RACGP, IHE.**

29 STRUCTURED DOCUMENTS (SD)

DESCRIPTION

The SD Working Group is responsible for design and implementation issues around documents, particularly CDA. The current release of CDA is R2, which is in the implementation phase, and a new release (R3) is under preparation.

PROGRESS AT THIS MEETING

The consolidated CDA story ballot continues through the balloting process. The consolidated CDA
story is a US realm specific document; as such, it's not clear how it is relevant to Australian interests or whether it would be appropriate for Australia to take part in the balloting. It is likely that it will be quite relevant to the NEHTA/National EHR course in the longer term. HL7 may publish an addendum that identifies all the US realm specific features, principally value sets, that would need to be changed for the document to be adopted in other realms.

CDA R3 development has stagnated, as the committee has been unable to come to a clear position over how to deliver the complexity needed for some uses without making CDA too hard for other uses. This has led to renewed interest in a CDA R2.x (several suggestions such as 2.5, or 2.1, were provided). This is some sort of half-way house – much more limited in scope but still a significant increase in the ability to represent complex clinical information. It remains to be seen whether this effort will be able to find a workable balance.

Work with Clinical Decision Support *CDS* (see report on CDS for more details)

The SD WG held a joint meeting with CDS and worked through the main areas where CDS was targeting SD and CCD standards for use in CDS systems. These are:

- **Virtual Medical Record vMR Project**
  The vMR is an abstract specification of EHR data satisfying CDS requirements and independent of implementation technology. Its use is for on-the-fly operation during rule execution and it thus differs from the SD and EHR approaches to records in that it does not assume persistence.
  vMR is being further developed with more Implementation Guides (IGs) and Template specifications which will apply against standard data models including SD specifications. These include CCD, Care Plan of PC, and for priority tasks of CDS eg. drug –drug interactions, vaccine advice, family history risk analysis and genomics.

- **Context Aware Knowledge System Info Button**
  The joint meeting worked through CDS Context Aware Knowledge System or "Info Button" which is being applied in the "CliniGuide" project development at the University of Utah. This will be used to retrieve medication lists and problem lists from EHR-based systems with integrated access to treatment guidelines and patient education materials. The project proposes to use a variation of the CCD standard as basis for the exchange. The simplicity and limitations of Info Button in this use are its focus on a single core clinical concept and context limited to the clinical task at hand. In this proposal CCD becomes the knowledge request payload. Only a subset of CCD aligning with VMR and relevant to knowledge request and retrieval would be required. It is intended to enhance this as a service based approach leading to DSTU Profile developed in association with SOA.
  CCD does not provide a Family History Model adequate for CDS, and is considered unsafe for practical CDS implementations: it is too complex (too hard to set attributes etc.). Nor is CCD considered satisfactory for Rules --it needs simplification, although Green CDA improves on this.

- **Patient Education Project**
  The Structured Documents – based Patient Education Project is developing a standard way of structuring the record of education given during an encounter for storage in the patient's EHR which will also provide a medico legal audit trail of that aspect of care. This is being linked with the Info Button Standard and will be compliant with US Meaningful Use.
- A reference implementation of these HL7 CDS standards is being developed in the Open CDS project led by CDS co-chair, Dr Kensaku Kawamoto. This project has over twenty collaborating organisations from industry, academia and health service providers. Internally, it uses the HL7 vMR which is built on the RIM. Data mappers work between the vMR and CCD as well as to other standard representations. The project is also building around open tools for terminology (including SNOMED) support (Apelon), knowledge and rule authoring and domain specific language (DSL) creation.

Committee Overview, Minutes & Documents:http://www.hl7.org/Special/committees/structure/index.cfm

Wiki: http://wiki.hl7.org/index.php?title=Structured_Documents

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue/Action/Recommendations	Recommended for action by
Clinical Decision Support in Information within Structured Documents and EHRs	Clinical information will be contained in NEHTA-specified Structured Documents, being brought through IT14-6-6 for use in data exchange, as it currently is within deployed EHR-based applications in Australia. It is important that this information meets requirements of CDS and can be extracted accordingly. HL7 CDS projects have found that this is not straight forward **Action: Groups working on CDA , EHR, Knowledge representation, Guidelines, and CDS review their requirements against CDA Implementation Guides, and that the this be done in conjunction with HL7 CDS-CDA work.**	**IT-014-09, IT-014-06-06 Knowledge Vendors, MSIA, RACGP**

30 TEMPLATES

DESCRIPTION

This group supports the HL7 mission to create and promote its standards by creating the procedures for creation and management of HL7 Templates. An HL7 template is a registered expression of a set of constraints on a balloted RIM derived model.

The Templates Work Group will:

- Create normative standards for the definition of HL7 templates;
- Define the procedures for administering a meta-data repository or template registry to serve as the home for templates defined by HL7 bodies, HL7 members and other parties; and
- Develop procedures and educational material to guide interested parties in the development and register HL7 templates.

The Work Group will have close, ongoing relationships with the following HL7 Work Groups:

- Vocabulary WG to ensure that template data structures make proper and consistent use of vocabulary domains ;
- Modeling and Methodology WG to ensure that the rules for creating templates are consistent with those for other HL7 artefacts;
- Attachments WG to ensure that the rules for creating templates are consistent with those used for claims attachments used within the HIPAA context; and
- Structured Documents WG to ensure that the rules for creating templates are consistent with the rules for creating HL7 structured documents.

PROGRESS AT THIS MEETING

HL7 Pilot Templates Registry

This initiative was described and discussion ensued about the merit of the project. The project scope is to ensure that the business requirements analysis is sufficient to ensure template artefacts can be successfully registered and maintained throughout their life cycle from initial proposal through to active use, including roles required for management and adoption. This is required because many groups create templates independently and there is a need for discovery, availability, methods for representation, what approval state they possess and how they can be accessed and used. The purpose of the project is to ensure that in using the templates, the user can be assured of the authenticity and purpose of a particular template. The potential problem is that there will be too many requirements and therefore drown the project.

The project has specified that the business requirements cover four broad main issues being firstly the issue of discovery of existing templates, knowing what is available and were they can be located. Part of this is also the assurance that this is from a trusted source. Secondly, the analysis and selection criteria for templates and knowing which ones are most appropriate to the particular requirement. This is part of provenance and quality assurance that includes having the information of the template origin and history. Thirdly, collaboration on templates adoption and amendment with the user community is fundamental. Lastly, the change management process and closing the loop by providing feedback to developers and sharing the lessons from implementation.

The outcome was the development of the documentation to propose validation of requirements broadly to provide input to Templates Registry. This is in alignment with the objectives of “improving Australian capacity to implement health informatics standards and eHealth systems by expanding local knowledge and expertise based on international best practice” and promoting free trade and its benefits to health ICT (by lowering the cost of integrating and implementing local health information systems, many of which are imported, and by reducing costs to Australian exporters) – both these outcomes require Australian requirements to be embedded into global standards so that they can be adopted in Australia, rather than having different standards across domestic and international markets” “(as specified in the implications for Australia guidelines of the HL7 Delegate Template Report_Explanation Guide.doc)

Template Server

A Template server provides the capability to register and centrally locate Templates so they can be easily searched and centrally governed. A Template server has been on the “wish list” for the Templates Committee for at least four years. Discussions held at the Committee meetings suggest it may still be some years away despite renewed interest in developing required elements such as the template interchange standard.

The main stumbling blocks are:

1. *The complex metadata requirements*

The required associated set of data elements (metadata) needed to manage storage and searching of templates has still not been specified or agreed. However, it is clear the requirements will be complex in order to satisfy all use cases.

A spokesman for Accenture indicated this would be solved in the upcoming Australian National Template server implementation by using the metadata from the original Templates DSTU (now more than four years old), placing the metadata in RDF format and using SPARQL queries to locate required templates. This is the equivalent of an SQL database and SQL queries but using web semantics and specifications from the world wide web consortium (W3C).

It was not clear that this would in fact address the issues that have led to the Templates DSTU not going forward.

An alternate suggestion was made by members of the New Zealand and Australian delegations that the MeTEOR metadata registry (Australian Institute of Health and Welfare- AIHW) may be a more manageable and immediately available solution to serve the metadata and search needs.

2. *Governance*

Significant concerns were expressed over how templates should be governed. These included trusted sources and potential liability arising from their use. The need for appropriate quality assurance was seen as vital. An alternate proposal, to use a google search for templates which had a regular naming convention, rather than a formal template server, did not receive support due to the governance issues that remained unaddressed.

To address some of these issues a new project was approved that will be jointly progressed with Templates, Structured Documents (SD) , Patient Care (PC) and Vocabulary (Vocab).

The Project Scope will be: “Business requirements analysis sufficient to ensure template artefacts can be successfully registered and maintained throughout their lifecycle.”

This project is needed because there are multiple organisations using diverse technology, creating templates. This project would allow discovery of templates and knowledge of their state.

The expected output will be an Information Model describing the required metadata for template registration and maintenance. It is planned to target a minimum data set to allow this to be achieved in a reasonable timeframe.

NEHTA (Andy Bond) was co-opted to act as an external reviewer of the detailed project documentation as it is developed.

Although explicit criticism of the proposal in the actual meeting was muted, the proposal raises many practical questions:

- Why this is being put forward as a new initiative without apparent reference to the registry requirements previously defined by Templates WG (HL7 Project 473), which are planned to be implemented in the templates registry pilot under HL7 (approved in January 2010 and awaiting resource delayed due to funding restrictions)?
- How it relates to, will contribute to, and draw from work in ISO/TC215 on ISO supposedly completed prior to approval of the proposed international standard, ISO 13972, Health informatics - Quality Requirements and Methodology for Detailed Clinical Models (DCMs)?
- Whether this particular project will attract sufficient support from HL7 leadership to result in a practical implementation, given the previously identified costs and difficulties of HL7 implementing an over-arching templates registry and the lack of resources to achieve this through existing projects?
- Whether the types of metadata and extended process governance structures being proposed are likely to be productive, practical and supported by the wider health informatics community, if HL7 were actually able to implement them?

Given these issues, it is suggested that Australian interests monitor developments with a view to supporting harmonisation of this proposed work with other activities within HL7, the ISO work on DCM quality processes.

Project to update the HL7 Templates DSTU

A project proposal was submitted to update the HL7 Templates DSTU in August 2011 with a recommendation to change the name to reflect the fact that the document defines an interchange format for templates. Volunteers are being sought to assist in the work.

Further information on this and previous meetings can be obtained from
http://wiki.hl7.org/index.php?title=Templates_-_HL7_Wiki

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Specification of business requirements for a templates registry.	An updated project proposal is being put forward to carry out a business requirements analysis for a templates registry, which can be an authoritative source of information about HL7 templates being used around the world and similar artefacts developed using other modelling paradigms. The proposal seems to be proceeding by default without strong support and connection to other existing work in the field and likely commitment of the resources needed to implement and maintain such a registry within the global eHealth community. **Action: IT-014 monitor developments with a view to supporting harmonisation of this proposed work with other activities within HL7, the ISO work on DCM quality processes.**	**IT-014 (through IT-014-09 and IT-014-02)**
Update of HL7 Templates DSTU	A project proposal was submitted in August 2011 to update the (now expired) HL7 Templates DSTU with a recommendation to change the name to reflect the fact that the document defines an interchange format for templates. Volunteers are being sought to assist in the work. **Action: There is no specific action for Australia at this time other than to monitor progress.**	**IT-014**
HL7 Templates Registry Project	HL7 Templates working group is working on the specification of a templates registry. Review and input into the business requirements specifically the metadata requirements, to ensure that it contains the potential Australian requirements. **Action: Investigate the use of the HL7 Templates Registry and to providing feedback of lessons learned and information obtained as part of the Australian Template Server project, to inform the international work.**	**NEHTA**
Template registration and management Project	Issue: This new project is looking for detailed input and resources **Action: Consideration should be given to providing feedback, "lessons learned" and information obtained as part of the Australian Template Server project, to inform the International work.**	**NEHTA, DoHA**
Template exchange format project	NEHTA is one of the few major national programs that is not a sponsor of this project. **Action: NEHTA should engage with this project to ensure that any template implementation in Australia is compatible with future international standards.**	**NEHTA, DoHA**

31 TC/215 LIAISON ACTIVITIES

DESCRIPTION

Opportunities presented and were taken for Heather Grain and Richard Dixon Hughes, both members of the Executive Council of ISO/TC 215 to meet with the incoming secretariat of TC 215 and also to participate in a meeting of the TC 215 Organisation and Business Plan Task Force, that was convened to take advantage of the number of Task Force members present at the HL7 meeting in San Diego.

PROGRESS AT THIS MEETING

A big issue with potentially huge implications is the changes in the leadership at the American Health Information Management Association (AHIMA) where the board of directors has become much more inward-looking. The CEO and COO departed several months ago and are just being replaced. Several Vice Presidents including Dr Don Mon (Chair-elect HL7 International) were retrenched on the Friday before the WGM and a restructure is underway. Don therefore had to pull out of coming to the WGM.

It is unclear what this means for the recent AHIMA commitment to take over the secretariat of ISO/TC215 from the Health Information Management Systems Society (HIMSS) and for Lisa Spellman, recently recruited into AHIMA to service the secretariat, which had previously been a function for two staff at HIMSS. Richard Dixon Hughes had several meetings with Lisa and discussed approaches to manage possible implications for the TC215 Secretariat, which is unlikely to be heavily resourced. He agreed to be part of a delegation to meet with AHIMA management at the TC 215 meeting in Chicago in October to give an international perspective on the role of the TC 215 secretariat.

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue / Action / Recommendations for Australia	Recommended for Action by
Management changes at AHIMA	Recent management changes at the American Health Information Management Association (AHIMA) threaten the smooth transfer of the secretariat of ISO TC 215 Health informatics from the Health Information Management Systems Society (HIMSS) and the ongoing level of support and resources needed to provide an effective secretariat service into the future. **Action: Richard Dixon Hughes (as Australian ISO/TC 215 HoD) and Heather Grain (Convenor TC 215/WG3) to monitor the situation, provide counsel to the incoming secretariat. There is no specific action for Australia at this time other than to monitor progress.**	**Richard Dixon Hughes** **Heather Grain**

32 TERMINFO

DESCRIPTION

Specification of a general approach to resolving issues related to the interface between HL7 information models and terminologies or code systems.
This project proved to be highly informative, but less than practical in its results.

PROGRESS AT THIS MEETING

Specific guidance is needed in order to ensure that HL7 V3 standards achieve their stated goal of semantic interoperability. When communicating clinical information represented using concepts from SNOMED CT and LOINC terminologies, in situations where aspects of the terminology and information models overlap. This is becoming more critically important as use of these messages, document and terminology standards in concept is increasingly being mandated by government authorities. SNOMED CT is intended to be used by HL7 to hold its own terminology.
SNOMED CT and LOINC are increasingly used in HL7 and there is interest in increasing their use.

This project is being resurrected as the original Terminfo document indicated that we would move to including other terminologies. A New Project Proposal was developed at the meeting:

> *TermInfo R2. This will be an Implementation Guide for using of SNOMED CT and LOINC in HL7 V3 artefacts (including CDA structures for SNOMED CT and LOINC documents).*

Alternative names suggested include: *Implementation of SNOMED CT* and *LOINC in Hl7 v3 artefacts*.

This work is intended to be proscriptive where it can be, but recognises that there will be occasions where the guidance cannot be followed. The work needs to provide information on best practice. The title needs to reflect whether the work is proscriptive or descriptive, and /or includes elements of both.

This is an implementation guide for all implementations of CDA and other V3 artefacts.

There are expectations that implementation guides are usually domain specific and this document would not be as the intent is to address all of HL7 V3. This may represent issues to Publishing Committee.

An implementation guide is a set of explicit instructions on how to build appropriate, conformance compliant inclusion of SNOMED CT and LOINC in artefacts.

Scope discussion: in V3 everything is mostly a model however some templates are documents. Should templates be included in this work? This requires further consideration. It will not include ICD10 etc.

There have been so many problems about the appropriate collaborative use of LOINC and SNOMED CT that including both is almost required. This needs to be resolved as there are significant issues and there is a need to clearly indicate where each is used.

Are there other standardised artefacts e.g. V2 that need to be addressed to resolve the current issues? This also requires further consideration.

There is insufficient structure in the underlying concept model of the terminologies, and therefore people would have difficulty claiming this work to be normative. HL7 have no control over these components. The document will none the less provide guidance on conformance as far as possible An informative document is explanatory, expository and provides recommendations for process and structure, but does not make rules which a normative document does. Additional capability for proper terminology management in existing systems will be developed over time and it will progress towards a more normative approach.

It was agreed that this work will be informative.

It is not anticipated that changes would be required to data types as a result of this work. It is not intended that this work directly produce CDA documents, though it will impact them.

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue/Action/Recommendations	Recommended for action by
TermInfo R2	This work has a direct impact upon CDA work and as such Australia should be actively engaged in this work. **Action: Include this work item on IT-014 international work program and ensure that delegations have suitable skills to contribute and represent the Australian position**	**IT-014, NEHTA, DOHA**

33 VOCABULARY

DESCRIPTION

The Vocabulary working group provides an organisation and repository for maintaining a coded vocabulary that, when used in conjunction with HL7 and related standards, will enable the exchange of clinical data and information so that sending and receiving systems have a shared, well defined, and unambiguous knowledge of the meaning of the data transferred. The purpose of the exchange of clinical data includes, but is not limited to: provision of clinical care, support of clinical and administrative research, execution of automated transaction oriented decision logic (medical logic modules), support of outcomes research, support of clinical trials, and to support data reporting to government and other authorized third parties.

To achieve this goal, they work cooperatively with all other groups that have an interest in coded vocabularies used in clinical computing. Some of the groups that this WG seek to work closely with include: standards development organisations, creators and maintainers of vocabularies, government agencies and regulatory bodies, clinical professional specialty groups, vocabulary content providers and vocabulary tool vendors.

The Vocabulary Work Group activities include:

- Document HL7 vocabulary design and maintain the documentation guidelines on the principles of vocabulary message content and structure over time – the Core Principles project defining the principles of how this should be done is a current major work item nearing completion;
- Maintain OID Registry with approval for new OID requests – including current consideration of ISO OID registry metadata standardisation;
- Maintain the V3 Vocab repository – Currently considering how IHTSDO and other organisations activities might manage more of the vocabulary registration processes, i.e. that HL7 will 'use' existing repositories where possible rather than maintain their own;
- Maintain table 0396 (V2 content for registered coding systems) including new requests, changes to existing entries, publishing on HL7 website; and
- Educate stakeholders via tutorials and improved documentation.

PROGRESS AT THIS MEETING

HL7 Facilitation of vocabulary content

The modifications to process required at harmonisation, including the use of SNOMED CT and LOINC content in HL7, directly require significant consideration of the up skilling of facilitators and all those involved with content of HL7 messages. Vocabulary have determined that they will develop educational material to suit this need and a draft of competencies has been established for further discussion with facilitators over the next few months.
Heather Grain is active in providing input to this process, as well as to quality assure educational initiatives in general.

Use of IHTSDO workbench to provide tooling for HL7 content

Information was provided by Kaiser Permanente (KP) staff about the utility of the workbench as well as their development of purpose specific reference sets. There was a brief discussion of the limitations and benefits of each of the reference terminologies used by KP as well as the use of interface terminologies to shield the clinicians from the reference terminologies. Examples of how refsets are used within KP from both a clinical and administrative perspective were provided.

Common Terminology Service - CTS2

This service has been finalised at OMG and the specification is available for free download from the OMG web site. The Vocabulary Committee will now prepare the HL7 services specification for normative ballot (currently a DSTU). The Vocabulary Committee is also considering whether to draft an informative implementation guide. Demonstrations were given during the meeting of the two CTS2 implementations developed as part of the OMG process. The first by the Mayo clinic takes a "toolbox" approach which allows a developer to rapidly build a CTS2 compliant software product that implements just the required parts of the specification. The second implementation by PHAST, the French pharmacy development standards organisation, is a more traditional software product implementing the lookup, search and value set functions of the CTS2 specification.
The Mayo clinic implemented a CTS2 implementer Software Development Kit (SDK). This can be implemented on any database platform (SQL, DB2 etc.). The SDK implements a CTS2 Development framework which provides all the web and common code, allowing rapid development of a CTS2 software product. Actual implementations are bundled together as "plugins". Each plugin has its own class path and may be implemented in JAVA, GROOVY, Scala or Clojure.

Build support is provided for Gradle and Maven. The plugin format is:

Plugins – pluginname.zip
pluginName.jar – service properties
/lib any 3rd party dependencies

A Plugin builder is provided. Each Plugin when developed, conforms to a common interface.

Next steps in development of the SDK:

- Solidify the Development Framework Service Interfaces
- Add a "compliance test" suite
- Add SOAP endpoints? (currently only REST)
- Add Java endpoints?
- Allow 'View' plugins – this would allow for custom presentations such as CSV, Excel etc.
- Development of implementation guides to support the community.

Two plugins have been developed:

- eXist – an XML database plugin
- NC BioPortal wrapper – a translator from the USA North Carolina NC Bioportal terminology server to/from CTS2 service format.

One demonstration implementation available is a SNOMED mapping browser which could be plugged into any CTS2 implementation. Another demonstration is a search function which returns all ontologies that meet the search criteria. This is implemented as a wrapper to the NC BioPortal.

The demonstration system uses the "Exist" XML database which has the HL7 MIF XML loaded. This allows searching of all HL7 V3 Terminology. Licensing is Apache II. The SDK and

demonstration implementations are all open source and will be hosted by Open Health Tools (OHT)

PHAST discussion – Nicholas Canu – France

This is another example of CTS2 in trial use.
It includes the creation of a CTS2 data model to help understand the HL7 SFM and provide directions about data details. It needs revision to address extensions, alignment with "core principles" and services granularity.

Some proposed extensions include:

- Concepts domains hierarchy
- Binding of one code – not supported by the current HL7 terminology model
- Concepts linked to structured descriptions
- Usage context understanding
    - Realms are jurisdictional domains
    - Templates "are" usage contexts
    - Links to templates
    -

Vocabulary will discuss options further with the Templates community.

Vocabulary Education

The Education working group are asking for tutorials to be reviewed in order to:

- have a more quality based approach;
- that content is able to be delivered within the time available;
- clearly identify the level and type of skills expected to be achieved by those who undertake tutorials; and
- identify the relationship between tutorials (pre-requisites etc.).

There is a need to:

- review all Vocabulary tutorial material and update course descriptions;
- identify gaps and needs; and
- update tutorial documentation.

It was agreed that the current Vocabulary 1 included far more content that was able to be delivered. The tutorial template was updated. The intended scope of educational offerings was considered, though not finalised. It includes:

- Introduction to HL7 Vocabulary (part of the current vocabulary 1);
- Vocabulary for Facilitators (part of the current vocabulary 1 and 2 with updates needed);
- Introduction to clinical terminology, including SNOMED-CT;
- Advanced Vocabulary (currently vocabulary 2) – still requires review;

- CTS – to be developed; and
    - Terminology Binding – to be developed.

It was decided that future HL7 face to face meeting would alternate between Introduction to Vocabulary, and Advanced Vocabulary with a topic specific offering being given as well (i.e. two offerings at most meetings covering vocabulary related topics).

Vocabulary and Anatomic Pathology (AP)

Presentation on PathLex and mapping to SNOMED CT was given. Pathlex is being "registered" as the official terminology for use in the Anatomic Pathology CDA templates. It is being loaded in a terminology server in France with a CTS2 backend.

PathLex is listed as an external terminology in HL7. The purpose and scope is similar to RadLex. The presentation indicated some lack of understanding of SNOMED CT hierarchy and intended use. There is a need to move to a poly-hierarchy for pathology rather than simpler representation processes to which pathologists are used.

There has been an attempt by anatomic pathology to understand how to accurately and consistently represent anatomic pathology using SNOMED CT. When attempting to represent pathology report content many SNOMED CT instances had only a morphologic abnormality concept which needs to be co-ordinated with a focus of 64572001 disease (disorder). The main issue is that many morphology concepts are not currently fully defined in association with a disorder.
Advice provided by vocabulary members: that there should be a small group of pathologists who understand the model of SNOMED CT to address the issues raised as many of these issues relate to a lack of understanding of the SNOMED CT concept model.

The morphological hierarchy has no context, and should not be used 'alone' to describe a clinical condition. There is clearly a need to review the requirements of anatomic pathology within SNOMED CT.

The storage of the information was also raised, and is a different issue. How concepts are stored is an implementation issue, the grammar that goes along with it is an implementation specific problem to address. AP need to provide mapping and specific grammar for post coordinated expressions, and how these are to be implemented in a system is up to each implementer how they will parse the information out and manage the storage and retrieval issues. The grammar is available from IHTSDO. There are members of AP who are going to the international IHTSDO meeting. The need to submit requests for additional content and the process for doing this must be understood.

It is recommended that the structure for distributing reference sets is SNOMED CT Release 2 and the details of this are available from the IHTSDO web site.

HL7 Value Sets and SNOMED CT tooling

Previous work has been done to map from HL7 value sets to SNOMED CT and this session is to discuss if, when, and how we migrate relevant HL7 content to SNOMED CT reference sets. In particular APHL – did a decomposition of table 70 and table 47 into the appropriate SNOMED CT representations to migrate specimen information to SNOMED CT.

The value sets were originally created in an undisciplined way and existing content is not necessarily properly semantically constructed. The way HL7 manage vocabulary at the moment is not materially, jurisdictionally or emotionally supported – it must change.

Current maintenance in HL7 doesn't have the resources to continue on the current path and duplicates, overlaps and gaps are present in the current system.

There are some content areas which could be done easily and some which are much more complex. Canada did route of administration and there were eighty-five concepts, out of those there were 10% which didn't exist in SNOMED CT. They were concepts such as inhalation as a route of administration, which it should not be as it is a process rather than a route – which is where the substance. Inhalation is inherently ambiguous, is it by nose or mouth, or tracheal tube – the route is where does it enter the body. Method can be injection, etc.

Where there are clinical value sets that have parallels within the SNOMED CT hierarchy, these are proposed as alternative value sets. It was agreed that we should minimise overlap with other reference terminologies.

If using HL7 code system for route of administration, and a value is needed something that couldn't be added to HL7 as it would make the problem worse, then what is to be done? Alternatives are to move everything to SNOMED CT, or have a mixed bag. The reason for migration is to avoid this problem. Ongoing map use is expensive and error prone. Canada have a policy of one time maps and conversion.

Proposed by Jim Case that we allow for two value sets for each field, one from the reference terminology and the other from HL7 with the goal to deprecate the 'old' HL7 value sets. This would mean that individual countries might choose to map as a mechanism of data migration, or might consider change of the data element and its content. This approach meets the need to change and the need to identify mechanisms which are achievable from a workload perspective. Once a value set is to be deprecated it can no longer be changed.

In sound terminology based approach supports synonymy, to deal with display names which is currently being managed outside the classic HL7 model.

Canadian problem: If you have to add a concept to an HL7 code system – the only way to do it if my users need it right away is to put it in another locally governed code system, requiring two OIDs in one value set, while using e.g. SNOMED CT a local reference set could be used.

What could happen is the workbench has the ability (with a little extra work) to, when submitting terminology changes to harmonisation, view the change suggestion, and on one screen, see this is what it looks like, make changes there in harmonisation until it is correctly structured, and move

that into the HL7 official sandbox when agreed. Move people can make changes for local use only.

Justification: the maintenance of the value sets, as people come up with something that isn't in SNOMED CT, it can be added in the HL7 name space and transition has a management and quality assured process.

There is a need for two interfaces, each easier to use than the current workbench. In the workbench you can create a set of tasks. For example the NHS created a ref set development business process – assign owner, developer, and reviewer, there is metadata associated and a deadline can be set, and the system then sends it to the developer and then to the reviewer when each are done, it then goes forward/back etc. until complete. HL7 need to come up with our own business processes and our own simple interfaces to, for example, create a value domain or value set. This was tried in HL7 vocabulary management but was not as successful as it could have been. Also needed is an interface that only exposes SNOMED CT terms and codes, as not all HL7 members have access to a full SNOMED CT and therefore do not have the right to access the workbench directly.

How to progress change

There is no universal content policy, other than the harmonisation process, for the creation, or discipline around the creation of terminology that goes in to HL7. If the concept can be justified the harmonisation process is largely of the relationship to the concept model, rather than sound terminological practice. This has resulted in lack of clarity, gaps and overlaps. The absence of a terminology structure, or significant ontological relationships, in the current representation is not sustainable.

A trial of the case and suggested mechanism for change will be made starting with:

- Orders and Observations
- Pharmacy

There is a need to ask each working group which value set they would like to 'fix' first? Vocabulary WG are seeking to restrain the code systems to a small number of terminologies and draw from these the value sets.

Or indicate that code set x will be deprecated and that the relevant committee provide a SNOMED CT based reference set to replace it.

Difference between ref set and value set

For every distribution there is a language specific preferred term. The reference set of preferred terms differs according to purpose and in some cases domain. This would not be considered as a value set but are in effect language reference sets. SNOMED CT Release 2 will have only synonyms, and fully defined term, and the preferred term will be defined by reference set which should make this problem easier to resolve.

At the next working group meeting ask David Markwell to help facilitate a discussion at a simple level of reference sets and value sets. This could become a feeder for education.

Russ Ham reported that he has worked on a tool that draws content from more than one terminology/code system. This can be achieved by the workbench model being mapped for each system.

IHTSDO Workbench question

Production of a content list of concepts and descriptions is one thing, but true utility is obtained through access to the picture of the definition and all the attributes and clauses that form the intentional definition – the reference set definition. Specification reference set is the definition of what a reference set contains. For example: there is a need to be able to say "I want these three concepts and all the children of this concept". This is equivalent to an intentional value set. The specification reference set is resolved to produce a 'flat' reference set. Russ Hamm indicated that this functionality doesn't exist in the workbench but it could be added. This is a functional requirement of HL7 tooling.

Specification ref set and the member reference set should both be distributed.

The question of whether we create post-coordinated expressions to represent the concepts within HL7 value sets was mentioned but requires further time and consideration.

PROJECT SCOPE STATEMENTS

Request for information for workbench

If the workbench were the terminology tool used by HL7 it would give a better opportunity to work with national release centres to propose changes to IHTSDO. The current agreement doesn't mandate the use of the workbench. HL7 have many members who are not members of IHTSDO which could limit the use of the terminology tooling within HL7. It is likely for a period of time that not all HL7 members would be allowed to use it. This might be something HL7 can live with, but others need to be aware of it.

The RFI is proposed to solicit information from the rest of the terminology industry to identify if there are other potential candidates to meet HL7 terminology management needs. This was discussed in January but has not progressed beyond the project scope statement.

There is a need for hard numbers on what it will cost to get where we have to get to.

From a tooling standpoint the objective is to establish a good set of requirements so that we can do an effective review of options. The steering division has put tooling requirements at the top of our requirements list. The Board may have modified that position.

IHTSDO have no plans or ability to respond to an RFI if one is provided. Any organisation should be encouraged to respond. It should be broken up into stages. It is unknown how much money is out there. If it is divided it into chunks for progressive development this may make finding the funding required more achievable.

There is an existing list of business requirements:
http://wiki.hl7.org/index.php?title=Proposed_Vocabulary_Tooling_Requirements

These requirements indicate what must, should and might be included in the vocabulary tool. There are some requirements far more important than others, such as the ability to export to MIF for publication support.

There was considerable discussion about whether we should develop an RFI (which may get limited response if potential responders don't know whether we will go ahead or not), or an RFP.

The meeting considered the requirements and identified priorities and Must haves (shown in the table below)

- Minimum = Must – functionality is there for those who understand the tool and will be establishing the new system.
- Required – Must in X years (needed ASAPp for all users, such as HL7 facilitators)
- Important = Should (can't wait 5 years for this, but don't necessarily need it in 'phase 1')
- Could = nice to have

Requirement	**Priority**	**Must**
User interface – needs to be accessible and usable to our casual users – e.g. vocabulary facilitators.		Required
Import / export external vocabularies (those outside of HL7)		Required
Management of the HL7 namespace extensions separately from the core of SNOMED CT terminology. There is the HL7 extension to SNOMED CT as well as the concepts that are HL7 specific.	Important	
Create and maintain code systems and value set		Minimum
Maintain code system and value set revision history	Important	
Create, and apply Maps between different code systems	Could	
Create/Maintain concept domains		Minimum
Support multilingual character representation		Required
Support multilingual translation (in the code systems - synonyms)	Could	
Support multilingual user interface	Could	
Multiple users – access – a central repository is expected		Minimum
Workflow manager – this includes business process design to support workflow, which includes control of editing tasks in sequence and in manner.	Important	
Conformance support – HL7 conformance – e.g. characteristics which must be associated with the terminology must be included. When a value set is created it guides the user to enter appropriate content and syntax.	Important	
User management (roles and groups)		Required
Backup and Restore – provided by the tool to ensure rebuild and usability		Minimum
Undo and redo support – multiple levels		Required

Support CTS2 interface (not necessarily a high priority)	Could	
Import/export to MIF		Minimum
Need to support value sets composed from multiple terminologies		Minimum
Need to be able to support value set assertion machinery used by HL7 – need to define the level of support		Minimum
Ability to identify core vs extension content easily – define this		Required
Ability for a user to create terminology changes in their own workspace and promote appropriate content to the HL7 extension or the core.		Required
There are quality, usable, standard educational materials available	Important	
Access to the source code for the software tool/s for HL7 maintenance purpose - Open source license (preferred)	Important	

The review must also consider the status of any required feature. Status indicates if the product being reviewed has this feature – available, in development, possible or not possible.

The cost and scope of training must also be identified.

Terminology Binding

Within the binding processes it is acknowledged that there is a need for a human readable binding syntax. There is a syntax, published by Stan Huff several years ago which is not correct, but has been used within HL7 and other organisations.

There is an urgent need to update/complete a document covering this area which uses the correct format. The wiki has information on this but it needs to be drawn together. The core principles information has been incorporated in the wiki. This impacts the writing of binding information in the implementation guides. Templates for bindings must have the right material expressed the right way. There is a request for additional guidance, on top of core principles to assist people in writing binding instructions for templates.

There is an agreed need for definitions of core binding, and examples of binding syntax. There is a problem with the MIF version 1, which is out of date as it relates to binding.

Issue: This issue is to be presented to Foundations and Technology steering division. There is now a normative binding design, and we are following up with educational materials etc. but it is not in our tools yet. There is a need to budget for this facility – and to argue that this work needs to be supported and escalated.

People have to understand what binding is, how and when to use it, how to correctly and consistently express it in documentation they are producing. They also need to know how to use the tools that allow them to capture and express it and produce machine readable output. The volunteer community does not have the time to complete this quickly or in the time frame required.

There is a plan to incorporate MIF 2 structures into the CDA schemas. ISO work is also being specified in this area and that may be the arena in which resources might be found.

Issue: There are also issues of readability of binding statements for other languages. Because the grammatical constructs of different languages are different, native speakers of each required language are needed to correctly represent the concepts. There is also the need for these people to understand the concepts being translated. The English version must be finished first, then the initial set of foreign language translations.

Having draft material that is available is better than nothing. There are informative documents of which the publishing committee should be aware. The wiki could be converted to pdf and published on the documents and presentations page on the wiki.

Issue: Evolving the version 2 vocabulary model into the v3 model. Three months ago we began an effort to start this work with InM and the version 2 editors. Ballots of V2.6 have had the addition of value set OIDS, code system OIDs to support connection of the terminology models.

This issue of V2 vocabulary model conversion to v3 Model needs to be included as a priority item in the work program for teleconference calls.

Testing of Binding

Discussion on inclusion of LOINC (as an example) in terminology binding statements. Given that we have black box testing, what type of methods and tools do we have to test these systems. Once the LOINC code is received it will be internally mapped to the internal system and displayed a string on the screen.

When mapping what level should the map be made? Once a decision is made if a particular code is required by a given national domain, how are variations managed effectively and safely? The base premise of mapping is that a single concept should never to map to more than one concept in the target code system.

There are many government conformance requirements to incorporate LOINC while the local system may use a different code system which is mapped. How can testers know whether they have the correct values?

The process of display of all values has been considered as the most reasonable and safe way to approach this problem. However, when used in systems the clinicians have found multiple displays of similar information confusing. The clinicians want to see information that is represented in one way consistently.

If a normal message is sent into the system then it is not the code set of LOINC codes, but a specific reference set. How do you test to this and what authority does the reference set have?

Issue: There should be at least a consistent, agreed approach to the receipt of a LOINC code that isn't part of my reference set. A laboratory should not be expected to perform a test which is not within their own test set. This should raise an error.

If a system was mapped X to Y and that system received a more detailed concept represented in Y than the one in X, the message shouldn't be rejected because it is a child of a concept understood in X. The system should get an error that forces it to go out to where it can access the library or list of functions to go up the tree and find information at the level used in the local system.

This indicates an issue of system behaviour related to mapping.

In HL7 and in binding we have said that it is the standard codes that flow between systems, and you use local codes within the system and to persist older data collection information. Vocabulary need to provide guidance so that people don't do things that are dangerous or inefficient – as in the example above.

Discussion on how we test conformance occurred. Those doing mapping need different procedures – those who persist their map values only, and those that persist both their mapped values and the standard values and those that persist the standard values and map on the fly.

Question on testing

There is a need to identify how to:

- test example message sent to EHR system and its black box testing; and
- what kind of things to test system.

There are studies that have shown native terminology in systems gives clinicians more errors as they have to think of significantly more things, system change and concept representation change.

A well implemented interface terminology always carries with the local interface term the underlying map term at all times. In Canada they don't wish to send and use the additional properties of multiple concept representation –they don't want to send both codes as vendors consider this too much programming. In the UK they have taken the same approach, to send all versions of the concept and description, but there have not been objections from vendors.

The code will have to be acceptable with no loss of information.

The LOINC code text must not lose information and this test must be tested and confirmed by domain experts. The standard code as well as the local code should be used. You persist or store what is perceived.

Vocabulary related ISO work items

Mapping work item

ISO have a work item, with ISO central in pre-ballot preparation, on the purpose, issues, skills etc required for mapping of concepts from one representational form to another. This report has been discussed in the HL7 Vocabulary community in the past. A copy of the work item will be forwarded when it is prepared for ballot.

Terminology Binding

HL7 balloted specification for bindings in core principles will progress into ISO with additional information will be added to relate and provide information on data types. This work item has been ballot as a new work item proposal in ISO and is expected to pass. It will be discussed further at the meeting in October in Chicago.

OID Registry Project

The OID registry project seeks to identify the minimum metadata requirements for OID registries. There are many projects underway on OIDs. Kai is working on this to get it ready and Ted Klein is attempting to find time to assist with this. There may be some delay in that project. The plan is to have a technical report to provide guidance for policies and procedures for OID registries, and the technical specification relates to the metadata collection associated with an OID registry. The document will address issues including:

- What should the model of the minimum set look like; and
- What is the schema for carrying that data.

This is a need to support conversion into national and international comparability. This will help OID registries share information.

There are issues around the curation of OID registration including: Who is the delegated authority within HL7 to issue OIDS? The documentation needs clarity around who can sub-assign OIDs.

Australia has assigned OIDS without 'owner' organisations being aware of this. V3 requires proper identification and we have imposed a cost on the implementers because of this but we have a volunteer curation process. This adds to the cost of implementation in systems and makes creation of duplications possible. If we are going to do this we must have a professional consideration and this appears to be a logical thing for the HL7 Terminology Authority.

Analysis is indicating that there could be 15-20 thousand OIDs registered in Australia alone.

There was a desire to establish a single automatic place for lookup and registration online for OIDs. The proposal for an API for this exists. However, this project has been sitting in the project system for some time and resources have not been assigned. This work requires monies from the tooling budget. It has been partially designed. We have called for volunteer help to do this, but because of the way we are now managing the OID registry, through a mirrored sequel server database, there would have to be work with the tooling committee to identify how to make this project active.

There is an outstanding item to improve the documentation on the OID registry including information in the OID implementation guide. This work has been unreasonably delayed, but is imminent to go to publication. There is a need to extend this publication. The front page of the wiki may need to be updated to make the documentation easier to find. Ted suggested working together with Grahame Grieve to assist improvement.

Professional Curation: HL7 has taken over the software development previously managed by volunteers. HL7 contracts out reviews of the content periodically. The HL7 executive committee would be uncomfortable about the need to manage and maintain an OID registry as a key component of HL7 V3.

Australia will register OIDs in Australia but also in HL7 – it is currently unclear when you are obliged to register in the HL7 international registry. Conformance requires registered OIDS, but is deliberately silent on whether local or international registration is required. Australia may register their own OIDS and HL7 international might mirror a copy of the national OIDs in their registry.

Ted Klein doesn't see safety issues related to different OIDs to identify the same entity if there is another OID for SNOMED CT for example – does this cause a problem? This causes interoperability problems but not necessarily a clinical safety issue. It is difficult to have HL7 as the minder of these activities. We don't curate that the creator of the OID actually has the authority to create an OID for a given purpose. It is impossible at the moment, even with significant tooling to ensure that there are no overlaps.

HL7 international was unwilling to take on the policing of individual national and organisational incompetence. We require that the current registry/s be searched prior to initiation of a new entry. Attempts are made to provide some oversight to represent major terminologies or value sets – and in some cases these are sent to the 'owners' of these terminologies to register, rather than having HL7 register them.

Question: If you register an external OID assigned to a code system, should you choose that OID for a code system? There are difficulties with the current registration form. Requests for suggestions for improvements should be forwarded to Ted.

Grahame Grieve and Ted Klein will improve the OID request form and written procedure, and be more prescriptive about items such as the description.

Searching of the OID registry is also proving difficult. Curation could be significantly improved in this area. This could be an activity of the Terminology Authority. This problem is voluminous enough that it can't be a voluntary activity.

Ted Klein will share with Grahame Grieve the current list of changes required to the OID registry.

This whole area could develop into a major problem and we need to act upon it. It was suggested that *Vocabulary take this issue forward to Tooling, Technical Steering Committee or John Quinn directly.*

This motion was moved by Grahame Grieve.

That Vocabulary working group to strongly urge John Quinn to develop/implement an API to support OID registry searching improvement and a registration API.

This motion was carried.

Traditional Medicine

Ted Klein is connected to the Traditional Chinese Medicine Technical Committee and Taskforce. There were new projects brought forward including a project on UMLS medical source design for literature for Chinese medicine (a Chinese medicine 'pubmed' format.)

Asif Syed and Ted Klein will discuss joint issues related to WHO technical advisory group work. It would be helpful if the classification being developed by WHO for TCM needs to be tied in with TC215 and TC249 working groups. These groups review new work items and identify if there is overlap and if so a special expert panel is established to support development and mutual reporting.

Common Terminology Services

There is an existing ISO publication on CTS1. There is a new work item on CTS2 and it was agreed that we will share these documents with WG2 and WG3 at TC215 and request their comments at appropriate times through the development process.

External terminology authority

Draft of a project statement identifying the requirements and terms of reference for HL7 terminology authority were discussed. Updates were made to the scope statement. Comment from Canada – this meeting is moving into issues of terminology implementation which needs and deserves more extensive international attendance and contributions.

The intent is that this Authority provide governance for the new content management system using IHTSDO tooling.

Modelling Ontology

There is a need to define concepts in the models and specify attributes of those concepts and this requirement fits well with the functionality provided by SNOMED CT. It would be useful in the models to say that this information concept is X concept (in SNOMED CT). The SNOMED CT R2 specification allows for annotations which would support this functionality requirement. Using the reference set process to package a model. HL7 will need a name space to undertake this work.

Issues:

1. There is no process in IHTSDO to recognise an organisation as an affiliate, to get a namespace HL7 has to be an affiliate. The relationship must therefore be resolved first. The namespace then can be easily established.
2. Prior to the establishment of the HL7 Terminology Authority the HL7 Management Board would act as the contact point.
3. Do we want a model namespace and a content namespace?

Originally the intent was to have an HL7 namespace of material which is not in the core of SNOMED CT, This proposal may mean that the HL7 namespace may have a high level concept to represent modelling concepts

Committee Overview, Minutes & Documents:
http://www.hl7.org./Special/committees/Vocab/docs.cfm
Wiki: http://wiki.hl7.org/index.php?title=Vocabulary

RECOMMENDATIONS ARISING FROM THE MEETING

Topic	Issue/Action/Recommendations	Recommended for action by
Vocabulary education needs	**Action: Australia to consider our priorities for tutorial development for Vocabulary**	**HL7 Australia**
Value Set Migration	The maintenance of value set information and where relevant migration to SNOMED CT based concepts (as HL7 migrate their data content to the HL7 namespace of SNOMED CT) will need to be considered for Australian content. This is an issue for non-clinical data, not just content one would normally consider using SNOMED CT for. **Action: Consider the impact of HL7 migration and the changes this may require for Australian Implementation Guides and other data components.**	**IT-014, IT-014-06, HL7 Australia and AIHW**
Value Set Migration	Identification of Australia's priorities for data migration should be identified in order to influence the decisions made for international migration. **Action: Identify priorities**	**IT-014, NEHTA, DOHA**
V2 Vocabulary Model development - Terminology Binding	Is this a priority issue for Australia? If so it is essential that we maintain active engagement in these processes. **Action: Determine national priority for this project and engagement.**	**IT-014**
Terminology Binding Project	ISO terminology binding project being led by HL7 vocabulary and modelling needs to be actively followed by Australia as a work item on our international engagement. **Action: Consider national priority for this project and ensure delegation skills are adequate to cover this work item**	**IT-014, NEHTA, DOHA**

34 FUTURE MEETINGS

The planned calendar for future HL7 working group meetings includes meetings at the following locations on the dates shown:

- San Antonio, Texas, 15-20 January 2012
- Vancouver, British Columbia, Canada, 13-18 May 2012
- Baltimore, Maryland, 9-14 September 2012 (26th Plenary and WGM)
- Phoenix, Arizona, 13-18 January 2013
- France (tentative) for May 2013 (as discussed in Affiliate Chairs meeting)

End of Report

35 APPENDIX A

ACRONYMNS

ArB	Architecture Review Board
AHIEC	The Australian Health Informatics Education Council
AIHW	Australian Institute of Health and Welfare
CDA	Clinical Document Architecture
CDS	Clinical Decision Support Workgroup
CIC	Clinical Interoperability Council Workgroup
CIMI	Clinical Information Modelling Initiative
CBCC	Community Based Collaborative Care Workgroup
CTS2	Common Terminology Services Release 2
DAM	Domain Analysis Model
DCM	Detailed Clinical Models
DICOM	Digital Imaging and Communication in Medicine
DSTU	Draft Standard for Trial Use
ECCF	Enterprise Compliance and Conformance Framework
EFMI	European Federation of Medical Informatics
EHR	Electronic Health Record Workgroup
eHGI	eHealth Governance Initiative
ELGA	Austrian CDA Implementation Guide in Development
epSOS	European Patients - Smart Open Services
HIE	Health Information Exchange
HITSP	Health Information Technology Standards Panel
HL7	Health Level 7 International
(HL7) ELC	HL7 E-Learning Course
IC	Implementation/Conformance Workgroup
IG	Implementation Guide
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standards Development Organisation
IMATF	International Membership and Affiliation Task Force
InM	Infrastructure and Messaging Workgroup
ISO	International Standards Organisation

ITS	Implementable Technology Specifications
IXS	Identity Cross-Reference Service
LOINC	Logical Observation Identifiers Names and Codes dataset
MDA	Model Driven Architecture
MIRTH	An open source cross-platform HL7 interface engine that enables bi-directional sending of HL7 messages between systems and applications over multiple transports available under the Mozilla Public License (MPL) 1.1 license – see www.mirthproject.org
MnM	Modeling and Methodology Workgroup
MSIA	Medical Software Industry Association
NATA	National Association of Testing Authorities
NIST	National Institute of Standards and Technology
NESAF	National e-Health Security and Access Framework
NHIN	(The USA) National Health Information Network
NQF	National quality (measures) framework
NWIP	New work item proposal
OID	Object Identifier
O&O	Orders and Observations Workgroup
OMG	Object Management Group
PA	Patient Administration Workgroup
PC	Patient Care Workgroup
PHER	Public Health and Emergency Response Workgroup
PIM	Platform Independent Model
PSM	Platform Specific Model
RIM	Reference Information Model. In the HL7 context this usually refers to the HL7 V3 Reference Information Model
RIMBAA	RIM Based Application Architecture
RLUS	Retrieve Locate, and Update Service
RM-ODP	Reference Model of Open Distributed Processing
SAIF	Services Aware Interoperability Framework
SDO	Standards Development Organization
SEC	Security
SHIPPS	Semantic Health Information Performance and Privacy Standard

SIG	Special Interest Group
SNOMED	Systematized Nomenclature of Medicine
SOA	Services Oriented Architecture
T3SD	Technical and Support Services Steering Division
TSC	Technical Steering Committee
vMR	Virtual Medical Record
WG	Working Group
WGM	Work Group Meeting