Report on the
HL7 Working Group Meeting
held in
San Diego, California,
7-12 January 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
EHR	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
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
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

Executive Summary

The first HL7 Working Group Meeting for 2007 was held in San Diego, California from 7 to 12 January, with the Detailed Clinical Models Group meeting on Friday 12th and Saturday 13th. Six Australians were present at the meetings out of some 500 persons attending from 22 different countries.

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 Australian organizations and personnel are leading efforts within both HL7 and the UK NHS to not only enhance V3 to ensure its implementability, but also to add to V2 principles and concepts that improve its robustness and usefulness.

Actions flowing from the HL7 Strategic Initiative occupied a significant amount of the informal and administrative discussion at this meeting. Fundamental changes associated with HL7 becoming a more professional organisation include: a full-time CEO with a strong representative role; competent technical support for standards development; and an enhanced funding model.

Recruitment of the CEO for HL7 has reached the contract negotiation stage. The finalisation of this process and subsequent announcement of the successful candidate was expected by the end of January 2007.

The Strategic Initiative has identified the importance of HL7 as a global SDO, but the challenges of obtaining and assimilating more effective input from global stakeholders and influencing global agendas remain significant. The substantial contributions of Australian representatives in helping HL7 to address these issues are strongly appreciated.

Although not part of the HL7 Working Group meetings, once again the Detailed Clinical Modelling (DCM) Collaborative met for 2 days to:

- Present on the many V3 Templating efforts; and

- Report from the NHS on CEN 13606 and Archetypes.

There is no doubt that interest in this area is growing and work in the shared modelling space is likely to be a priority for national e-health programs and standards developers and implementers, for example, the NHS, and *openEHR*.

The Australian work on implementing Archetypes in V2 was presented and generated much excitement and positive comment within the HL7 community, particularly amongst the senior members.

The Australian work on incorporating Digital Signatures within HL7 messages was presented. It has been agreed that the Security TC will review this work and provide some recommendations for future development.

Service and Provider Directories have been endorsed as a project with the Healthcare Services Specification Project (HSSP).

The EHR Functional Model passed ballot reconciliation.

The debate on HL7 V3 versus Service Oriented Architecture continued throughout the meeting, but really culminated in a debate conducted by Ken Ruben of the US on Wednesday night. This helped enlighten many participants and spectators as to the differences, for example, Services can be used to assist in the creation and delivery of a message; and Services are not data, nor does data have to be an integral part

of a Service before it can perform its function, whilst the actual message containing (clinical) data can be V3.

During the meeting there was significant progress made between a number of Committees, such as Infrastructure & Messaging (INM), Modelling & Methodology (MnM), Orders & Observation (O&O) and Service Orientated Architecture (SOA) to further develop the new dynamic model, which is of particular significance to Australia. Also the activities of the SOA Special Interest Group (SIG) and the perspectives on SOA are now a key part of this work. Further progress on this was expected throughout this meeting and the upcoming May 2007 meeting.

1 Introduction

The first HL7 Working Group Meeting for 2007 was held in San Diego, California from 7 to 12 January. This meeting was notable for its sizeable attendance, with over 500 registered attendees, and representations from 21 countries outside the USA. There were substantial delegations from national implementation programs in the UK, The Netherlands and Canada, comprising both managers and technical experts strongly committed to implementing the next generation of HL7 standards based on HL7 v3. The US Department of Trade sponsored delegations from Brazil (4 people) and Malaysia (3 people).

The Australian delegation comprised six people. David Rowed, Chris Lynton-Moll, Sam Heard and Heather Grain were subsidised via funding from the Department of Health and Ageing; while Max Walker and Grahame Grieve were supported by the Department of Human Services, Victoria, and Jiva Medical, respectively.

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 standards for clinical and administrative data applications. 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 core 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 sixteen 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 twenty-three 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 seven 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, and its (ballot package) drafting and publications group meets bi-weekly. During the reconciliation of over three thousand comments on the conformance criteria for the EHR Systems Functional Model, breakout groups on the components of the Functional Model (Direct Care, Supportive Information and Information Infrastructure) were also meeting weekly by telephone.

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

Twenty-two countries (including the USA) were represented in Dan Diego. HL7 currently has twenty-seven recognised International Affiliates (listed in Attachment 2), and negotiations with five other countries are in process.

Twenty eight percent (28%) of HL7 membership is US based and 45% is European (largest proportion from the UK and Germany). However, the US accounts for 53% of HL7's revenue.

As usual, 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

United Kingdom (UK)

The Implementation Report by Charlie McKay indicated a conceptual change by the implementation group due to the increase in the number of organizations and members involved with active implementation initiatives.

NHS Study presentation by Laura Sato

Key Findings of the study were presented and these included the following:

- 13606 may be useful in defining detailed clinical models for re-use across projects, both human and machine readable

- NHS initiatives are not likely to work unless a hierarchy of archetypes are established whose top level is informed by an established clinical semantic model or framework etc. The SCT concept model, or ISO/DTS22789 Conceptual framework for patient findings and problems in terminologies (a current work item for ISO TC215 WG3), may provide the solution for this implementation issue.

- Technical requirements for interoperating with SCT and HL7V3 will eventually be needed.

Next steps:

A three month pilot project to test ideas related to establishing a suitable archetypes hierarchy will be undertaken. This will also test current tools available and/or define further requirements for them. The tests will define human and other resource requirements that would be needed to implement archetypes such as governance, tools, and integration with existing NHS business models.

ISO and CEN

The ISO report was presented by Dr Kwak (Korea), Chair of TC/215, regarding the recent harmonisation efforts between HL7, ISO and CEN.

The CEN report provided by K. Molenaar, Chair of TC 251, and Steven Kay, identified clearly and in more detail, specific work items of joint interest.

These harmonisation initiatives are ongoing. Topics for collaboration were identified, including:

Archetypes/templates

13606/CDA/openehr

ICH messages

Term info

HISA and SOA

Identifiers

EHRs

e-prescribing

clinical domains and patient need

emergency data set

There needs to be further work done on the identification initiatives already underway, and their harmonisation between ISO and HL7, as the ISO work item is more extensive and has a different purpose to existing HL7 activities.

Netherlands

Frans van Bommell presented an overview of the activities of ebXML.

<u>International Mentors Group (IMG) presentation by John Ritter</u>

This is an initiative to find fledgling HL7 chapters and to work out how to assist them get the education and involvement that they need. Delegates at this meeting were sponsored from Brazil (four people) and Malaysia (three people).

4.2   Collaboration with other major SDOs

Senior HL7 representatives confirmed their desire to collaborate with other international and global SDOs. The Board renewed agreements with other organizations such as IHE. They also reviewed relationships with other organizations such as Harmonisation and NATO Health Care.

4.3   ISO, HL7, CEN Collaboration

A group with representatives from each organisation met in Washington following the signing of a broad agreement in Geneva in October 2006, and will issue a report on how the groups aim to proceed. It is clear that the organisations' leaders want to bring their efforts together where appropriate and not duplicate effort. This is threatening to some in the US but they did not raise any serious objections to the proposal of full collaboration – yet to be fully progressed and realized.

Data Types

Unification of data types is considered an important international agenda. The current specifications that are considered useful are the HL7 v3 abstract data types and the *open*EHR data types.

There is general consensus and growing organisational support for a combined HL7/ISO document for datatypes. CEN would also be supportive of this document. This is an outgrowth from the New ITS project and is sponsored by the NHS.

There is a taskforce for Datatypes R2 to start advancing the next cycle of this work.

5   Organisational Issues

The major item of business, and of concern, of an organisational nature, was the HL7 strategic initiative.

There is still general unease and tension relating to the organisational restructure. However this did not seem to have a large impact on the actual work of the organisation and overall the general tone of the meeting was positive.

Recruitment of the CEO for HL7 has reached the contract negotiation stage. The finalisation of this process and subsequent announcement of the successful candidate was expected by the end of January 2007.

5.1   Board Meeting

The HL7.org Board convened on the 9th of January.

Hugh Walker reported on Architecture Review Board (ARB) activities. The main points were as follows:

- The requirements were identified to ensure quality is retained while going forward.

- There are also a number of activities based on HL7, which are occurring outside

HL7, these need to be encouraged to be brought into HL7

The Board approved

- $100K to fix up tooling, and asked the tooling committee to review the possibility of using "off the shelf" products

- Policy on Professional Courtesy at WGM's was released.

- HL7 will extend meeting room availability to support meetings with other SDO's (on the SDO's request).

- International Affiliates recommended formal inclusion of HL7 Romania.

- A new process was established to capture statements on the status of V3 so that these can be reviewed and responded to where necessary.

Project management office update, as follows:

- An RFQ has been released for a new website build.

- A E-Learning vendor has been engaged. – A 90 to 150 day production cycle has been agreed.

- A Technical editor was sought. However, the recruitment process proved that what was required was not simply a Technical editor. This is now treated as a project to address the interfaces required to ensure publication performs smoothly. This project will continue until it eventually resolves the editing problem.

A new board representative was appointed to T3F, Virginia Lorenzy.

5.2   Other organisational issues

The XML SIG has negotiated with Infrastructure and Messaging TC (INM) to take on ITS (Implementation Technical Specification) and has been re-named the ITS SIG. This is seen by many as an interim step towards resolving ITS issues.

6   Standards Development

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

6.1   V2.6

V2.6 has finally passed ballot.

6.2   V2.7

Australia via the Community Based Collaborative Care (CBCC) SIG has submitted the Collaborative Care suite of messages for inclusion into V2.7. These have already passed CBCC SIG and Patient Care TC Committee Ballots at the January 2006 WGM.

6.3   V3

A V3 instance editor and MIF validation tooling were demonstrated by NHS/Eclipse OHF and are in the process of being released.

VHA demonstrated some UML/XML work by Dave Carlson – details can be found at

http://www.xmlmodelling.com. This offers the prospect of a new path for HL7 for methodology and tools, and a small group from VHA & NHS will investigate this in detail between now and the next meeting.

6.4   V3 ITS

The New ITS development (aimed at addressing emerging implementation concerns from the UK experience) is now a formal HL7 project and a number of specifications will be balloted in the next ballot cycle.

6.5   EHR

The Function Model (with the added conformance statements) was in ballot reconciliation and should be passed. All negative ballots were reconciled by Tuesday evening and this session involved dealing with the minor ballot issues. The main problem that arose was that many issues dealt with during the draft standard phase were raised again.

Profiles are now being prepared for Emergency Care systems and Legal EHR or Personal Health Record systems. HL7 has agreed to host the profiles in the National Institute for Standards and Technology (NIST) repository using a standard set of meta-data.

The final standard will be free.

The proposed next steps include:

- Using profiles as quality improvement triggers

- Outreach to potential users

- Keeping ballot comments and dealing with proposed changes based on previous changes – by developing a proper change log

- Alignment with other HL7 TC artifacts (links with other TCs), such as using the functional model as the map

6.6   Patient Care

After a very long sequence of terms, Dan Russler did not re-stand for the Patient Care (PC) Co-Chair position. He will concentrate on HL7 Board activities but will remain a member of the group. He has been very influential in guiding the care-focused modeling of this group and been very supportive of Australian needs both at the V2 and V3 levels, and in Community Health. It is hoped that he will remain an active resource for PC. Dr Larry McKnight was unanimously elected to fill Dan's Co-Chair position. Larry is both a physician and engineer and appears to have the expertise required to carry Australian clinical needs forward, but lacks the knowledge of the history of Australia's important inputs. This will have to be managed by Australian delegations at PC and Community Based Collaborative Care.

Patient Care Provision DSTU has passed ballot after the reconciliation of outstanding negatives. This has been very much influenced by Australian Shared Care, Referral, and EHR requirements and was developed with a major contribution from Heath Frankel.

The Condition Tracking modeling by Patient Care has been problematic and the Condition class is being deprecated to be replaced by a Concern class, which will support what might be considered to be "Issue" tracking. This is still being worked

on. It has the potential to emphasize problem <u>perspective</u> which IT –014-06-06 recognised as a necessary enhancement in V2. This area is critical to care planning and problem oriented recording and merits collaboration. The modeling is generically useful regardless of whether or not V3 is used.

Allergy / Adverse Reaction is now being modeled via the Concern class. This is being led by PC, working closely with Pharmacy, and also involving Clinical Decision Support. There was a joint meeting between the three groups on this. Each has a need for representing the concept.

Chapters 11 and 12 are currently in order for V2.6 but Patient Care's approach was initially to deprecate them unless volunteers come forward to continue the work. It was stressed that this remains an Australian priority, and with our enhancements for V2.6, the 'low-baggage' Collaborative Care message for V2.7, and the Archetyped Data in V2.6, there is an industry-friendly transition strategy for highly-structured clinical communications.

The Australian Archetyped Data in V2 Project was presented to the group by Chris Lynton-Moll, and there is strong interest in this from those committed to V2, and general support within the group for this. This was a point of discussion with many senior HL7 members outside the group which continued to be extremely positive and hence encouraging to say the least.

A proliferation of Patient Care Clinical Domain SIGs has been taking place to incorporate specialty clinical groups coming into HL7. There were no further such SIGs approved at this meeting, and a new initiative being put forward by Ed Hammond may address this need.

Patient Care also did the Ballot Reconciliation for Care Composition.

6.7   Community Based Collaborative Care

The Community Based Collaborative Care now also carries the responsibility for privacy and consent. As a result considerable committee time was spent on privacy issues and the Privacy Ballot Reconciliation.

Implementation and Policy issues were discussed from many countries' perspective. There were common issues of role based access, masking, and how these are to be handled.   The group decision was that all requirements must be able to be messaged, and that national policies will dictate implementation and not be incorporated into the standard.

The concept of the shared secret is being introduced in both the Canadian and the UK environment. This is not an approach Australia has considered at this point. The shared secret approach is operationalised through a text string with a keyword requiring the patient to provide access by entering the keyword. The keyword is imbedded in the record.

A specific request was made to consider requirements for privacy management of masking of drugs. After considerable discussion the suggestion was made that there should be a consistent approach to this issue, rather than handling different types of health information and building standards for each different area. This will require further discussion and monitoring.

There was recognition that there is a need to develop a taxonomy for the representation of privacy and access control as the current international approaches do not have a consistent communication language.

Use cases will be developed to assist in further development. There is a need to capture all policy possibilities and to ensure that future messaging standards can support these policy requirements. This group is to develop the messages to communicate effectively privacy architecture, consent and access control information.

Chris Lynton-Moll presented a brief discussion on encoding Archetypes in version 2 HL7 messages. After discussion moved a motion (passed) that Community Based Collaborative Care SIG take up a work item that will sponsor the use of Archetypes in transfer of detailed patient information. Australia will continue to bring information and updates on progress with Archetypes back to this SIG.

Peter Kress reported on the Center for Ageing Services Technologies (CAST) and the American Health Information Management Association (AHIMA) project. There is a particular emphasis on assessment and developing a number of Use Cases. More recently there has been work done on an IHE Profile with representatives from several bodies

The CCD (Continuity of Care Document) has passed ballot & therefore potentially makes the project simpler.

Wiki at http://continuityofcaretaskgroup.pbwiki.com/ for details.

6.8 Vocabulary

Domain and Value Set Definitions and Bindings in Static Models

This item is intended to inform development of the requirements for terminology implementation in systems. The definitions and examples are provided to assist in consistency of meaning and to aid implementation. The group has not identified the target audience for this work. This work has some relationship to archetype activities.

Details of modifications to the document are, in summary:

- The vocabulary domain is now called the concept domain as this is easier to explain to the less initiated.

- Value Set management was discussed at length. Rules were established for the creation of a new value set and for the maintenance responsibilities of value sets used in HL7

Date and time of value set used when data is created must be maintained and must 'travel with' the data if rules and potential representations are to be clearly and safely communicated. This was followed through with I&M on the Tuesday, where this concept was confirmed. The impact of this decision to support data traceability will require further rule definition, but is based upon effective date of the value set at the time of data creation. This is a new requirement.

Assessment instruments

The issue of standardisation of structure and process for the management and maintenance and communication of assessment instruments was discussed. SNOMED has named 730 assessment instruments already, and there are over two thousand mental health instruments with no data standards for these.   This is a significant issue that the group decided to consider from the generic perspective in order to support assessment instruments and the concepts required for decision support rules.

A presentation was given by Thomas White NY State Office of Mental Health. He represented the problems required to be addressed to clearly identify meaning and reference range/s of variables used in assessment. These included:

- Determined by text of question and allowable response set

- Altered by wording, order, presentation, assessment method

- Further altered by dynamic tailoring language and actual order asked

Implications for further development included:

- When modeling items, most fully store questions, answers, answer lists, internal coded values, and contextual instructions, ideally in a fashion supporting re-use

- Model instruments must be modeled to capture context and order of items

- Semantically, conceptual unit is instrument version plus question and answer.

Additional issues identified include the need to maintain information on the sequence in which questions are asked or processed as this can alter the result. The intention is that these can be modeled abstractly with common goals and the business logic needed for variable names, codes, and validation navigation.

Glossary of terms in HL7

A new proposal will be developed through fortnightly tele-conferences to create a harmonised proposal for addressing assessment instrument problem space. The objective of this work item is to create an implementation guide with a proof of concept document that describes HL7's approach to representing survey instruments. This will assist system builders in developing better and more consistent systems (the goal is to reduce software development time and to improve consistency and safety)

A presentation was given on the need to develop a harmonised glossary of terms for HL7. As ISO already have a project of this type, with an associated web based tool to support ongoing maintenance Heather Grain suggested that this work be done jointly, with ISO activities occurring first, then HL7 joining the process. This was well received in concept, and further discussions will occur out of the meeting to progress this item.

Value set definitions as they relate to compositional value sets

It has been recognised that value sets may contain a combination of representational forms. This needs a standardized structure, particularly for the provision of post-coordination within the statement. It was considered that putting the definition of the complex value set into the value set rather than into the binding is probably the best idea. The mechanism for composition representation within a field might overlap or conflict or may need to be restricted so that the information is not put in a different attribute rather than in the single field.   There is a need to be able to indicate that this value set contains complex expressions. There is more than one way of writing the expression e.g.: is it an exhaustive list, or canonical forms. Further discussion and design will be undertaken to more clearly identify a method to specify a post-coordinated expression as a member within an enumerated value set.

Outstanding issues on binding

The idea of static binding vs. dynamic binding has to do with whether the intention is to bind with a set of unchanging concepts or to bind with a name space and what ever is associated with the name space is what one binds to at the time of data

capture. Dynamic binding means that the most current version of the value set is the one appropriate at that time.

Concept 1: Design time binding – specifies the value set name in the static model itself.

In Run time binding the domain name is only in the static model or data type property and at run time a vocabulary server takes contextual information (realm) and knowing the message type, attribute domain and the realm can resolve, through a terminology server, the value set that applies at that particular point in time.

Concept 2: Consistent through the document is the idea that versions of value sets would be tracked by dates rather than by numbers, and for people who are versioning their terminology by numbers, dates would be assigned to each version so that one binds to a version based upon a time/date that that version was effective.

Metadata and rules for capturing run-time (static and dynamic) binding information were broadly identified. This activity was not completed. The information identified is fairly static, but there will be additional attributes and annotations added as this is incorporated into the fuller modeling work for messaging.

Representing Drug Delivery Device concepts in RxNorm

The meeting considered four new semantic types of drug delivery devices.

1. Drug and device: e.g. pre-filled syringe, patch, MDI

2. Drug and drug: eg Z-Pack, OCPs - packages that have different ingredients (eg Pills or doses) to be taken every day.

3. Drug Delivery Device and drug: Anaphylaxis kit (pre-filled syringe)

4. Drug Delivery Device and Drug Delivery Device: a kit that contains another kit

Further work will be required to extend and define both the representation of these concepts, as the business case requires these concepts to be different for the purpose of ordering.

The Vocabulary TC will follow the proposed SOA SIG – HSSP processes as proposed for developing the CTS II requirement document, however, further work and collaborative activities is required.

The Vocabulary TC will adopt the LexGrid resources as a starting set of use cases as the basis for CTS II. There is no requirement that LexGrid APIs or functionality must be preserved.

6.9   Conformance

The ballot issues from v2.6 were all passed.

There were lengthy HL7 V2.7 discussions, for example, should there be a minimum and maximum length defined, or only a maximum length? It was decided that both minimum and maximum lengths are required for implementable profiles. Note: in earlier versions "n" was implicitly understood to be "n..".

Starting with v2.7 the length can be defined in the standard where it is necessary to assure correct functional behaviour.

Two profiles are conformant to each other, if the length definition within both is identical. These are also compatible to each other if the upper and lower bound of the sender falls within the limits of the receiver. The table below provides some

samples of this requirement:

Examples of (conformant) Length Definitions

Sender	Receiver	conformant
[2..5]	[2..5]	yes
[3..5]	[1..10]	yes
[2..5]	[4..5]	no
[5..10]	[7..*]	no
[1..*]	[1..1000]	no

A new work item was introduced to develop a query conformance profile for HL7 v2.7. The Q1/2 discussions on minimum and maximum lengths were unanimously passed by Infrastructure and Messaging. This will result in Chapter chairs having to revisit their segment tables and to re-define the element lengths.

Several other problems were dealt with, such as the V2.6 MSH 9 states that all three components are required, but the DTD does not specify this. Frank Oemig will check the DTD to see how it is generated.

The Ballot reconciliation of remaining version 3 issues took place. There were seven major negative issues and twenty-six minor negative issues. All ballot items were dealt with.

Discussion continued on the conformance implementation manual, particularly vocabulary domains, data type constraints, in particular, mandatory version required.

Message Workbench

The latest update is v6.6.
An automatic registry of profiles with UID shows up in MSH-21, this then brings up the conformance profile to validate the message. A validation service can now run from desk- top service tray.
The Message generation service can now include value sets e.g. glucose test and its expected values.

Message Maker

Minor updates and amendments have been addressed in v1.5.4. This will provide a core set of HL7 Java APIs:

- Message generation;

- Message validation;

- Profile validation; and

- Encoding transformation

The Message Maker 2.0 should be released by May 2007.

- Web Services

  o Message generation and message validation

- Testing framework – to support testing of HL7 systems

  o Based on configurable actors

      o   Targeting IHE and HITSP use case scenarios

A strategy was developed to move towards the Implementation Committee and the Conformance SIG becoming a Technical Committee.

6.10 CDA: Clinical Document Architecture and Structured Documents

Preparations are beginning for CDA Release 9.

The Public Health and Emergency Response SIG have prepared Use Cases (CDA) to stimulate debate on when CDA would be used and when a message (V2 or V3) would be used. One of the unique requirements is that sometime a Patient/Client is not involved in the Use Case.

The resulting debate raised the following:

- When should CDA be used? A clinical document is an XML schema. It is also possible to embed images, so that a hierarchical structure can exist. CDA can handle unstructured text.

- The data can be static medical information, which does not have V2 or V3 messaging capability.

- IHE has mechanism (XDR) for exchanging documents without needing message wrappers.

- For authentication and attestation, then a document is required.

- In some cases it has been decided that anyone not involved in direct care would receive a CDA and there would be no message transaction.

- Work is being done on LOINC to form questions, so that consistency can be maintained between documents.

- R2 does not quite handle everything required. In emergency response questions and data collected evolve as the case evolves.

- As well as a Clinical Statement, a Public Health Statement, Clinical Model & Public Health Model may be needed.

The need for standardized forms was noted, for example, for Cyclone Katrina cases, there were five different Emergency Shelter Requirement forms used.

6.11 Templates/ Modelling and Methodology

The UK presented a brief outline of their work to combine RMIM specifications into a single message or CDA document. Dan Russler stated that IHE now has a simple template mechanism, which allows Schematron post-processing of CDAs to ensure that the actual document conforms to the specification (although the specifications are in text). Both only allow post-processing.

The need for a repository for templates was raised again.

Ken Lunn stated that the NHS has a template implementation, which they want ratified by HL7. Suppliers need a standard representation for templates or they will have to implement a different template mechanism.

6.12 Service Orientated Architecture and Healthcare Services Specification Project (HSSP)

Many issues around Messages vs. Services remain unclear within HL7 and generate concern within the organization. These seem to include confusion of concept and disagreement regarding the application of these.

David Rowed recommended a hierarchy of rigorous definitions working up from generic concepts to HL7 Messages and SOA as an important part of managing the ongoing confusion around this. IBM has some work on this and it will be put on the Wiki.

The group discussed and canvassed the new Services areas to be worked on this year.

From these the following areas were selected by votes for 2007:

1. HSSP Services Interoperability Profile. Kevin and John Koch:

2. Security – Privacy Services. Don Jorgenson the lead

3. Service and Provider Directories. Max Walker to carry this

4. Cohort Selection. Charlie Mead to carry this

Issues such as PKI and Provider Authentication have been placed under the umbrella of the security project. This also includes anonymisation.

The need for Archetype Repository / Servers was recognized. Following out-of-session meetings with Ken Rubin, Sam Heard and David Rowed, it was decided that the group would lead the set up of a registry for archetypes, templates and CDA which would 'reposit' other structures as discussed earlier. It was agreed it was too early for relevant Services definitions at this point.

There was agreement to work with SOA on the repository requirements in DCM.

6.13 Patient Administration

Balloted documents have been identified to contain some information that is for real people. This will be reviewed and must be changed.

The committee's activity was considered insufficient to require a third co-chair. If an additional co-chair is needed at a later stage then an election will be held.

There is a need to review the Person related information segments to support the data requirements of the ISO client identification standard.

6.14 Security

Reports were given on many activities throughout America and Europe, by Glen Marshall and Bernd Blobel.

The Security TC has taken on the 'Digital signatures' in v2.x messages as a new work item. This will add great benefit to the Standards Australia IT-014-06 project. Questions were raised regarding the policy behind this and the requirement to understand this was raised.

6.15 Terminfo

Ninety-eight comments were received on the latest version of this document and the Disposition of Comments is still to be completed.

A specific use case was discussed in detail, regarding the need to use SNOMED and a code from other code system/s in one concept. This is a requirement in the USA where reporting must meet FDA requirements, some of which are not done using SNOMED. SNOMED will be used where it is available. There was a great deal of debate on this issue.

Migration strategies towards tightly constrained semantically accurate and safe communication need to be identified for example, the availability of a map.

Identification of approaches and how to move forward were also considered for inclusion in the document.

There was considerable discussion on the need to more accurately and clearly identify representation for drug administration routes. This work will be progressed for the next meeting. Route is likely to be broken into concepts such as the method (e.g. syringe), the type of route (intramuscular) the location of the route (leg muscle), and type of delivery (injection).

6.16 New HL7 Clinical Group

David Rowed met with Ed Hammond at Ed's request and discussed a new clinical group that he is setting up. He had introduced this idea the previous day at the Cardiology SIG. This is intended to be a high-level, domain-focused activity, which will not work at the level of technical detail of Patient Care. It is a new activity outside the traditional SIG / TC infrastructure, and will address the needs, especially content, of clinicians bringing their needs to HL7. It is expected that this group will work closely with PC and obviate the need for more clinical domain SIGs. Details of set-up and operation will be worked out over the next two months. There will be a full day meeting on the Thursday at the next meeting. This will clash with Clinical Statement, but the focus being so non-technical, that is not seen to be a problem. This activity offers a clearer path for Australia to ensure that its overall, and evolving, clinical needs are adequately met by HL7 which has been difficult in the past.

6.17 Clinical Guidelines

The clinical guidelines special interest group discussed projects towards convergence models. It was suggested that a conference be held with relevant stakeholders to identify greatest areas of need in creating, maintaining and evaluating guidelines. This will be most likely pursued outside the HL7 process as a non-committee related event. There were also discussions on the very different approaches used to construct guideline content knowledge – it was broadly agreed that there was no model that supported all kinds of knowledge. This led to a suggestion that very specific kinds of knowledge could be used as the basis of standardization, with an eye to harmonising where possible between models - for instance a suitable model to support drug-drug interactions. This work is ongoing and related to existing development of models to support decision points in care provision currently being developed in the areas of order sets modeling (specific protocol definition), and patient care plan modeling (care provision domain).

6.18   Detailed Clinical Models

Although not part of the HL7 Working Group meetings, once again the Detailed Clinical Modelling (DCM) Collaborative met for two days to:

- Present on the many V3 Templating efforts and

- Report from the NHS on CEN 13606 and Archetypes.

There is no doubt that interest in this area is growing and work in the shared modelling space is likely to be a priority for national e-health programs and standards developers and implementers, for example, the NHS and Open*EHR.* This is complementary to the NEHTA Clinical Information Project, however a computable formalism is seen as critical to the success of these efforts. DCM must not be left as just an indexed repository of models and must have much more utility and applicability than this. The group is in danger of losing its way if not kept on track.

The SOA group will work with DCM on the repository aspect of DCM.

Details of the Mission, Scope, Meeting Minutes etc can be found on http://detailedclinicalmodels.org/wiki/index.php?title=Main_Page

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 continuing to evolve and there is significant work being undertaken, particularly that lead by the UK, to enhance v 3's 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 this and harmonise international standards. Standards Australia and HL7 Australia will continue to monitor developments.

Of particular success at this WGM, which all culminates from work done both in Australia and at other WGM's, was adoption of Service and Provider Directories in the HSSP, the agreement of the Security TC to take up as a work item, a review of the Australian work on Digital Signatures, and the inclusion of Archetypes in HL7 through the Community Based Collaborative Care SIG.

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, Implementation, Marketing, Outreach Committee for Clinical Research, Process Improvement, Publishing, and Tooling.

- Special interest groups encourage sharing of common experiences in particular interest areas. Active special interest groups are Arden Syntax, Attachments, Clinical Genomics, Clinical Guidelines, Clinical Trials, Community Based Health Services, Conformance, Government Projects, Imaging Integration, Java, Laboratory, Lab Automation Point of Care Testing, Patient Safety, Pediatric Data Standards, Pharmacy, Public Health and Emergency Response, Templates, XML.

- 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, Control/Query, Financial Management, Electronic Health Records, Medical Records, Modeling & Methodology, Orders/Observations, Personnel Management, Patient Administration, Patient Care, Regulated Clinical Research Information Management, Security, Scheduling & Logistics, Structured Documents and Vocabulary.

Currently active special interest groups and task forces are: Anatomical Pathology, Arden Syntax, (Claims) Attachments, Cardiology, Clinical Guidelines, Clinical Guidelines, Clinical Genomics, Community Based Collaborative Care, Conformance, Emergency Care, Generation of Anaesthesia Standards, Government Projects, Healthcare Devices, Imaging Integration, Java, Laboratory, Patient Safety, Paediatric Data Standards, Pharmacy, Public Health and Emergency Response, Service Oriented Architecture, Templates, XML, Ballot Task Force, Clinical Statements, Common Message Element Types, Dynamic Model, Harmonization, Terminfo, Tooling Collaborative.

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