



**Report on the
HL7 Working Group Meeting
held in
Cologne, Germany,
29 April – 4 May 2007**

This Report was compiled by David Rowlands, Executive Chair, Standards Australia's Health Informatics Technical Committee (IT-014) from material supplied by all Australian representatives at the Meeting.

29 June 2007

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List of Acronyms

ADL	Archetype Definition Language
AHIC	American Health Informatics Community
AHML	Australian Healthcare Messaging Laboratory
ANSI	American National Standards Institute
CCHIT	(US) Certification Commission for Health Information Technology
CDA	Clinical Document Architecture
CEN	Commite Europeen de Normalisation
CMET	Common Message Element
DCM	Detailed Clinical Model
DICOM	Digital Imaging and Communications in Medicine
DMIM	Domain Message Information Model
DoHA	(Australian Government) Department of Health and Ageing
DSTU	Draft Standards for Trial Use
HER	Electronic Health Record
EHRS	Electronic Health Record System
HISO	(New Zealand) Health Information Standards Organisation
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
HTTP	HyperText Transfer Protocol
IHE	Integrating the Healthcare Enterprise
ISO	International Organization for Standardization
ITS	(HL7) Implementation Technical specification
LOINC	Logical Observation Identifiers Names and Codes
NCI	(US) National Cancer Institute
NCI EVS	NCI's Enterprise Vocabulary Service
NEHTA	(Australian) National E-Health Transition Authority
NHIN	(US) National Health Information Network
NHS	(UK) National Health Service
NIH	(US) National Institutes of Health
OCL	Object Constraint Language
OID	Object Identifier
OMG	Object Management Group
ONCHIT	Office of the National Coordinator for Health Information Technology
OSI	Open Systems Interconnection
OWL	Web Ontology Language
PDF	Portable Document Format
PHR	Personal Health Record
RHIO	(US) Regional Health Information Organisation
RIM	(HL7) Reference Information Model
RMIM	Refined Message Information Model
SDO	Standards Development Organisation
SIG	Special Interest Group
SMTP	Simple Mail Transfer Protocol
SNOMED	Systematised Nomenclature of Medicine
SOA	Service Oriented Architecture
SOAP	Simple Object Access Protocol

List of Acronyms (continued)

TCP/IP	Transmission Control Protocol/Internet Protocol
UML	Unified Modelling Language
VHA	(US) Veterans' Health Administration
WG	Working Group
XDS	(IHE's) cross enterprise Data Sharing protocol
XML	eXtensible Markup Language

Acknowledgements

Standards are central to Australia's national e-health agenda, and awareness of the status of international standardisation is important to standards developers, the health ICT industry and the health sector generally. The contributions from Australian delegates to the Cologne meeting to this report are therefore gratefully acknowledged.

1 Introduction

The second HL7 Working Group Meeting for 2007 was held in Cologne, Germany from 29 April to 4 May. Attendance at this meeting was lower than usual, at around 340 registered attendees from 25 countries, including 20 International Affiliates.

There were eleven Australians in attendance, including the Standards Australia delegation of David Rowlands, Richard Dixon-Hughes, Dick Harding, Klaus Veil, Heather Grain and Jane Gilbert (funded via the Department of Health and Ageing) and Max Walker (funded by the Department of Human Services, Victoria).

2 Background

Health Level Seven is a leading, global, accredited standards development organization (SDO) operating in the healthcare arena. Health Level Seven's domain is clinical and administrative data. Other SDOs produce standards (sometimes called specifications or protocols) for healthcare domains such as medical devices, imaging or insurance transactions

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

HL7 develops specifications, the most widely used being a messaging standard that enables disparate healthcare applications to exchange key sets of clinical and administrative data.

Members of Health Level Seven are known collectively as the Working Group, which is organized into technical committees and special interest groups. The technical committees are directly responsible for the content of the Standards.

HL7's Mission is to be an international community of healthcare subject matter experts and information scientists collaborating to create standards for the exchange, management and integration of electronic healthcare information. HL7 promotes the use of such standards within and among healthcare organizations to increase the effectiveness and efficiency of healthcare delivery for the benefit of all.

"Level Seven" refers to the highest level of the International Organization for Standardization (ISO) communications model for Open Systems Interconnection (OSI) - the application level. The application level addresses definition of the data to be exchanged, the timing of the interchange, and the communication of certain errors to the application. The seventh level supports such functions as security checks, participant identification, availability checks, exchange mechanism negotiations and, most importantly, data exchange structuring.

Standards development in HL7 is undertaken via 16 Technical Committees (TCs), which are listed in Attachment 1, some of which have subordinate Special Interest Groups (SIGs) to address new areas that may need coverage in HL7's published standards. There are currently 21 active SIGs. Draft standards developed by these groups are balloted by members of the relevant TC, and if successful proceed to full HL7 membership ballot. Typically there are three ballot cycles per year. As for other recognised SDOs, balloted material can be commented on as well as voted by the eligible balloting pool, and all comments must be individually reconciled and the agreed TC responses fed back to the commenter.

HL7 currently also has nine administrative committees, a Technical Steering Committee comprising all TC and SIG co-chairs, an Architectural Review Board and several Task Groups.

HL7 Working Group (WG) Meetings are held three times per year, shortly after each ballot cycle. Their primary purpose is to enable the progression of draft standards through the balloting and publication cycles - TCs and SIGs meet to draft and/or edit standards, prepare material for balloting, reconcile ballot responses, etc. TC, SIG and administrative committee meetings are generally held concurrently, which requires significant coordination to ensure Australia's interests are represented.

Standards development activities continue intensively between meetings via teleconferencing, email and face to face where there are clusters of participants within geographic proximity. For example, the Electronic Health Records (EHR) TC meets weekly via teleconference, as do its Personal Health Record (PHR), Interoperability and Legal EHR working parties.

The Working Meetings also provide opportunities for the HL7 Board, Technical Steering Committee, International Council and other standing committees and task groups to meet.

3 Objectives

Australia participates in international standards development activities in accordance with its obligations under World Trade Organisation treaties. The overarching objectives are to promote free trade and its benefits (by lowering the cost of integrating and implementing health information systems, many of which are imported, and by reducing costs to Australian exporters – both 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); and to improve Australian capacity in health informatics and health standards development by expanding domestic knowledge and experience based on international best practice.

Specific objectives for international standardization via HL7 during 2006-07 include:

- Monitoring and influencing HL7's strategic positioning as a global SDO, encouraging its collaboration with other global SDOs and the assessing the strategic positioning of its key products (HL7 V2x, V3, CDA, EHR Models, etc.) so as to maximise Australia's capacity to ensure that our health messaging and related requirements are supported unambiguously by international standards.

- Negotiating the inclusion of Australian healthcare messaging requirements into HL7 V2.6, 2.7 and V3 specifications for:
 - Patient administration
 - Diagnostics (pathology, radiology), and
 - Collaborative care.
- Negotiating the inclusion of Australian health sector requirements into the conformance framework for the HL7 EHR-S Functional Model and the proposed EHR Interoperability Model DSTU; negotiating towards harmonisation of CEN/ISO 13606 and HL7 V3; and negotiating international standardization of the terms and definitions used in EHR related standards.
- Assessing HL7's approach to and compatibility with service oriented architectures, as input into Australia's national direction setting; and negotiating the inclusion of Australian health sector requirements, and in particular those described by NEHTA, into service specifications being jointly developed by HL7 and the Object Management Group (OMG).
- Assessing the positioning, development, implementation, utility and effectiveness of HL7's Clinical Document Architecture (CDA), for input into Australia's national direction setting.
- Assessing and exploring approaches to the carriage of archetypes in HL7 V2 messages for referral, diagnostic results and collaborative care, for input into Australia's national direction setting.
- Negotiating towards the international harmonisation of common data types that will meet Australia's identified requirements.

Additional Australian interests may be pursued opportunistically, and additional specific objectives may arise from time to time as a result of the development of Australia's national e-health agenda and other national interests.

4 International

27 countries (including the USA) were represented in Cologne. HL7 currently has 27 recognised International Affiliates (listed in Attachment 2), and negotiations with 5 other countries are in process.

Updates presented to the HL7 International Council Meeting provided an overview of the state-of-play across the HL7 community.

4.1 International Affiliate Activities

Argentina

HL7 Argentina is currently developing a V2.6 claims implementation guide. With HL7 Spain they have developed training materials in Spanish and have delivered a series of courses focusing on CDA and V3.

Australia

HL7 Australia continues to focus on standards provision, education, support and certification. Education topics have included web services, terminologies and pathology/diagnostic imaging implementation, and the HL7 Australia website is getting over 15,000 hits per month. NEHTA has announced the selection of HL7 as Australia's messaging and communication standard, with support for V2 where it is already heavily used, HSSP & CDA R2 in more emergent areas and a longer term move to V3.

Austria

HL7 Austria is seeking to become a new affiliate. Austria has a national healthcare access card initiative underway, and is in the early stages of a national EHR development based on V3/CDA.

Canada

HL7 Canada is currently in transition into the Standards Collaborative, which is housed within Canada Health Infoway and supports Canada's SDOs (HL7, ISO, DICOM, IHT, IHE etc) via a single secretariat. The interim executive for the collaborative organisation has been established for 3 – 6 months until elections can be held.

HL7 Canada's membership is growing, due at least in part to Infoway's public support. The 2008 HL7 Plenary will be held in Vancouver in September 2008.

Finland

CDA R2 is the basis for the national interoperability initiative. A national e-prescribing project has failed, but HL7 Finland is now engaged with the Governmentt on a follow up project. V2 is still in widespread use and there is limited enthusiasm from the implemented base to move to other versions.

France

HL7 France is conducting education and training activities focusing on V3 and CDA, including in-depth courses for implementers. They held a significant meeting for VIPs with political power to explain HL7 requirements and processes. This meeting was held in the French Senate, and was successful but follow up is on hold pending the elections.

Germany

HL7 Germany has maintained a presence at major health informatics events and has strong work program in localizing HL7 standards and supporting IHE. It is actively involved in the national project specifying and implementing a health telematics platform.

Greece

The HL7 Hellas website was presented. They are conducting many seminars and conferences, and doing work on the extraction of data from medical devices into the

EHR. They are hoping to host IHIC in 2008. The Affiliates Council noted that ISO TC215's Joint Working Group meeting will be in Istanbul in October 2008, and there would be advantages in this being contiguous with the IHIC.

Japan

HL7 Japan is looking to host the May 2009 HL7 Working Group meeting. The Ministry of Health is developing HIPAA-like regulations

New Zealand

HL7 NZ is working on preparations for the International HL7 Interoperability Conference, to be held on 31 August and 1 September 2007. A call for papers has been released.

Singapore

HL7 Singapore is progressing towards affiliateship;

A presentation of the Singapore health system's roadmap for healthcare and biomedical science goals from the government was given. The Ministry of Health has released iN2015 - Healthcare & Biomedical Sciences Goals, and specific programs include the National Health Information Exchange, a seamless and secure information exchange in the healthcare value chain; and the Integrated Healthcare Continuum, enabling treatment at most appropriate locations.

The Government will identify and set nation-wide standards for healthcare IT infrastructure. This should include standardized data definitions and formats for medical records to be shared.

Singapore has implemented V2 widely, is using V3 RIM in the development of a cluster EHR and is looking to explore use of CDA.

Spain

HL7 Spain is very active with education and certification activities, and is positioning for V3.

Sweden

HL7 Sweden is raising awareness re V3. The Government is working on a conceptual model for healthcare, and HL7 Sweden is working with them to translate this into a V3 model. They are also looking at how to work with terminologies (chiefly SNOMED) and identifiers.

UK

HL7 UK is conducting seminars on healthcare systems' interoperability. Wales and Scotland are beginning their national programs and since interoperability with England is important, HL7 UK is looking to develop UK profiles (Connecting for Health profiles are just for England). Connecting for Health is now targeting CDA and looking to use the HL7 UK lab profile. HL7 UK has been contracted to develop a communications and marketing strategy.

New Affiliates

Austria and Singapore are in the process of becoming HL7 Affiliates, Lithuania, and Estonia are reasonably well advanced in their planning, and several Asian countries have also signaled their intention to join.

4.2 HL7 International Conferences/Events

The 2007 International HL7 Interoperability Conference (IHIC) will be held in Auckland on Friday, 31 August and Saturday, 1 September. Its focus will be on helping the wider healthcare community understand how to realize value from HL7 Version 3 and the Clinical Document Architecture (CDA), by sharing development and implementation experiences.

The conference program is available at <http://www.ihic.hl7.org.nz>.

The 2008 IHIC will be held in Greece, with the venue and timing yet to be determined. The Affiliates Council suggested a timeframe contiguous with the 2008 ISO TC215 Joint Working Group Meeting which will be held in Istanbul in October 2008.

HL7 is concerned about the lower than usual attendance in Cologne. The average attendance for the last four USA meetings is 545 and 430 people attended in the Netherlands. The Cologne attendance translates to a poor financial outcome, and the Board will need to assess the implications for the May 2009 meeting, which is scheduled for Kyoto.

The Finance Committee is recommending to the Board not to run any WG meeting that is expected to incur a loss. Affiliates were asked to provide feedback on why attendances are relatively low in Cologne; how additional attendees can be attracted; and how international WGMs could be made more financially viable – any comments to meetingtips@HL7.org.

The Japanese delegation pointed out that Asian turnout is likely to be much greater than usual in Kyoto. HL7 Board will make a decision on the May 2009 venue by August 2007.

4.3 Collaboration with other major SDOs

Senior HL7 representatives again confirmed their desire to collaborate with other international and global SDOs.

SDO Joint Initiative

A variety of standardization stakeholders including e-health program leaders and the health ICT vendor community have called for greater collaboration and cooperation between global SDOs to ensure that available standards are complementary rather than duplicative and competitive. One of Standards Australia's international standardization objectives for 2006-07 is to encourage this.

A significant step was taken towards this collaboration and cooperation at the ISO and CEN JWG meetings in Geneva in October 2006, with the signing of a broad agreement between ISO TC215, CEN TC251 and HL7. This was followed up at a meeting in Washington DC in November 2006 in which a small working group (including David Rowlands from Australia) began articulating the principles, processes and priorities via which it will come to life.

A draft Charter for SDO harmonisation was discussed at the recent ISO TC251 meetings in Montreal, and is now proceeding to simultaneous, fast-tracked ballots in ISO and CEN and to the HL7 Board. Essentially, the Charter:

- Articulates a series of affirmations about the need to collaborate on global standardisation and standards development, and aims to achieve “one standard-one test”;
- Commits to an integrated work program across the signatories, common processes for selection of projects, and common, cooperative communications; and
- Commits to resolve issues as they are identified.

This initiative will be guided by a Joint Initiative Council (of SDO leaders), supported by a Joint Working Group that will coordinate planning, etc. activities.

The draft Charter on SDO Harmonisation has been circulated to International Affiliate Chairs and the Affiliates Council urged the Board to accept it (motion passed 15 for; 0 against; 1 abstention). The Board subsequently endorsed the Charter.

(Note – ISO and CEN national member bodies are currently balloting the Charter. Early feedback from SO and CEN is that there is concern about the composition of the Council, as it represents a change from the usual ISO/CEN member representation model).

Regulated products.

This is one of the joint initiative items.

The European Commission (EC) had contacted CEN regarding six work items coming from the International Conference on Harmonisation through HL7 and into ISO. The EC concern was essentially that US commercial interests might be favoured via HL7 leadership of these activities.

Joint processes were developed and work has since progressed collaboratively. The initial drafts (Release 1) have been balloted and passed with comments. Release 2, with significant improvements, is now being planned and its development will be led by CEN but using a project team derived from ISO, CEN and HL7.

ISO TC215 report

Progress of HL7 items currently before ISO is as follows.

- ISO 17113 Health Informatics – Exchange of information between healthcare information systems – development of messages (based on HL7 V3) is in press

- ISO 27931, HL7 V2.5 Messaging Standard is in DIS stage;
- ISO 27932 Clinical Document Architecture (release 2) is in DIS stage;
- ISO 21090 - Harmonised data types for healthcare information interchange is up for NWIP ballot
- ISO 27931 Common Terminology Services (Release 1); and
- ISO TS 27790 Document Registry Framework.

A series of new work item proposals are also being considered that are of interest to HL7.

- Pharmacovigilance – Individual case safety report is up for NWIP ballot (being undertaken via the Vienna Agreement between CEN and ISO, with ISO leading);
- Pharmacovigilance – Structures and Controlled Vocabularies for Laboratory Test Units for the Reporting of Laboratory Results is NWIP (being undertaken via the Vienna Agreement between CEN and ISO, with ISO leading);
- Identification of medicinal products – Data elements and structures for the exchange of regulated product information for drug dictionaries;
- Structure and controlled vocabularies for pharmaceutical product identifiers;
- Structure and controlled vocabularies for pharmaceutical ingredients;
- Structure and controlled vocabularies for pharmaceutical units of measurements; and
- Structure and controlled vocabularies for Pharmaceutical dose form, units of presentation and routes of administration.

CEN report

An official mandate from the European Commission exists that requires CEN CENELEC and ETSI to accept a coordinated workplan over the next 3 years. This will require (European Standards Organisation) ESO harmonization. A draft was discussed in Brussels on the 2nd May 2007.

Focal points for these ESO work plans include:

- TC251's participation in global developments;
- Guidance for national standards bodies;
- Bringing forward national initiatives;
- ESO's being required to liaise with international consortia; and
- Reviewing current work items with international impacts.

ebXML

Franz Van Bommel (Netherlands) presented a report to the Affiliates Council on the results of a study of ebXML in the health domain that had been commissioned at the ISO TC 215 meeting in Jeju in April 2006. He noted that:

- ISO is a member of the MOU Management group that collaborates on E-business standards – other members include IEC, ITU, UN/CEFACT and the private sector OASIS organisation;
- The MOU seeks to ensure that the stakeholder business requirements of open, interoperable and internationally accepted standards are met – avoiding duplication of work between SDO's and ensuring intersect oral coherence and open development standards; and
- It also provides the framework for OASIS and UN/CEFACT to collaborate on the application of ebXML.
- Electronic Business XML (ebXML) combines the best of several worlds:
 - It draws on W3C and its recommendations for the Internet;
 - OASIS provides industry input and core e-business infrastructure standards; and
 - UN/CEFACT – has linkages with world-wide business, industry and government through TBGs for semantics and industry support.
- Specific UN/CEFACT and EC/ISSS groups relevant to healthcare are:
 - UN/CEFACT TBG 10: International Trade and Business Processes Group (TBG) 10 Healthcare: Group for EDI/XML Standardisation in Healthcare; and
 - EEG9, European Board for EDI/EG Standardization Expert Group 9 in Healthcare (Chaired by Franz Van Bommel).
- UN/CEFACT and OASIS provide a framework for awareness and legislation with the associated shared knowledge being encapsulated in the ISO 15000 series of standards.
- The volume of inter-sectoral Core Components (building blocks) that are represented by agreed Core Component Technology Specifications (CCTS), supported by independent tools, with capacity to be adapted to multiple languages, continues to grow.
- There was a collaboration meeting of TBG 10, HL7 and OASIS experts at the January HL7 WG meeting in San Diego where the following were noted:
 - HL7 already uses some technical parts of the ebXML framework;
 - All use syntax independent business modelling based on UML concepts;
 - The "Ride" project in Europe (roadmap, ebBP, IHE);

- TBG 10's XML Core Components for healthcare - aligning HL7 CMETS and CEN GPICS (led by Edgar Glück of Norway);
- ISO CDA registry framework; and
- Moves toward eInvoicing, ePayment, eProcurement, eb/MS for emergency alerts; XML messaging for health insurers and claims processing , NIST, NHS CFH applications.

A questionnaire survey of experts was conducted to assess potential uses for ebXML in TC215/HL7 and the healthcare sector. The survey and outcomes of Working Group discussions with the organisations is encapsulated in the following findings and recommendations:

- The use of ebXML is growing rapidly and there is considerable potential for better integration between health and the wider business sector through common use of ebXML;
- ebXML has a sound technical base, also useful in health - ISO/HL7 should apply the open, proven ISO 15000 series of standards to achieve an architecture that horizontally serves more domains (with ebMS – message service specification - as the baseline);
- ISO/HL7 should also support the TBG 10 Core Component development and adopt all payload-independent ebXML standards;
- TC 215 could provide use cases and identify needs – involving clinical know-how;
- There is a need for the SDOs to work together for better semantics (including data types);
- Potential early application areas include: document handling, electronic healthcare billing, smartcard-based applications (Identity and Insurance Status checks), accounting, health insurance;
- Continue working group as an ebXML Task Force in order to:
 - Raise ebXML awareness in TC 215/WGs;
 - Identify activities where ebXML should be considered or adopted;
 - Liaise with OASIS on adopting technical parts of ebXML in health;
 - Liaise with UN/CEFACT on semantics, data types, core components;
 - Liaise with HL7 for input, harmonisation and technology;
 - Liaise with clinical/business interests for ebXML opportunities; and
 - Refine and develop proposals for consideration at 2008 Plenary.

TC 215 has resolved to:

1. continue the ebXML Working Group as a Task Force for at least another year
2. establish a formal liaison relationship with the HL7 XML SIG (renamed ITS Implementable Technology SIG)

3. establish a formal A-Liaisons with both OASIS and UN/CEFACT

International Mentoring

Funding was provided by the US Trade and Development Agency to bring Brazilian and Malaysian delegations to the San Diego HL7 meeting, to assist them in building their capacity, presumably with perceived longer term benefit to US industries.

Delegates from Singapore, Lithuania, Argentina and Austria attended in Cologne. It is hoped to attract 10-30 delegates from emerging HL7 countries to the Plenary Meeting in Atlanta in September this year.

The International mentoring Group is developing a library of translated HL7 documents, and aims to minimize learning time by providing easy access to online resources. The Group is also providing assistance in creating dialogue with vendors and governments, by developing templates, etc. International Affiliates were requested to nominate locals who can be first ports of call for new entrants; and by identifying documents that provide overviews, lessons learned, etc

Personal Health record – Functional Model

Development of the PHR FM has been largely US based thus far. The EHR TC called for international input to ensure this work becomes globally relevant.

ISO/CEN/HL7 Coordination

A Coordination Meeting is now held at every HL7 meeting. In Cologne this was attended by more than 50 people who are active across the three SDOs. Key topics included CEN13606/V3 harmonisation and detailed clinical models.

- 13603/V3 harmonisation.

Nevertheless, there remains very strong commitment to the harmonisation project. There is growing international interest in EHR interoperability and the standards that support this. CEN13606, CDA and Clinical Statements are all specified at high levels of abstraction, and require detailed implementation guides. There are existing pieces of work that can be built upon for this development.

- Detailed Clinical Models (DCM).

There is also strong interest in harmonising the specification of models for the representation of commonly used clinical concepts (e.g. blood pressure). The group of clinical informaticians that has been working towards that are focussing on:

- Harmonising a ‘top ten’ concepts; and
- Developing a set of specifications for a repository of such concepts.

It is hoped to expand involvement in this activity by staging a workshop in Brisbane between Medinfo and ISO TC215. The work shop will be held on Saturday, August 25 at the Saville Hotel, Southbank – registrations through Elizabeth.hanley@standards.org.au.

5 Organisational Issues

This was the first HL7 Working Group meeting at which the new CEO, Dr Charles Jaffe, was present. Dr Jaffe has been an active member of HL7 for the past 14 years and has served in various leadership positions and on a diverse range of technical and operational committees. As CEO, he will serve as a global ambassador and foster relationships with key standards stakeholders. He will act as the key HL7 industry spokesperson.

Dr Jaffe will be supported in this role by Intel Corporation, paying his salary but supporting his full-time focus on HL7. Dr Jaffe will be attending Medinfo and the ISO TC215 Joint Working group meetings in Brisbane in August 2007, and the HL7 International HL7 Interoperability Conference in Auckland thereafter.

5.1 Strategic Initiative Task Force

The HL7 strategic initiative for a comprehensive review of its structure and processes commenced in 2005 with the view of improving the efficiency of the standards development process, funded by a grant from the Robert Wood Johnson Foundation. The overall goals are to:

- Restructure the organization to address longer-term goals;
- Support HL7's role at the international and affiliate level; and
- More efficiently and expeditiously develop standards.

Updates included:

- Board composition and election processes will change. There will be four general directors (from the general membership), two Affiliate directors (elected from the Affiliates) and 3 specific directors (e.g. with financial skills) – allocated to support strategic objectives as experts. The nomination process has been reviewed. The Nominating Committee will be used for HL7 representatives. Affiliates will need to develop their own processes for nominating representatives;
- Co-chair elections – alternative processes are being investigated;
- The Affiliates Council requested that the Board introduce a one member one vote policy for approval of standards and election of personnel (currently, people may be members of HL7 through multiple channels); and further, that the Board investigate creation of a global registry of HL7 members to support this.

This was amended to establishing a task group to do further work on this item, and the amended motion was passed (13 for; 1 against; 2 abstentions);

- The newly appointed CEO, Dr Charles Jaffe, stated that his primary objectives include reaching out to the Affiliate organizations; and improving organisational effectiveness at the international and operational levels. Outreach activities include listening to Affiliates, vendors/integrators, agencies/regulators, providers/payers, etc.

Re-constitution of the Board will give opportunities for this business focus. A new vision statement for HL7 is to be developed, plus a roadmap for its attainment. A new financial strategy with a sharpened value proposition that can be readily marketed will be developed. Business efficiencies will be made, and bylaws and policies updated. A change management consultant has been hired to assist with the transitions.

The web site is about to be redeveloped, and the decision on whether there should be a US affiliate is still under discussion.

- The Involvement Task Force has been developing strategies for healthy participation in HL7. It aims to encourage new participants while retaining existing ones. The Task Force is developing participant surveys, and working on training and mentoring strategies. At the Cologne meeting, a morning slideshow was used to assist matching people with the topics they are interested in.

5.2 Other organisational issues

Patient Administration

The Patient Administration technical committee has absorbed the functions of the now defunct Personnel Management TC, and its terms of reference have been amended accordingly.

The updated mission statement and charter are:

Mission

This group supports the HL7 mission to create and promote its standards by identifying requirements and providing messages to communicate the following:

- Demographic and administrative data used to describe patients, persons, service delivery locations, devices and patient encounters, including healthcare providers, places, and organisations, and their relationships in the context of healthcare encounters; and
- Administrative data to describe resources and regulatory topics.

Charter

This group will produce normative standards for messages about the following:

- Administrative demographic events in the context of healthcare; and
- Specific personnel and organization data including demographic details activation and termination dates, status and associated supporting documentation including an assigned entity's credentials, responsibilities, privileges and qualifications.

Implementation/Conformance

The Implementation and Conformance SIGs have been merged and the combined entity elevated to a Technical Committee. The mission and charter are as follows.

Mission

The mission of the Implementation/Conformance Technical Committee (ICTC) is to support post-publication activities that enhance the successful implementation of HL7 standards. The committee seeks to make successful implementation of HL7 specifications a collaborative activity involving the technical committees developing the specifications and consumers using them to solve real-world interoperability challenges. Collaborative activities include the localization of HL7 standards to suit specific real-world situations, the creation of implementation guides, and the mechanisms to specify conformance for HL7 standards.

Charter

The Implementation/Conformance Technical Committee (IC TC) provides a forum for users of HL7 standards to share best practices, success stories, and challenges related to the use of HL7 standards in specific real-world situations:

- During development of proposed standards the IC TC provides assistance to HL7 implementers in conjunction with the applicable technical committees and special interest groups; and
- The committee is a conduit for end-users to provide feedback into the standard development process and to formulate proposed enhancements to the standards.

The IC TC consults with technical committees to develop specifications related to conformance. Conformance is used here as 'the determination that an HL7 standard has been faithfully implemented'. The IC TC consults with any TC or SIG in the development of conformance clauses, definitions or rules contained in any HL7 standard. The IC TC develops normative conformance language for the following based on historical precedent from the Conformance SIG:

- The IC TC has the editorial responsibility for V2.x chapter 2B;
- The IC TC produces normative conformance definitions for HL7 V3 based on the normative specifications for constraint and localization produced by the MnM TC; and
- The IC TC has editorial responsibility for reflecting the definition of conformance in the HL7 Development Framework (HDF).

Web site redevelopment

It is intended to award an RFP for HL7's site redevelopment by July 31st. The first preview is expected in August, with a review of the proposed new site in early September. Project completion is scheduled for mid November.

Success criteria for the site include:

- Aesthetics – global look and feel;

- General content – standard look and feel across most pages;
- Document management role based rights based to allow leads as well as co-chairs to put up documents. This includes an objective of requiring only 3 clicks to a document;
- General web management – role based functionality;
- On line collaboration;
- Affiliate communications; and
- Site performance.

Feedback on other requirements should be provided as soon as possible to the group. More details are available on the HL7 we site.

6 Standards Development

Australia's involvement in HL7 standards development reflects the objectives and priorities expressed in section 3 above.

6.1 V2.5.1

V2.5.1 is essentially complete and is being prepared for publication. It will be published on the web site and be available to download. Chapter 1 has been substantially improved.

6.2 V2.6

V2.6 will be available as soon as possible (no time frame given) and will be available on CD.

6.3 RIM Harmonisation Publication

The next version of the RIM should be available in early May, and the related vocabulary soon after. The next ballot will be based upon harmonisation work done in March this year.

6.4 EHR

This was the first EHR TC meeting for about three years that has not been preoccupied with ballot reconciliation.

EHR Systems Functional Model

The EHR TC commenced in 2003. It was agreed at that time that ISO would work on EHR definitions (ISO TR 20514) and record architecture (ISO TS 18308) while HL7 worked on EHR system functionality. The EHR-S FM was released as a Draft

Standard for Trial Use (DSTU) in 2005, with substantial international input. Conformance criteria were then developed, and the development of domain specific profiles commenced. The FM has been adopted as a basis for conformance testing in the USA and in some other countries.

The EHR-S FM has now been published as a full HL7 standard and achieved ANSI accreditation in February 2007. The publication set includes the FM, a How To guide, a sample profile and a Glossary. The first profile has also been published – for Emergency Care.

The EHR-S FM is currently being balloted for inclusion as an ISO TC215 new work item, with the intention of publishing it as a full international standard. It is downloadable at http://www.hl7.org/ehr/downloads/index_2007.asp.

Other TC activities include development of the EHR Interoperability Model (published as a DSTU); the PHR FM; a Legal Profile; and other profiles for Behavioural Health, Paediatrics and clinical research.

Personal Health Record Functional Model

The PHR FM is largely based on the US Connecting for Health work (<http://www.connectingforhealth.org/>), and there is a need to tie the EHR and PHR FMs together. At a recent two day workshop of the PHR FM, areas of intersection and difference between the two were identified, and the following structure for the PHR FM developed.

- Personal Health – functions related to health status, etc
- Financial – functions related to insurance, etc
- Providers – functions related to healthcare providers, etc
- Administration – functions related to the management of the record itself
- Information infrastructure – functions related to supporting the PHR, e.g. consent
- Other resources

The concept of what would be subject to conformance testing (it is a profile of the EHR-S FM, rather than the FM itself) is beginning to be considered. However, what constitutes a profile for a PHR merits some discussion.

Profiles

The first finalized Functional Model profile – for Emergency care – has been published. Profiles essentially select, from the Functional Model's master set, those functions and associated conformance criteria that apply to a specific healthcare domain. The Emergency Department profile is available at http://www.hl7.org/ehr/downloads/index_2007.asp.

Interoperability Working Group

Areas of focus for the Interoperability Working Group within the EHR TC are:

- "Coming to Terms" White Paper – a compilation and analysis of industry definitions of "Interoperability". This document will be available on the HL7 EHR

TC website (<http://www.hl7.org/ehr/index.asp>) in the near future. It describes interoperability at three levels:

- Technical – concerning structure, syntax and reliable communication;
 - Semantic – with full meaning preserved; and
 - Process – integral to healthcare delivery) processes and work flows;
- EHR Interoperability Model (EHR/IM) - characteristics of interoperable electronic health records (as opposed to the systems). This is now a Draft Standard for Trial Use and was published in February 2007. The EHR/IM describes:
 - What - EHR interoperability characteristics; and
 - Why – the rationale); but
 - Not how – this is the realm of architectures and implementations.

The essential structure of the EHR/IM is as follows.

Health(care) Delivery

Interoperable EHR

Comprised of discrete Acts (Actions)

Comprised of persistent Act Records

Act Occurs

Act is documented by an Act Record in the EHR

(Act Record is Persistent Evidence of Act Occurrence)

Acts have a chronology of occurrence

Act Records have a corresponding chronology

Acts are a common unit of service in health(care)

Act Records are a common unit of record of the EHR

The EHR/IM is available at http://www.hl7.org/ehr/downloads/index_2007.asp.

Next Steps include:

- Developing an “EHR/IM story” slide set, to communicate the intent and nature of the model;
 - Reviewing and revising the current draft and preparing for public comment;
 - Capturing input and revising the model; and
 - Preparing the draft for normative ballot.
- EHR Lifecycle Model (EHR/LM) – depicts EHR lifecycle events. This now a working draft. EHR lifecycle events include:
 - Origination and Retention
 - Amendment
 - Verification
 - Access, View
 - Translation

- Transmittal and Disclosure
- Receipt and Retention
- De-identification, Aliasing, Re-Identification
- Archival

Sections of the document are currently:

- 1 - Background
- 2 - Purpose
- 3 - Objectives
- 4 - Health(care) Delivery
- 5 - The Health(care) Act
- 6 - The Act Record
- 7 - The Act/Act Record Paradigm
- 8 - The Act Record Interchange Paradigm
- 9 - Events in the Act Record Lifecycle
- 10 - EHR Lifecycle Event Initiators
- 11 - Description of EHR Lifecycle Events
- 12 - System Roles in the EHR Record Lifecycle
- 13 - The Downstream EHR Record Lifecycle
- 14 - Legal Perspective
- 15 - Conformance Criteria

Next Steps include:

- Continuing internal review and revision;
 - Preparing the draft for public review and comment;
 - Capturing input and revise model; and
 - Preparing the draft for DSTU ballot.
- The preceding three work items fit together as a set of EHR standards as depicted below. The ISO TS 18308 – Requirements of an EHR architecture could easily be imported as an initial column in this table.

	EHR System Functional Model (EHR/S/FM)	EHR Interoperability Model (EHR/IM)	EHR Lifecycle Model (EHR/LM)
Focus	Functions of EHR Systems	Characteristics of Interoperable EHR Records	Key Events in EHR Record Lifecycle
Specifies	~ 150 Functions	~ 100 Characteristics	16 Events
Status May 2007	HL7 Normative ANSI Approved ISO Work Item	HL7 DSTU 2008: Normative?	HL7 Draft in Development 2007: DSTU?

- EHR/IM – development of a CDAR2 Profile. This is a specification of CDAR2 as an implementation of the Common EHR Record Unit, mapped to the EHR/IM Sections 3 and 4. It provides a crosswalk of CDAR2 attributes vis-à-vis

requirements of the EHR Interoperability Model. It will be presented as a sample profile embedded in the EHR/IM DSTU;

- EHR/IM – development of a legal profile EHR/LM). This is an assessment of the EHR Interoperability Model requirements applicable to a fully formed, legally qualified record. It is US realm specific;
- Review of ISO 21089, "Trusted End-to-End Information Flows"; This is an ISO Technical Report, published 2004, providing a framework for end-to-end trusted information flows. It was originally focused on messaging paradigms, but requires review in light of developments in the ER domain. It is now due for review;
- Health Record Banking Alliance. This is an alliance promoting health record banks for retention of personal health records, providing a framework combining many key concepts of robust health record management with aspects of financial banking, such as trusted fiduciaries, personal accounts, privacy/ security, consumer control, etc., and authorized "deposit" and withdrawal" of health records to/from personal HRB accounts.
- ONC/AHIC/HITSP Use Case Intersections – This is an assessment of how/where ONC/AHIC/HITSP use cases intersect with HL7 EHR Model requirements.

6.5 Patient Care

DSTU Status

All documentation for Patient Care material that is now in DSTU has been completed and accepted.

Care Plans

There was a need to review the Patient Care committee's common understanding of Care Plan - it is generally understood that the Care Plan is the "entire healthcare workflow."

MESH (1968, NLM): N 04.590.233.624 defines Patient care planning as – "Usually a written medical and nursing care program designed for a particular patient."

The following definition (developed in joint committee with Decision Support) was presented:

"A care plan is an ordered assembly of expected or planned Acts (in Definition mood), including observations, services, appointments, procedures and setting of goals, usually organized in phases or sessions, which have the objective of organizing and managing health care activity. Care plans are often focused upon one or more health care problems, with the expected of one or more favorable outcomes. Care plans may include orders sets as actionable elements, usually supporting a single session or phase."

Accordingly:

- A care plan is a plan that exists for a specified condition. For example, if a patient has pneumonia, there are particular known conditions/concerns/problems (like impaired gas exchange or risk for falls), goals (such as O2 saturation greater than 90%, or 0 falls), and related orders (such as assistance in rising; fluid intake);
- An instantiated care plan is one that is used as presented, or that may be expanded or constricted when implemented specific to a given patient. The instantiation will be in Event mood;
- A "guideline" is an uninstantiated care plan. It is a "generic" or "off the shelf" and is not patient-specific. It has a Definition mood;
- A care plan, when instantiated for a patient, will have ad hoc changes/editions that are patient-specific;
- Tracking includes the pathway to the goal, and as such, it includes orders to be carried out, and includes measurement of progress to the goals in the care plan. Tracking includes the data to support evaluation of whether goals are met, or why they are not met;
- Care plan participants include clinicians or non-clinicians defining, prescribing, delivering, reporting on, or influencing the care of the individual. The existing DMIM was created to explicitly support non-clinician participation;
- Outcomes are the observations of actual results or conditions in the context of related goals.

Patient Care TC has included Care Plan in the ballot in the past, but without receiving comments. It has been kept out of DSTU until the committee is comfortable with its details.

Australia has care plan artifacts that need to be supported by the ongoing committee Care Plan work. A Population Care Plan will also need to be supported (e.g. preventive health care for the sake of public health, or managing an epidemic).

Care Plan and Order Sets Meeting with Decision Support TC (DS)

It was noted that a new model for Order Sets looks very similar to the existing model for Care Plan.

It was agreed to ensure the following use cases are met in a harmonized Care Plan model:

1. Guideline (generic, not patient-specific);
2. Instantiation that is patient-specific;
3. Patient-specific ad hoc changes to the plan; and
4. Tracking goals, orders, pathways

William Goossen (Netherlands) presented the existing Care Plan RMIM REPC_RM000200UV, currently Draft status in the ballot in the Care Provision Domain. It represents a single instance of a Care Plan and consists of 3 major parts, one of which is the set of details referred to as DefinedCare, where ObservationDefinition, SubstanceAdministrationDefinition, ProcedureDefinition, EncounterDefinition, and ActDefinition lie. DefinedCare is not required for a Guideline. The activities in the Guideline differ from the Planned Care (Care Plan) in that they have different Mood codes.

The relationship(s) and distinctions between Guideline and Care Plan are unclear. The rationale for putting Guideline in the Care Plan is to support of the use of a given order in the Care Plan and its expected outcome. The Care Plan then references the Guideline in Definition mood.

There is concern that the Guideline as modeled in the Care Plan implies that there is a structured set of activities, when in practice Guidelines are not always that. The work to date has instead used constrained but specific, explicitly delineated scenarios of Guidelines. This concern may be resolved by using a specific reference point to associate the Care Plan with a specific referenceable piece of a Guideline.

A hierarchy was suggested, such as the following in Definition mood.

```
Guideline
  Careplan
    Order Set (or Set of Requests)
      Act (1 order or request)
```

Though referenceable, a discussion and defining Guideline is out of scope for this meeting. Remaining outline:

```
Careplan (Definition mood)
  → Instance target
  Order set (Def. mood)
    → Observations.....}
    → Goals.....} Instance target
    → Request procedures.....}

  Act (1 order) (Def. mood)
```

Relationship between Messages and Documents

The work on Structured Documents emphasizes the requirements of the header information and wrapper. It otherwise tries to use the Clinical Statement Model. The body of a structured document should be consistent with Care Plan, in that the mutual goal is to align the Care Plan model so that structured documents provide the data required for instantiation of Care Plan in Patient Care models.

Issues include:

- Whether the DefinedCare block in the PC RMIM remains useful;

- Structured documents have implemented Order Sets, which in Patient Care are a subset of a Care Plan. However, in structured documents, the order sets specify observations, goals to be set, procedures to plan or request, meds to order, etc., and may be linked to problems/problem sets;
- Maintenance – Patient Care may need to feed new requirements to Structured Docs, such as:
 - Encounter
 - Ordering the scheduling of an Encounter (such as “appointment with cardiologist in 2 weeks”) is not the same as ordering a procedure. (This is explicitly described in the Care Statement and is DSTU.)
 - Generic Act (Act in Definition mood or Intent mood) to cover non-procedure Acts supported by Patient Care.

The Patient Care TC and the Decision Support TC will work jointly to create a new set of definitions of Care Plans and Order Sets.

Assessment Scales:

William Goossen presented work on assessment scales done in the Netherlands. This proposes a generic structure for scales.

Frank Oemig (AGFA, Germany) also presented. Frank also uses one model for the structure of scales for v3. He is currently using the clinical statement and uses a “has_component” for the sub-variables.

Issues discussed included:

- Variable scores, should they be coded or numbers?
- Neither model handles complex calculation use cases;
- Is the has_component relationship correct.

Care Plan in NHS (UK)

Rik Smithies presented current NHS (UK) approach to using CDA, Statements, and Templates. Key points included:

- They are using V3 and Clinical Statement-based messages;
- The initial messages were refinements of CS, with harmonizations;
- The initial work had no common clinical structures (using CMETs for roles, organizations, etc., not Acts);
- Connecting For Health (CFH) then developed clinical content as a library of CMETs. This is aligned with CFH business models;
- Most models are currently at a fairly high level so far, more like care structures than “archetypes” – e.g. Finding, Battery, Medication. Some are more developed, such as blood pressure;

- Pure CS-based messages are hard to implement;
- CFH wanted to allow text based messages with codes behind them, and decided CDA was most useful, with constraints. Their solution was to model in “CMETs” then apply these indirectly as constraints to plain CDA. CMETs become Templates to the CDA model;
- NHS specifications require that all message instances are 100% compliant with CDA by passing the CDA schema test;
- Templates, in the form of RMIMs, are also published but are more specific, explaining how each concept is represented in the Clinical Statement part of CDA;
- XSLT transforms are available that validate message on the wire against CFH Templates;
- Transforms map CDA class names to the specific class names used. Then a check is done against schemas that know about specific class names and its specifics; and
- The result is an RMIM-based approach to templating CDA that works with, and is orthogonal to, any RMIM based content models

Ian Townsend (NHS) reviewed EmergencyDepartment, BloodPressure templates. Discussion centred on whether different template ID's applied for similar but still unique templates – e.g. blood pressure vs. orthostatic blood pressure. NHS does not have that requirement for blood pressure, but their methodology calls for creating another template when new specifics are warranted.

Several other templates have been developed including Ht, Wt, Temp, Treatment, RiskToPatient, SupplyMedication, Administrative Procedure, Diagnosis, Finding, Care Event, AllergicOrAdverseReaction, AllergyPropensity, Finding, and many more, all under Template ID Constraint NPFIT-000024. Schematron ensures that business rules and template mapping rules are enforced to prevent inappropriate use of templates with one another.

Ian will send public website link to the Patient Care listserv.

Ruth Kidd (NHS) presented archetype processes in the NHS Connecting for Health project. Working with Ocean Informatics, this has involved defining clinical content models to determine their feasibility for use. The content domain in this discussion is Major Clinical Topics in Maternity.

The modeling project involves the use of maximum data sets when gathering requirements and mapping to archetypes usage. Archetypes are further constrained for use in multiple templates. They have used openEHR as a basis. The documents presented are available on the OpenEHR wiki.

William reviewed the related methodology used in the Netherlands, and discussed related transforms supported by tools used by the NHS. He presented Apgar Score and Blood Pressure examples, with their vocabulary, models, et al. These are very similar to UK models for the same. This emphasizes the need for the Detailed

Clinical Modeling (DCM) Initiative, which aims to harmonise these models. DCM is currently focused on a registry and searchable repository of technical representation format(s).

Action items:

- Patient Care TC will model each assessment scale, and identify appropriate coding for each; and
- Since Patient Care expects ongoing responsibility for the review and maintenance of models for consistency, et al, a means of harmonization is needed. Patient Care will investigate the registry and its apparent usability for this.

6.6 Community Based Collaborative Care (CBCC)

Archotyping in V2

To compensate for weaknesses encountered in the last year in version 2 clinical information, Standards Australia is investigating the carriage of archtyped data in V2. To date, V2 has made heavy use of OBR/OBX segments to carry significant detail in the message load. However, it is clear that these are insufficient to support these items. Standards Australia is also carrying out projects around the locations of digital signatures, hierarchical designators (OIDS), etc.

Limitations of traditional approach include:

- Implementation-specific obstacles may exist where engines or other products may not successfully translate with the use of multiple vocabularies;
- Implementation difficulties with data that requires post-coordination;
- Though individual implementations can be made to work, creating a solution that spans multiple implementations well is a greater difficulty.

CBCC is seeking Patient Care's endorsement to work on new segments for these purposes, with the aim of presenting ideas in the September 2007 WGM.

Outside of HL7 Australia, there is no Patient Care representation of V2 expertise to assist. The current charge of the Patient Care committee is to focus on V3, unless there is a compelling case for V2 work and the V2 work can be done with resources acquired by the proposing participants.

The requirements of government mandates to use V2 fits an HL7 proviso for using resources otherwise spent on V3 to meet the V2 need.

There was some discussion about whether adding new segments to existing V2 message definitions constitutes new messages, or acceptable modifications with optional use of the new segments. There may be significant pushback on the use of new segments in messages outside of Chapter 12.

CBCC will do the work to develop the new segments and to carry that work, when ready, to the TC's with custody of the messages affected by these segments.

There is general agreement that Australia has made significant and meaningful attempts to make V2 work as-is, and the proposal for Australia to work on new segments for V2 was agreed.

Consent and Privacy

A round table discuss was held regard initiatives and attitudes to Consent and Privacy from jurisdictions around the globe.

One interesting aspect was the NHS, who having set up a doctrine, found that their suppliers could not develop the rules in their software to match the doctrine in time for the implementation schedule, and modified the doctrine to suit the implementation schedule.

The Security TC expressed an interest in taking over the Domain of Privacy & Consent. This would be welcomed by most involved.

eConsent

eConsent ballot reconciliation was conducted.

CAST Project Report

The Continuity of Care Task Group has completed phase one of its initiative to support health information exchange standards for aging services including functional status and wellness content. The results of phase one are available from the wiki located at continuityofcaredtaskgroup.pbwiki.com and are currently being summarized in a white paper, which can be reviewed in early draft on the wiki. An expert committee representing diverse stakeholders met for four months to progress phase one work.

Many of the committee's members are expected to continue participation in phase two work which is currently being scoped. Phase two work is expected to culminate in mid 2008 with the completion of actual aging services provider and vendor demonstrations of standardized exchange of health information including functional status and wellness content. Particular focus will be given to how standardized health care information can be exchanged with consumers (personal health records) as well as providers (health information exchanges).

Key accomplishments of phase one include:

- Adoption of NCVHS recommendations for standardizing regulatory and other assessments including guidelines for the use of Clinical Loinc, Snomed CT, and HI7 CDA and Messaging standards;
- Adoption of HL7 Continuity of Care Document (CCD) exchange of clinical information including functional status and wellness content;
- Preparation of draft definitions of functional status and wellness content topics, extending CCD definitions for contribution to future standards work;

- Development of a limited catalog of assessments measuring functional status and wellness content;
- Identification of criteria for prioritizing (we used the term privileging) assessments for standardization work;
- Prioritization of five assessments for initial standardization work (including MDS, OASIS, INTERAI HC, Geriatric Depression Scale (GDS), and Functional Independence Measure (FIM));
- Development of a list of Use Case categories and actors to describe use of functional status and wellness information;
- Brainstorming of use cases within each use case category, and prioritized three use cases for each of the privileged assessments. Alpha drafts of many of the identified use cases have been completed;
- Joining with other stakeholders to successfully lobby for inclusion of a Functional Status Profile in the 2008 IHE Interoperability Connectathon. MDS Section G, Geriatric Depression Scale, Braden Scale and the Numerical Pain Scale will be included; and
- Scoping of a process for standardizing each of the five privileged assessments.

Phase Two efforts are currently being scoped and are expected to be realized in several iterations over the next fifteen months. Deliverables will include:

- Formalization of a reference set of use cases for aging services health and wellness information exchange through beta, draft, and final versions including a process for field and expert review;
- Continued development of Functional Status Assessment Catalog;
- Establishment of Clinical LOINC encoding for each of prioritized (privileged) assessment;
- Establishment of Snomed CT usefully related semantic matches for prioritized assessment components;
- Development of HL7 CCD implementation guide supporting incorporation of privileged assessments in HL7 Clinical Care Documents;
- Development of processes for rapidly extending the number of assessments encodable in the CCD beyond the initial five prioritized (privileged) assessments;
- Ongoing contribution and participation in the IHE Functional Status Profile for participation in 2008 Connectathon; and support for aging services industry vendor and provider participation in the Connectathon;
- Support for formal demonstration projects among aging services vendors and providers implementing the CCD implementation guide for real life information exchange.

6.7 Conformance

Conformance SIG and the Implementation Committee merged to become the Implementation Conformance Committee

This should increase the profile of conformance amongst the HL7 community, improve the implementable detail of the conformance section and introduce development of implementable conformance points for validation (which may help the Standards Australia effort for developing conformance criteria).

Use of V3 tables in V2

There was significant discussion on removing lengths from the V2 standard (from v2.7) and specifying them in conformance profiles. Klaus Veil suggests that lengths should still be in the Standard and that conformance profiles should constrain them further. If this is not followed up by Australia then the lengths will be removed from v2.7.

Conformance frameworks

There was discussion on the creation of a conformance points document. NIST (USA) will produce draft and send for comment.

Canada is developing a conformance framework. This should be reviewed in light of NeHTA's aim to build a Conformance methodology/framework. Canada is also developing a Validation Tooling Framework (v2 and v3).

To date, most of the Canadian Conformance work has concentrated on analysing the conformance of messages created by a Sender system. There has been little or no emphasis on what Receiver systems do when they receive such messages.

DSTUs

There was discussion around problems with groups going from a Draft Standard for Trial Use (DSTU) to a Normative Standard. The issues seem to reflect the fact that there are no clear guidelines on the process or what requirements and criteria are for the levels to be met before approval to a Normative Standard.

Dicom Validation Tools

AGFA and Phillips have developed a Dicom Validation Toolkit that:

- Validates point to point;
- Workand with IHE;
- Uses Dicom definition files (profiles);
- Links with the NIST web service to use their HL7 validation tool; and

- Checks data from both sender and receiver systems after multiple transactions to make sure the correct data has been populated

V2 – V3 Mapping project

Mappings were collected from various countries/projects, then reviewed and reproduced in a standard format. These will be enhanced to produce a clear set of V2 & v3 examples in the next 5 months, then an XSLT will be produced to assist V2 – V3 translations.

Implementation Registry

This former Implementation Committee project aims to build an exemplar set of implementation guides, including guidelines and principles that define good domain implementation guidance including binding of vocabularies by realm.

6.8 Structured Documents (and CDA: Clinical Document Architecture)

The TC has a Wiki site:

informatics.mayo.edu/wiki/index.php/structured_documents_TC

User name is wiki and password is wikiwiki

This site includes discussion and background documents that support the committee's activities and supports the understanding and use of CDA documentation.

Clinical Document Architecture R3 open issues

The purpose of this document is to collect suggested enhancements to CDA Release 3 (the next version of CDA).

There was some concern about committing to a next release but the group agreed that CDA Release 3 should be ready for publication in 2010. Clinical Statements will be a central core to this development to make harmonisation and retention of semantic content consistent within HL7 (covered in M&M). There is also concern that individual domains may have difficulties with this process and differences in models will persist across committees.

There was considerable discussion on the problem of multiple modelling approaches – this group was not keen to be responsible for reconciliation of these variations.

There is the need to be able to use the same V3 semantic model in messages or documents and there is also a need for consistent modelling of a given concept across domains (where appropriate – variations in granularity are sometimes appropriate for the same concept in different domains). Clinical Statements were thought to be the vehicle for solution of this common need. This is possibly an issue to go to the Technical Directorate for resolution.

Discussion of CDA and implementation issues

The need exists for a standardised approach to a language of discourse for describing information system requirements. The need for agreement on how to express clinical information was discussed. There is a terminology model of clinical knowledge – represented by SNOMED, but there is not a similarly governed or structured information model for the structure of content. This issue relates both to the issue of messaging – formatting of clinical documents for specific purposes, and to storage.

Registration of enhancement requests and their disposition

The meeting considered building a database for handling enhancement requests – there is a need to coordinate the suggestions to manage the mechanism to handle each of them. The current wiki approach is fine for small numbers, but a more controlled and easily referenced data base would make management quicker and easier. A general process for management of changes / suggestions for CDA will be developed. The suggested structure would allocate a unique id to each suggestion and require a defined type of action – include in existing project no.X or for next release of document Y. These are listed currently as outstanding requests, pending requests, withdrawn requests and disposed requests. Discussion of mechanisms for categorising requests was also discussed.

This requirement has already started to arise in Standards Australia – consideration of this type of tool to assist standards version management and quality review of documents in Australia should be considered.

CDA R2 errata

An errata document has been developed. The errata include useful explanations and information. This is not an official HL7 document, but is made available to assist in the use of CDA documentation.

There was discussion on the data type schema used in the document and that this will need to be reviewed at some time.

General Model Inconstancies

The problem discussed is that different modeling approaches (CMETs) are being used across a broad set of use cases in healthcare leading to inconsistent representation of concept groups within messages and documents. There should be a level of commonality driven from the RIM. This may be valid where there is a specific business case to be supported, but the feeling of the room was that this is not likely to be the cause in most cases.

The bottom up development approach may be the cause. It is likely that a single committee doesn't realise that another area has touched this. Clinical Statement Model could be the constraining structure to inform. The Clinical Statement Model becomes the superset – a tool to support this use case would be a strategic mechanism to support more consistent development within domains. The development of a tool that makes it easier to pick up the clinical statement elements required to support a specific development, but also to identify gaps/discrepancies. A level of consistency across domains is required.

Clinical statements and 'sibling' statements could be used to identify cross patterns. Statement levels could be associated to these organisational levels. Tooling assistance to trace derivations would be useful. There is a need within clinical statements to have minimal cross reference to each other whether this would meet all use cases is not determined, but it does meet the one defined below.

Templates

Template specifications describe templates as static models of information. There are ballot comments that indicate that this approach does not work. A divergence of purpose has arisen between the original purpose of templates and the way they are being used in CDA.

CDA have used a template to provide a named set of constraints and applying that to a model to produce a further model. There is still variety of opinion on what a template is and what it should do. There are HL7 implementation guides that use templates. A template needs to be computable. You can not currently write a static model that just says observation code must be a SNOMED code as this is not particularly useful

An HL7 Template must be ITS independent, enforceable without human intervention, be able to be applied to RIM based structures. The conformance statements in CDA are ITS independent, though other elements of the documents are not, and this could be an area where archetypes are helpful.

People implementing CDA are creating constraints and automating those constraints against the CDA XML. From the ITS as an implementer perspective this is reasonable, and useful. The more people develop tools that can work in this way the more implementable the products become, including products such as archetypes. The semantics of these processes is clearly developing and emerging. Formal tools to provide abstract models are needed, but implementers can't wait for these. One of the fundamentals is that anything put into an extension must be able to be ignored, safely by the recipient if there is no standardised approach to these extensions – this is a major issue when sharing outside those organisations where the extension is understood.

There will need to be some clarification of the static nature of templates. Agreements on methodology and tooling need to be resolved and developed.

Comment: There was discussion on whether templates should be ITS independent conformance statements (their pure intent) or implementable automated constraints. The formalism is seen as valuable but so is the real world need of the implementer, which is not so well served by this approach. This is an emerging issue for CDA as implementation moves ahead of the tools available. Australia needs to be aware of these developments and that there will be, in some cases significant modifications to the formal representations informed by these implementations. The need for more extensive implementation guides was identified and would seem a relevant high priority item.

Privacy architecture

International approaches to privacy implementation in EHRs were discussed. The architecture required to support privacy and access control management was discussed and specifically the mathematical requirements for incorporation of national policy and role based functional context based access control were discussed and harmonised with ISO PDS 22600-3 PMAC implementation. This work is highly relevant to NEHTA's privacy implementation requirements. There will be a need to introduce Australian policy into these concepts.

A recommendation for HL7 RIM Change has been prepared. This document includes representations of access control requirements – but does not fit with ISO work. There is also considerable ontological work required to make this work appropriately in an automated environment. The intention is the CCD would be able to include these concepts with a message.

The current set of concepts suggested for describing privacy requirements seems of poor quality and ontologically inconsistent. These concept representations should be monitored and contributed to actively by Australia to ensure that HL7 is able to appropriately represent our requirements for the representation of access control requirements. The current concepts at HL7 need significant work. NEHTA could consider developing an approach to these.

The need to identify required vocabulary for privacy to assist implementation was identified. The number of policies and variations need to be identified. In order to have an international standard there is a need to represent a variety of policy regimes and they may have their own laws and preferences.

The group identified the need to establish a work item on the use of a coded vocabulary to represent concepts of privacy as a single code is unlikely to meet the needs of this information group. How to make this operational as well as consistent is a major issue. A variety of technical approaches may be needed future work on this item will be managed through the security group, with input from the vocabulary group on semantic content representation. Identification of the administrative signaling necessary to distribute policy information and what is the technical assurance mechanism will be a major future work item.

Issues of privacy policy / access control implementation were also discussed. Privacy messaging requirements arise from a combination of personal preferences and organisations' and governmental policies. These policies include legislation, but may also more general organisational and local customs. These requirements might also relate to policy at a given time. Messages need to be able to include label records with all of the applicable privacy policies.

When accessing a record assertion of the appropriate role of, e.g.: public health worker may give access (by law) to notifiable disease information, though this is not available to clinicians where the patient has refused to share. There will not be a single mechanism to handle this complexity. Shared activities on privacy and consent, authorisation, pseudonomisation, digital signatures will be undertaken to support a consistent approach.

This approach was also established in the previous privacy discussion group. This is a significant movement forward as a consistent mechanism to handle the variety of

requirements will emerge, though there will be considerable, complex work to achieve this. This is an area in which Australia has contributed significantly to discussions and will need to monitor progress to ensure flexibility and suitability of the final outcome.

Structured Documents and Security joint meeting re Digital Signatures

The practical implementation of digital signatures within messages is an issue. There is a need to define more clearly how to maintain control of the keys in the message. There needs to be discussion on the policy of the Certification Authority (CA) of who issues the keys. The strategy is to develop and collect real use cases that indicate a use of these technologies and involve the security TC to introduce changes needed to manage these instances.

6.9 Healthcare Services Specification Project (HSSP)

The Service and Provider Directories Project (led by Max Walker) was formally endorsed at the January WGM. In between the meetings a draft specification was developed. This was presented to the Service Oriented Architecture (SOA) SIG for comment. A formal plan was developed to progress the project, which includes the development of a power point presentation to explain it, distribution of documents to the SOA list and the establishment of a conference call(s) to obtain input from interested parties.

The current title for the specification is the Health, Community Services and Provider Directory. This may be changed before proceeding to ballot in January.

Discussions were held around feedback provided after being through the exercise of developing a draft. It was decided that a "light" version of the boiler plate should be produced that clearly indicates which sections of the Specification Template should be filled in and which should be optional for the first draft, to assist and streamline further projects.

A relationship has been established with Eclipse\Open-HIT and there is now a commitment from them to implement the Standards produced by HSSP.

The Entity Identification Service (EIS), Record Locator Utility Service (RLUS) and Common Terminology Service (CTS) specifications are now HL7 DSTU's. EIS has received 6 letters of intent from the OMG Request for Purchase (RFP) process while RLUS has received 5. The RFP for CDS was issued in February with a deadline of September 2007.

Aside from the Services & Provider Directories project the other new projects for 2007 are CTS II (Vocabulary), Cohort, Security (including privacy) and SIP (Services interacting with other Services). There was also some discussion regarding a potential project around SOA and Web Services for Healthcare.

Security Services will be supported by the Security TC, but run under the HSSP banner.

6.10 Data Types

Harmonised data types are being balloted in parallel in HL7, ISO and CEN.

The HL7 ballot is closed with mostly negative results. There are 200 comments, most of which are negative major – this means that in its current form, this work will not pass. This is not surprising – it was expected that multiple iterations might be required.

The ISO specification will not take the place of the HL7 generic specification. At the moment there is an abstract specification – i.e. an in principle specification of how the types work but that does not relate to implementation. A second document relates to xml implementation and is an Implementable Technology Specification (ITS).

The failure of this ballot means that there is an opportunity for closer harmony in the process and reflects a lack of understanding of common ground. Clarification of misunderstandings is necessary and might require more detailed process review.

Responses to the ballot are not yet received from ISO/CEN as their ballot processes are much longer than HL7 ballot periods.

6.11 Pathology

ELINCS

ELINCS is an Implementation Guide for the use of HL7 Version 2.4 that was created for the California Health Care Foundation (CHCF) and is intended to standardise the electronic reporting of test results from clinical laboratories to electronic health record (EHR) systems. It was developed in 2005 and updated in October 2006. Refer to <http://www.chcf.org/topics/chronicdisease/index.cfm?itemID=111047>. ELINCS makes extensive use of LOINC.

HL7 has accepted responsibility for the ongoing maintenance of ELINCS. Associated with this are contractual obligations to firstly address compliance issues between ELINCS and HL7 V2.4, and secondly to align ELINCS to the various HITSP profiles, for example http://www.hhs.gov/healthit/ahic/materials/02_07/ce/hitsp.doc. A small, but very focussed group is working on the first obligation above.

This work may have very little direct relevance to Australia and IT14/6/5 in the near term – the focus is very firmly on the contractual tasks which are entirely US-based. However ELINCS and HITSP are examples of the current generation of Implementation Specifications for Laboratory and IT14/6/5 should be cognisant of these in its work to produce the definitive Australian Implementation Guide for HL7 V2.x.

Ballot Reconciliation

The main work of the Laboratory SIG was to continue reconciliation of outstanding V3 Ballot issues from the last time the Laboratory domains (CMETs, Specimen and Result domains) were balloted. This is incredibly detailed and tedious work but it does provide the Quality process in standards development. There is a desire to

have these three domains ready for the next ballot cycle, but this depends on satisfactory resolution of the remaining issues by teleconferences during the next few weeks.

SNOMED and Pathology

R Harding had several discussions with Patrick Mitchell-Jones who was previously Project Lead for the NHS V3 Pathology project. The NHS is pioneering use of SNOMED in V3 pathology. They have been focussed on creating a number of subsets of SNOMED which facilitate its use in the v3 lab models and on creating a guide on how these should be used. The main person involved in this is Ian Green who works for Connecting for Health. Patrick understands that NEHTA have had some contact with the team that is doing this work.

In discussion about the relevance of that CfH work to the V2 situation (that is, is the CfH work directly relevant to Australia), several experts urged caution. The V3 work can and does make greater use of explicitly-modelled attributes such as specimen and method. There might be benefit in using V2.5 which has the new SPM (Specimen) segment. At the very least, Australia will have to provide explicit guidance on how to use the HL7 V2.x attributes that may not be required when LOINC is involved. Actual implementation of SNOMED into existing V2 messages will require considerable resources from each vendor of Pathology laboratory Information Systems.

Dot Notation in Pathology result messages

There is little fundamentally opposed to Australia's use of dot-notation in obx-4, provided that we can adequately guard against backward compatibility issues. GE Medical Systems are currently using dot notation in this way, and Paul Schluter has promised to send what material he has on the GE usage.

When finalised, IT14/6/5 should document its usage of dot notation for inclusion in V2.7.

6.12 Vocabulary and Terminfo

A new contract has been let to the National Library of Medicine to consider the requirements for mapping vocabulary concepts to HL7 document concepts. This project is to take all vocabulary items expressed specifically in HL7 documents into a repository to support both automation and access. All structures and tooling identified as unknown (without a place in the RIM) have now been resolved, and must be confirmed. This project has potential for harmonisation with the Glossary work at ISO.

There are still some content issues related to duplications and lack of clarity of vocabulary across domains. Remaining content issues are related to the domain context (e.g. where there are multiple representations in the standards the mapping tool allows you to view each concept, and the value set information, to assist committees determining which is the best value set). The tooling for capturing mapping decisions from technical committees is nearing completion. A demonstration of CHI Mapping Proposal Submission Interface was given. This is an HL7 tool developed by Mayo Clinic. The tool produces an XML representation of the

mapping that is computer processable. Some of these maps include value sets that are represented using SNOMEDCT code values.

It is expected that the number of value sets will double before the task is complete. Neither this tooling, nor any of the other mechanisms in place for HL7 vocabulary will work at this time with the master repository contents in the RIM.

Comment: the mapping tool, though interesting and useful, particularly for domain variation and value set interfaces (eg interface terms to use in different domains) doesn't include sufficient decision logic to meet the need for automated mapping in the context of ICD10-AM coding rules – the concepts can be mapped, but the rules are not currently able to be represented.

Vocabulary and Pharmacy Joint Meeting

This meeting developed a new Concept Domain called “Administrations for Medicinal Substances”.

This work involves standardising a comprehensive approach to the representation of route of administration. This term is used in different ways – a clinical context and a pharmaceutical concept and patient instructions and in manufacturing systems. The concept required in this instance is specifically for the actual route of how the medication it is given to the patient. There was a request from Europe to consider the extension of these concepts to represent different contexts of use for this information. Further discussion on the proposed solutions to clarifying the concepts in the route of administration (where a substance is being introduced to the body) and then the location at which you are doing it, then the method by which you're doing it and what the substance is (its form – tablet) were undertaken. Further discussions will take place with the intention of a final proposal by the next meeting in September.

This is a very fruitful discussion of which Australia needs to be aware and the results of which should be strongly informative to NEHTA initiatives.

Further discussion also took place on standardising the approach to expressing the pre-coordinated code as a post coordinated expression in a way that ensures accurate semantic decomposition for decision support.

There was discussion as to how to handle the situation where there is NO CODE, effectively a 'missing' element. A policy on the process appropriate for handling requests for codes and how the system should handle items where there is no issue of codes. To handle this problem it was proposed that a new flavour of null representation be included: unc – no code. The definition proposed is 'the actual value has not yet been encoded within the approved value set of the domain' i.e. original text available but not coded. Where a request for a code has been sent, but a code does not yet exist this code could also be used. Terminology service receives request considers it and issues a suitable code to anyone who is interested, together with the original request id and text string

This seems a useful concept that will be supportive of processing concept likely to occur as we endeavour to develop smart mechanisms for implementation of terminology value sets.

An implementation issue was identified - when a code is issued, how do we establish that every one who has received/used the UNC record can now add the newly issued code to the correct records. The proposed solutions are:

- that it is the responsibility of the sender of a message with an UNC to inform their recipients that this message is revised with the new code? In response to this systems should be aware that any UNC record may be subject to revision and have appropriate audit trail process in place to allow that revision;
- Senders of messages should not be expected to inform their recipients that the UNC has been replaced; and/or
- All codes issued for UNC's should be published together with the original text that they are issued with this restriction.

Though Australia is nearing the implementation of systems that will require this facility, we aren't really there yet. A watching brief on this work its appropriate.

Common Terminology Services

The Common Terminology Services (CTS) document is to be revised to include automated support for terminology system content management. The scope of CTS2 (second version) development includes more elements that that will involve/support SOA and OMG to produce a more integrated and useful result.

This project will define the minimum set of requirements for interoperability across disparate health applications to ensure semantic interoperability using terminological systems. It will specify rules for electronically accessing terminology content and the minimum set of functional characteristics a terminology resource must possess for use in HL7 including the characteristics of a terminology as a set of application programming interfaces (API). This is essential for implementation and management of terminological systems.

Working documents can be found at: <http://hssp.wikispaces.com/cts2>
Regular Teleconferences are held each fortnight at 6am Australian Eastern Standard Time, Thursdays starting May 23rd.

This process is NOT:

- Software – though software exists that implement the specification (e.g.: Apelon);
- A complete terminology service:
 - The scope of CTS was purposely restricted to the functionality needed to design, implement and deploy an HL7 Version 3 compliant software package
 - A common vocabulary data structure

CTS2 is intended to be a logical extension of the initial CTS specification that will define the requirements and functionality required for a terminology servers beyond

the scope originally outlined in CTS. To achieve this, the existing CTS document will have the following changes:

- Address corrections / omission in CTS;
- Extend the level of functionality provided in the CTS beyond the scope of HL7;
- Be backwards compatible;
- CTS 2 will define a common model to standardize the components required to represent vocabulary sources, including code systems, value sets, concept codes, relationships.

Work will be based on the definition from CTS and the Value Set Definition and Binding Document, and both the Vocabulary NLM projects. This common model should represent sources beyond HL7 including those represented in the UMLS. Various models will be considered from sources including, ISO11179, LexGrid (Mayo Clinic), Ontology Definition Model (ODM) and XMDR.

This work will also consider increased information on vocabulary management:

- Administration
- Search / access
- Sub-setting (value sets)
- Translation / Mapping
- Authoring
- Classification / Inference

and functional roles

- Vocabulary Authoring - creation of new code systems, adding new concept codes and relationships, splitting / merging concept codes.
- Managing post-coordination and extension sets.
- Vocabulary Governance
- Vocabulary Publishing
- Vocabulary Usage

These elements are relevant to the work being undertaken at ISO to identify best practice in terminology governance. There is a need for harmonisation with the two documents which serve different but related purposes.

TermInfo meeting

TermInfo is a project to identify clearly and support the implementation of how formal terminologies such as SNOMED are used in HL7 V3.

Resolution of ballot issues was undertaken. Specific issues included:

- SNOMED CT qualifiers in post-coordination than are available in the mood code. This is why SNOMED CT is not prohibitive of these extensions.

This guide includes conformance statements that allow the receiver of a message to understand the format rules that were applied to the terminology representation in the message.

A new section will be added to the document to indicate how it should be read as it is currently confusing if you are not highly familiar with the material.

This ballot reconciliation is improving the document and making it reflect more clearly requirements for use with CDA. At this meeting, amongst a range of improvements were the addition of simpler language introductions to encourage. The document now describes not only SNOMED, though it generally uses this as the example, it has been modified to be more generic for clinical terminologies and will handle LOINC (or it seems to). The document throughout indicates where specific code systems can be asserted.

Realm Specific Vocabulary Bindings

This work is being undertaken for the US initially and deals with content sets and tooling generated to work with harmonisation tooling to support realm binding.

A Harmonization Proposal Generator has been developed that:

- Provides vocabulary browsing capability (with a Rose Tree (HL7 toolset) look and feel;
- Separates concept (vocabulary) domains and value sets;
- Autogenerates XML formatted harmonization proposals;
- Includes user update capability to the vocabulary repository;
- Is Eclipse based (Java/SWT), uses Common Terminology Services (CTS) APIs for data access and provides Wizard interfaces to guide harmonization proposal generation. XML proposals can be transformed to a human readable proposal; and
- Uses existing HL7 vocabulary update schemas and java code.

The benefits will include more accurate representation of the required change request; users being able to see the results of their request; lower turn around time for approved proposals to be represented in the RIM repository; less hand generation of XML; and reduced errors.

The tool gives the facility to increase the amount of HL7 vocabulary that is mapped and is ready for decisions by HL7 on binding. It includes both V3 and V2.5 content. Remaining content issues are to be resolved. Errors and issues are being identified during the loading process, documented and taken into a resolution process. Most are technical corrections only.

Issues include:

- What is the decision pool – who gets to be in the realm, who decides;
- What should be the decision process?
- Is balloting involved?

- Should it be shared between the vocab TC and the domain TC or should it be only the domain TC?
- Where/when should the decisions and/or voting take place?
- What should be the publication format for these bindings?
- Usability in other realms. Upon determination to use any of the proposed mappings for the US realm, TC should evaluate whether these bindings would make sense for a representative realm binding. The TC may declare the binding in both the US and representative realms.

Because these issues have such a broad scope, decisions need to be discussed at harmonisation to ensure that they meet needs. The appropriate decision process needs consideration.

Note - The management of this type of process will be a major issue in Australia if we move to implementation of terminologies in a V3 shared EHR environment. We are not yet ready to establish a management structure or process but there is the opportunity to learn from the process being developed here to support our own procedural developments in the future.

6.13 Clinical Interoperability Council (CIC)

In the US there is currently a window of opportunity to engage clinical sources and end users of health information. Many clinical groups (professional societies and institutes) are being funded to establish data repositories and information strategies to support these. This is being driven by the desire to improve evidence based practice, support and compare clinical trials, and derive secondary data about the effectiveness of healthcare

However, most of these clinical groups are working independently, not sharing their data concepts nor the methodologies for their development. HL7 is trying to bring a consistent approach to these activities, and sees a concurrent opportunity to engage clinicians to ensure that its technical standards development is requirements driven

The clinicians concerned tend not to be interested in technologies (messaging, storage, etc), nor standards per se. HL7 already has some clinical SIGs – e.g. emergency care, paediatrics, but the intent now is to bring together a “pure clinical” coordinating group who will inform HL7 about the data they need to deliver health care, the rules and protocols for decision making, the triggers for decision making and action-taking etc. The group will be coordinating only – the specification work will be undertaken back in the professional societies, institutes, etc. Information from these groups can then be modeled within HL7’s SIGs, which are essentially staffed by clinical informaticians, then passed to the technical specialists who can develop the requisite technical artifacts

The aim is to have the first meeting of the CIC in September in Atlanta. HL7 would like to see this as an international activity, and is seeking global participation. Ed Hammond and Brian McCourt were elected as interim co-chairs for the CIC, with a term of one-year or less.

It should be noted that if this clinical engagement strategy is successful, there may be a need to realign some existing structures and processes.

Clinical Data Standards Interchange Consortium (CDISC)

CDISC's activities are closely related to this. CDISC is a global, open, multidisciplinary, non-profit organization initiated in 1997 as a volunteer group. It incorporated in 2000, and now has more than 170 member corporations including academic research centers, biopharmaceutical companies, technology and service providers, etc. It has Coordinating Committees in Europe and Japan, plus 7 User Networks spanning the U.S.A.

Through a consensus-based approach (COP-001), CDISC has established worldwide industry standards to support the electronic acquisition, exchange, submission and archiving of clinical research data and metadata to improve data quality and streamline medical and biopharmaceutical product development and research processes. Its standards are freely available on the CDISC website (www.cdisc.org).

The business problems CDISC are addressing include workflows – reporting unexpected or serious adverse events does not fit into normal clinical care workflows and takes excessive time. For clinicians doing research today, 60 % of trials are via data collected on paper and data are entered 4-7 times, including 2-3 times by the clinicians. 30-40% of data are collected by eClinical point solutions, and an average active study site has 3 disparate solutions.

There are obvious synergies and needs for harmonization between those developing clinical data standards for the administration and delivery of care, secondary uses and research.

CDISC's key activities for 2007 include maintaining its core standards; moving more into clinical data collection standards; building global alliances so CDISC standards can be global; and communicating their existence.

CDISC has a terminology initiative, to define and support the terminology needs of the CDISC models across the clinical trial continuum. They will be using the National Cancer Institute's Enterprise Vocabulary Services (NCI EVS). NCI EVS is closely related to US FDA & CDC activities.

The NCI EVS produces two terminology products: the NCI Thesaurus (NCIt) a cancer focused terminology, and the NCI Metathesaurus (Meta) a mapping between many terminologies. NCIt provides the following main features:

- Concept codes that exhibit concept orientation, permanence and non-semantic construction;
- Preferred terms for each concept that are the NCI's canonical lexical token for that concept; and
- English language definitions, and synonyms.

Of these the concept code is the most important, as it provides unambiguous linkage to a specific meaning and is machine interpretable. The semantics of NCIt include

description logic roles that are used to assert relationships and that have the potential to become a resource for data discovery, data management, and making inferences about data in future releases of the NCI' core repositories and registries. An Editorial Policy document briefly describing the policies governing change to NCI content is included with the semantics information. See http://ncicb.nci.nih.gov/NCICB/infrastructure/cacore_overview/vocabulary for more information.

Clinical data initiatives

Existing clinical data initiatives include:

- DEEDS – Several projects have been directed toward establishment of data standards for the domain of Emergency Medicine. Perhaps best known is the Data Elements for Emergency Department Systems (DEEDS) project sponsored by the Centers for Disease Control and Prevention. DEEDS is used by HL7 in the Emergency Department Claims Attachment developed as part of HIPAA implementation.
- Anaesthetics Information Management System (AIMS) This initiative is developing a common anaesthesia record and has international input – for example, it has drawn heavily on work from the Australian Patient Safety Foundation. They have developed a data set and data dictionary, are well advanced in building a domain terminology as a SNOMED extension, and are looking at messaging and knowledge representation implications.
- Cardiology and TB projects. Both of these US projects are funded via the National Institute of Health's Roadmap grants, and both focus on methodologies for developing data standards in therapeutic areas. The aims are to enable development of domain specific content for EHRs; enable data sharing, pooling and aggregation; and enable re-use of clinical data. Their products will include common data sets, and this has involved harmonizing a wide range of existing data sets and standards developed by disparate stakeholder groups.

The cardiology project will deliver common data elements and associated domain specific terminology; a domain analysis model; a CDA specification set and implementation guide; and a translation of the data elements into a clinical trial methodology. The data standards will be housed in the NCI's data standards repository.

The primary use case for the TB project is to take data from an EHR or registry entry to notify clinical trials of a potential new study entrant. However, the project has discovered that this use case does not translate well outside the US, especially to developing countries that might be particularly interested in TB. A data element set has been established by researching existing TB-related data standards and rationalizing this with an extended clinical specialty group.

- The Brighton Collaboration is an international voluntary collaboration to facilitate the development, evaluation, and dissemination of high quality information about the safety of human vaccines. The Collaboration's goal is to enable comparability of vaccine safety data across clinical trials and evidence bases, and it is developing:

- Standardised case definitions for adverse immunization events;
- Common data elements; and
- Evidence based tools for vaccine trials.

The Collaborative is currently comprises over 1400 people from around 90 countries (www.brightoncollaboration.org).

Recommendations:

- That IT-014 identifies relevant clinicians/clinical groups in Australia to participate (e.g. colleges), so this can be a global endeavour; and
- IT-014 endeavours to get an appropriate clinician to the Atlanta (September) meeting.

6.14 V3 Dynamic Model

There has rarely been a structured discussion of dynamic model issues and the unstructured debates that have occurred have never reached any substantive conclusion, nor are they likely to. There is additional incentive to finalise issues regarding Dynamic Modelling particularly as people try to argue the merits of SOA versus messaging, and similar issues regarding the use of CDA versus messages. Neither SOA nor CDA have any aspects of a Dynamic model.

The Dynamic Model debate received added impetus from two independent groups:

- Orders and Observations Technical Committee have decided to devote three sessions from the next WGM to discussion of Dynamic Model issues. There was considerable discussion about how to get some productive work done on this matter. R Harding was "volunteered" by the co-chairs of the Laboratory SIG to organise a structured way forward on this; and
- Independently, Modelling and Methodology Technical Committee have raised the Dynamic Model as one of their "hot topics" and have scheduled an out-of-cycle meeting on the issue to be held in Boston on June 21-22. R Harding will be attending and has volunteered to provide some base material to structure the debate and to provide a draft agenda for this meeting.

6.15 Publishing

The HL7 Board has retained consultants to review a range of editorial issues related to V3. R Harding has been invited to contribute to this initiative, firstly by providing a list of immediate issues before end of May and secondly by providing two subsequent lists prior to the September WGM.

7 Conclusions

Overall, satisfactory progress was made towards the achievement of Australian objectives for international standardization.

Australia continues to influence HL7's strategic positioning as a global SDO and encourage its collaboration with other global SDOs through representation on the Board, Advisory Committee, Technical Steering Committee, numerous Technical Committees and SIGs, the Strategic Initiatives Task Force and SDO Coordination Groups, as well as via informal channels. Australia's participation in these groups (many by election or invitation) reflects both acknowledgement of our technical and managerial expertise and sustained efforts at relationship building and management on the parts of Standards Australia and HL7 Australia.

The strategic positioning of HL7's key products (HL7 V2x, V3, CDA, EHR Models, etc.) is still evolving but the realisation is growing that significant enhancements to V3 are necessary to enhance its implementability and thus its viability. Australian organizations and personnel (Jiva Medical/Grahame Grieve; Ocean Informatics/Tom Beale and Sam Heard; HL7 Board/Klaus Veil) are leading efforts within both HL7 and the NHS to resolve these concerns and harmonise international standards. Standards Australia and HL7 Australia will continue to monitor developments.

Work on healthcare services specifications appears to be progressing satisfactorily, with significant Australian involvement, and CDA appears to be picking up momentum internationally although it remains early days in its implementations.

Inclusion of Australia's requirements into HL7 standards such as patient administration, diagnostic and collaborative care messaging and the EHR Functional Model is now routine and progressing satisfactorily and although further work is required, there are no current concerns.

Attachment 1 – HL7's Technical Committees and Special Interest Groups

HL7 working groups are characterized as being administrative, special interest or technical:

- Standing Administrative committees focus on organizational or promotional activities. Current administrative committees include the following areas: Education, Electronic Services, International, International Mentoring, Marketing, Organisational Review, Outreach Committee for Clinical Research, Process Improvement, and Publishing.
- Special interest groups encourage sharing of common experiences in particular interest areas. Currently active special interest groups and task forces are: Anatomical Pathology, Anaesthesiology, Arden Syntax, (Claims) Attachments, Cardiology, Clinical Guidelines, Clinical Genomics, Clinical Interoperability Council, Community Based Collaborative Care, Emergency Care, Government Projects, Healthcare Devices, Imaging Integration, Laboratory, Patient Safety, Paediatric Data Standards, Pharmacy, Public Health and Emergency Response, Service Oriented Architecture, Templates, and Tooling.
- Technical committees are chartered by the HL7 Board of Directors upon member petition specifically to create, maintain, and extend the HL7 Protocol Specifications. Technical committees frame the actual language of the specifications, conduct formal balloting on that language, and then recommend approval to the whole HL7 organization via full membership ballot.

Currently active technical committees are: CCOW, Clinical Decision Support, Electronic Health Records, Financial Management, Implementation/Conformance, Infrastructure and Messaging, ITS, Modeling & Methodology, Orders/Observations, Patient Administration, Patient Care, Regulated Clinical Research Information Management, Security, Scheduling & Logistics, Structured Documents and Vocabulary.

Attachment 2 – HL7 International Affiliates

Current HL7 International Affiliates are:

Argentina
Australia
Brazil
Canada
China
Croatia
Czech Republic
Denmark
Finland
France
Germany
Greece
India
Ireland
Italy
Japan
Korea
Mexico
New Zealand
Spain
Sweden
Switzerland
Taiwan
The Netherlands
Turkey
United Kingdom
Uruguay