Health Level Seven (HL7) Inc
22nd Annual Plenary & Working Group Meeting
Vancouver, Canada, 14-19 September 2008

Meeting Report

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Introduction

The September 2008 HL7 Annual Plenary and Working Group Meeting (Vancouver Meeting) was held in the Sheraton Vancouver Wall Centre Hotel, Vancouver, British Columbia, Canada from 14 to 19 September 2008.

This report provides an update on the activities of HL7 Inc as a global standards development organization and Australian engagement in international HL7 activities, highlighting issues relevant to achieving the Standards Australia IT 014 objectives for international health informatics standards participation and influence at HL7.

This report was prepared by Richard Dixon Hughes, drawing heavily on contributions from some of those that attended. Original reports from Heather Grain, Richard (Dick) Harding, and Dr Ken Harvey, along with several other supporting documents are provided as separate accompanying files for reference and further information.

Key Points

- With the Australian Government providing funding support for 9 delegates and a further 6 Australian delegates being supported by their employers, the total Australian contingent of 15 was sufficient for Australia to be seen to be contributing and better able to influence outcomes at the Vancouver Meeting. Further details on Australian and other participants and the work program are presented in section 2 below and Attachment A to this report.

- Since 2005, several Australians have actively participated in the HL7 "Strategic Initiative" review that sought to migrate HL7 into a more strategically focussed and capable organisation, while continuing to benefit from the support of its volunteer community. It is 18 months since the appointment of Dr Charles Jaffe as full-time CEO, 12 months since John Quinn took on the role of Chief Technology Officer (CTO), and some nine months since the HL7 Board devolved responsibility for coordination and delivery of technical standards to a re-structured Technical Steering Committee (TSC) working with the CTO.

- While the path has been rocky at times, the new structure of TSC supported by the ArB, four constituted Steering Divisions, Work Groups and Project Management Office (PMO) has matured to the extent that the organisation is now more able to respond to its major stakeholders and engage in strategic initiatives. The structure (as presented in previous reports) is summarised in Attachment B.

- The HL7 strategic Road Map developed by the HL7 Board with the Advisory Council and key stakeholder forums has been extensively reviewed, simplified and was officially published at the Vancouver Meeting (see section 4 below for details). It comprises a set of Roadmap Strategies (Attachment C below) and a Technical Plan setting out the tasks required (at Attachment D below).

  Action. NEHTA, HL7 Australia, Jurisdictions, IT-014, MSIA, HISA and their members should regularly review the Roadmap documents to ensure they reflect Australian needs (e.g. in relation to support of v2 enhancements for the medium-term). Proposed changes should, if possible, be agreed locally then officially communicated (via HL7 Australia) to the newly-formed Roadmap Task Force, with copies to HL7 Board and TSC and be actively followed through at following WGMs.

- The HL7 Roadmap Task Force (RTF) includes only one person from outside the US (Dr Ken Lunn) and is far more US-centric than the HL7 Board of Directors. Possible action. While all but one of the RTF are also on the Board of HL7, it would be appropriate to see if Australia could argue for at least one more independent member with an international perspective – if not an Australian, someone like Don Newsham (Canada) the convener of the HL7/CEN/ISO JWG..

- Under the guidance of Dr Charlie Mead and the Architecture Board (ArB), a group of highly talented and experienced HL7 experts has been working with CTO, John Quinn, to reconcile the HL7's evolving approaches to services, documents, messages, workflow and domain analysis. After considerable near full-time effort the ArB has released the initial draft of the HL7 SAEAF (Services Aware Enterprise Architecture Framework – pronounced "safe") to address this cornerstone issue. See section 5 below for more information about SAEAF.

- There is growing awareness at the level of the HL7 Board of Directors that HL7's principal customers are increasingly national Health IT programs (otherwise known as "Profiler-Enforcer Organisations" or "PEOs").

  These include Canada Health Infoway, the NHS and ONCHIT and engagement with these PEOs needs to be reflected in the way HL7 does business as the cost of professional standards development cannot be borne from meeting fees and memberships alone.

- Australia has been working intensively for some three years to progress the ISO 21090 *Health informatics - Harmonized data types for information interchange* standard to finalisation. This project, being spearheaded by Grahame Grieve, is one of the first joint projects under the ISO/CEN/HL7 Joint Initiative, and is the subject of a recent 5-month parallel HL7, ISO DIS and CEN ENQ ballot, closing September/ October 2008. A relatively small, but significant, number of negative comments were received from HL7 members and considered in Vancouver along with plans for bringing the work to conclusion as a co-branded international, European and ANSI-HL7 standard as detailed in section 10 below.

- Jane Gilbert, Director Australian Health Messaging Laboratory at the University of Ballarat, was elected a Co-chair of the HL7 Implementation/ Conformance WG

- Project Cypress is an open collaborative group including US NIST, Canada Health Infoway, CCHIT and IHE that are looking into harmonising requirements and methods for testing conformance and interoperability of healthcare systems. Possible outcomes include common test requirements, test data and test files. NEHTA, AHML and IHE Australia should note the activity and ensure that Australian customers and eHealth systems suppliers can also benefit. See section 19.1 below.

- HL7 Board Election. The following candidates were successful in the elections for positions on the HL7 Board of Directors:
  - Chair Elect. Bob Dolin MD
  - Secretary. Jill Kaufmann PhD, to replace Frieda Hall from 1 Jan 09
  - Director elected by members at large: Stan Huff MD PhD (from 1 Jan 09)
  - Director elected by members at large: Don Mon PhD (from1 Jan 09)
  - Director elected by Affiliates: Catherine E Chronaki (from 1 Jan 09)

- It was noted that IHE France and HL7 France are planning to operate as a single organisation with a single membership, a single budget and a joint work program. Potential action. This may warrant further consideration in Australia.

- Further implementation experience in other countries, in particular:
  - Roll out of eHealth services in Finland, including ePrescription (using HL7 v3 and CDA) and universal health record (EHR/PHR) archive
  - Large-scale HL7v3 messaging for laboratory integration in the Brazilian SIGA Saúde project
  - UK NHS introduction of balloted HL7v3 message for Lab messaging
  - The French Dossier Pharmaceutique (DP) project

- HL7v3 messaging is now part of day-to-day operation of the NHS in England. Large volumes of v3 messages have been processed (>10 million bookings, >116 million prescriptions, >240K medical record transfers). The need for technical design of new HL7v3 messages is dropping off with a shift toward CDA document interchange profiles for new domains. These content-focussed profiles are designed by analysts and clinical informaticians rather than message engineers. Archetypes seem set to play a role as an approach to profiling.

  Implication for Australia. Message/document engineering/standards, content profiling by domain experts and compatible tools are all required as part of a national eHealth program with a shift in emphasis to content capture as the program evolves.

- Combining HL7v3 messaging and CDA approaches with the use of *open*EHR/13606 archetypes within eHealth programs is a theme that is recurring more frequently, possibly driven by UK NHS work. Many on the ArB take this seriously, as do major initiatives in Brazil, Canada, Finland, USA (NCI) and Scandinavia

  Potential action. Australia should be prepared to invest resources engaging with and building on local skills with archetype technology to assist and benefit from these trends.

- Work is proceeding on "Domain Analysis Model" (DAM) projects to capture use cases in and develop dynamic models in various clinical areas. Under SAEAF, these will provide the focal point from which HL7 will define future v2 and v3 messages, CDA documents and services, but the engagement is mainly with US-domiciled clinical and regulatory bodies. Some of these projects have been highlighted at the HL7 Clinical Interoperability Council (CIC) and include:
  - TB Domain Analysis Model (DAM) and Cardiovascular DAM (of potential interest to Respiratory Physicians and Public Health Authorities)
  - Immunization (POIZ) DAM. (of potential interest to Medicare Australia, Public Health Authorities and Primary Care)
  - Long-term Care (LTC) DAM (led by Isobel Frean, an Australian now in UK)
  - Diabetes DAM (at pre-proposal stage)

- **Implication for Australia.** Engagement in clinical DAM projects (at least to the level of contributing/reviewing use cases) is essential if the resulting artefacts are to be useful in Australia. There is a danger that they will be highly US-centric and hard to modify, once approved.

- Those working in clinical terminologies and standardised clinical content for EHR/PHR applications may find the presentation and paper given by Dr David Markwell (UK) to the CIC of interest. The paper draws on recent experience with HL7 TermInfo and the NHS CfH use of *open*EHR archetypes. Copies have been provided in the documents accompanying this report.

- The activities of the Community Based Collaborative Care (CBCC) WG of which Max Walker (DHSV) is currently a Co-chair have become dominated by work on an eConsent standard being promoted by the US DHHS SAMHSA to the detriment of other work on HL7 standards required for non-acute care and welfare services.

  Proposed action. Max Walker to take up potential formation of a separate WG to progress interests in the non-acute care and welfare service domain with Australian interests including IT-014-06 before the January WGM.

Other Significant Points

Plenary Session

- The theme of the 2008 plenary session was *"The Role of IT in Healthcare Policy"* and featured sessions on:

- Canada - the work of Canada Health Infoway in progressing Canada's vision for Healthcare IT and the practical outcomes for the province of British Columbia

- USA – presentations from the McCain (Republican) and Obama (Democrat) presidential campaigns on their healthcare strategies emphasising the role of ICT

- Strategic directions and role of standards in the EU, emerging countries (focussed on South America) and Singapore.

In particular, delegates noted that:

- The two presentations from Canada are particularly relevant to the development and delivery of an effective eHealth strategy in Australia – but also highlight the scale of investment likely to be required in order to achieve this goal.

- The Obama campaign pledged to invest USD $10 billion a year over the next five years (i.e. $50 billion) to move the US health care system to broad adoption of standards-based electronic health systems, including electronic health records. Requirements for full implementation of health IT will also be phased in, with a commitment of the necessary federal resources needed to make it happen.

- Evaluation in both the US and EU suggests that the benefits of eHealth may be high for patients, public health, clinical research, third-party payers and health systems but individual health service providers often have little interest or capacity to invest in "external" interoperability - therefore incentives are needed.

The content of the plenary presentations is summarised in section 7 below.

Health Informatics SDO Harmonisation

A meeting of the ISO/IEC/HL7 Joint Working Group (JWG) was held in conjunction with the Vancouver Meeting and is reported at section 8 below.

At a recent meeting of the peak Joint Initiative Council (JIC), CDISC was accepted as a fourth member of the Joint Initiative (initially on a provisional basis) following the unanimous agreement of the founding members - ISO/TC 215, CEN/TC 251 and HL7.

The policies and processes for initiating, approving and progressing standards work under Joint Task Forces have been approved and promulgated and were noted.

Other issues considered at the JWG included:

- Review of the joint work program and the development of effective formal processes for registering new work and monitoring the program to identify overlaps and gaps
- Progress with the ISO 21090 Harmonized data types standard and proposed action to finalise it following some minority negative votes in the HL7 ballot
- Discussion of harmonization issues arising from: - the ISO standards glossary project; the Individual Case Safety Report (Pharmacovigilance) project; differences between HL7, ISO and CEN in specifying Units of Measure; and the handling/ specification of identifiers for subjects of care under HL7 and ISO standards
- The need for policies on maintaining and revising joint standards and, also, CEN or HL7 standards that become full ISO standards but are then updated at source

Recommendations for refining and clarifying the processes for initiating and conducting joint projects continue to flow from JWG reviewing experiences with a range of projects that are being progressed as joint projects (data types, pharmacovigilance etc) and from existing HL7 and CEN standards that are progressed to full ISO standards (e.g. EHR-S Functional Model, CDA R1, HL7v2.5 and HL7v3 RIM, EN13606).

Proposed action. Effective cross-representation between HL7, ISO and IHTSDO offer significant opportunities to simplify and speed the process of standards development and should continue to be supported by continued involvement of Australian representatives and the role played by Standards Australia in providing the JWG Secretariat.

Affiliates Council and International Input

A summary of the matters discussed at the Affiliates Council on Sunday, 14 September is provided at section 9 below.

Under the new structure of HL7 introduced in 2007, two members of the HL7 Board of Directors are elected by the Affiliates. They are:

- Michael van Campen (Canada), whose first two-year term as a director commenced in January 2008 and runs to December 2009, and
- Dr Kai Heitmann (Germany), whose term concludes on 31 December 2008

Catherine Chronaki, a senior software engineer at the FORTH Institute of Computer Science in Heraklion, Greece, has been elected by the Affiliates to take over when Dr Heitmann's term expires in January 2009.

In addition to having two Affiliate directors, there is considerable international input through direct Denis Giokas (CTO of Canada Health Infoway) and Dr Ken Lunn (NHS Connecting for Health) also being directors. During his term which finished in January 2008, Klaus Veil also provided an international perspective and is still influential at Board level, participating as an observer at Board meetings in his role as Chair of HL7 Australia.

One Member One Vote (OMOV)

The One Member One Vote (OMOV) issue relates to the fact that organisations and individuals participating in HL7 through local Affiliates do not have a direct vote in HL7 matters, even though they may be organizations that pay significant fees to belong to the Affiliate. Instead, each Affiliate receives a quota of votes that relates to their relative size; management of those votes is then a matter for each Affiliate according to its rules.

While it has served members of HL7 Australia well, with low fees and cheap access to many HL7 resources, in addition to being complex and potentially inequitable, the current business model will not be sustainable for HL7 as a global organisation if a separate US Affiliate is formed. The OMOV Task Force has been considering the alternatives and has put forward a model in which:

- Dues would be paid centrally to HL7 International and redistributed to Affiliates, including a new US Affiliate
- Members would allocate % to specific Affiliates
- HL7 would provide a global directory, seen as a must to allow for transparency in voting and member rights

Proposed action. HL7 Australia and Australian member interests (including benefactors) continue monitoring developments in HL7 governance and Affiliate structure and, also, contributing to HL7's consideration of these issues and (if possible) convene discussions to develop local consensus on a position that enables both the formation of a US Affiliate and international growth within a sustainable organisation that has a single global set of interoperable standards.

Harmonisation of HL7 Standards and Tooling

The scope and quantity of work required of HL7 has increased dramatically over the last 5 years and the ability to ensure that all standards produced are consistent and cohesive has become increasingly difficult.

Tools designed to assist in this work (i.e. capture and publication of models, data sets and specifications) have been in place within HL7 for many years, however HL7 has recognised the need to modify and extend these tools to deal with the increased complexity of the task, including the need to maintain both V2 and V3 and manage associated terminology. The tools have also become outdated and are no longer compatible with current computing platforms and must now be upgraded to lessen the load on the volunteer workforce, which has not been able to keep up with the volume of activity.

As set out more fully in section 6 below, a strategy has been identified of focusing on the facilitators' workbench and vocabulary tooling, to support the following approach.

1. Establish MIF interchange via participation in NHS Static Model Designer Project
2. Liaise with OHT Projects for tooling components – Rational Modeler etc
3. Transform publishing processing to MIF based
4. Upgrade GForge
5. Upgrade Schema Generator to generate from MIF 2
6. Produce documentation and training material for all tools

This requires the HL7 administration to confirm the gaps and decide where to invest in order to progress the development plan. The board is seeking more money to support these developments. This is seen as the highest priority for the organisation.

Australian implications. It is likely that adjusting to these requirements will in the short term require additional effort from our volunteers, and in the long term, that financial support for the process of HL7 management and maintenance will be required. It is not possible to identify in what form this may occur. The States, DOHA and NEHTA should be aware of these issues.

CDA Products and Services Directory

The Marketing Council (led by Jill Kaufman) have developed a register of CDA products (e.g. tools) and services, this can be accessed from the hl7.org website at: http://www.hl7.org/documentcenter/public/standards/CDA_Prod_Service_Report.pdf.

While this directory is in its pilot stage with 7 product vendors and 8 service vendors being listed, parties in Australia interested in implementing CDA and, also, potential suppliers need to be aware of it. The Marketing Council is now asking Affiliates to assist with the CDA Product and Services Guide by:

- Helping get local participation in the guide
- Putting links to the guide on the Affiliate website

Other registers are under development/consideration for HL7v3 messaging, SOA, EHR-S Functional Model and PHR-S Functional Model. HL7 Board Member Jill Kaufman (jillkauf@us.ibm.com) may be contacted to add any products or services to the registers.

Proposed action. HL7 Australia to confirm details for including products and services on the CDA Product and Services Directory, monitor progress on the other directories and ensure that Australian interests including HL7 Australia membership, NEHTA, MSIA, Chik Services and Australian jurisdictional authorities are aware of, and provided with, the directories, and that relevant Australian contributors are included in the directories.

HL7 Ambassador Program

The Ambassador program authorizes experienced members of the HL7 community to deliver short officially endorsed presentations on particular topics [see section 12 below for more detail]. As yet, no Australian has yet sought endorsement as an HL7 Global Ambassador and the only use of the program in the Asia-Pacific was a single briefing at a Health Conference in Singapore in mid-2008.

Proposed action. HL7 Australia and eHealth event organisers in Australia should consider whether local engagement with the Ambassador Program could be encouraged through:

- Supporting suitable Australians to write new Ambassador briefings
- Supporting suitable Australians applying to be an HL7 Global Ambassador
- Looking for conferences and meetings where Ambassadors could be sponsored to present on suitable HL7 topics

Web-based HL7 e-Learning Course

As previously reported, this intensive 10-week web-based course covering HL7 foundations, HL7v2 messaging, HL7v3 messaging and CDA was originally developed in Argentina to support distance-based learning in Latin America. The online content includes team assignments with online tutorial support from instructors experienced in HL7 implementations.

The Vancouver meeting was given feedback on the results of the first pilot of the course in English, which involved both native English-speaking and NESB students (e.g. US, EU, India, China) [see section 11 below for detail]. Around 10 students took the course from Australia. Richard Dixon Hughes questioned some of the feedback based on his personal contacts with a local student and, by invitation, he assisted in reviewing comments and strongly suggested to the Education Committee that the content be re-cast into a common foundation element – to be followed by separate specialist modules on v2, v3 and CDA. He remains concerned that the originators seem proud that the course was found to be difficult and that a highly competent interface engineer had found it unnecessarily demanding – requiring near full-time commitment. The major success metric used to date has been enrolments – it was suggested and agreed that completion and pass rates also be given.

This training program is a potentially valuable resource as a major "force multiplier" in leveraging human capital needed for interconnectivity in Australia as it moves forward with its eHealth agenda. Experience has already shown that the training content must be monitored to ensure that it reflects mainstream views of the global HL7 community.

Proposed action. HL7 Australia and relevant Australian interests (including NEHTA) need to consider how this course should be used in Australia. It is considered vital that local experts review and contribute to the development of the content to ensure that it meets Australian needs, noting that the current concept has already been refined significantly and that HL7 and HL7 Argentina have significant IPRs in the material.

Allowing for Tutorial Attendance in Planning HL7 Delegations

It was once traditional that new attendees at their first HL7 Working Group Meeting would be funded to attend several of the half-day tutorial sessions run in conjunction with the meetings to ensure that they had the background needed for participation in the international work of HL7.

One delegate, who had participated in a previous Working Group Meeting but only attended an HL7 tutorial for the first time in Vancouver, stressed the importance of delegates being able to attend some of the tutorials during each of their first few Working Group meetings in order to build expertise more rapidly within Australia and enable delegates to participate more effectively in the detailed standards work.

Action required. Some tutorial attendance should be allowed when determining how many people need to attend an HL7 Working Group Meeting as the ability of otherwise talented individuals to contribute meaningfully depends on their developing an understanding of the HL7 products and standards development environment.

Upcoming HL7 meetings

The following upcoming HL7 meetings should be noted by Australians who have the interest and ability in participating

- January 2009 HL7 Working Group Meeting, Orlando
  11-16 January 2009 at the Hilton in Disney World, Lake Buena Vista, Florida, USA

- May 2009 HL7 Working Group Meeting, Kyoto, Japan
  10-15 May 2009 at the Kyoto International Conference Center

  Preceded by IHIC 2009 on 8-9 May at the same venue

Australia has been a strong advocate of ensuring that HL7, as a global organisation, hold a proportion of Working Group meetings outside North America; however, this position has been strongly challenged by the HL7 administration concerned at the additional burdens that they face from international travel and the financial impact of lower attendances from the US not being adequately offset by additional international delegates.

Notwithstanding the difficulties, the HL7 Board has committed to holding one Working Group Meeting per year outside the US; however, there is an expectation that they will be used to strengthen HL7 strategically and are financially viable, or at worst, any financial losses are acceptable to the organisation (i.e. do not put the organisation at financial peril).

Unfortunately, HL7's projections for the Kyoto meeting, indicate a potential loss of $US 162K compared with the average recent profit of around $US 66K – an unfavourable differential of $US 228K.

As a country in the Asia-Pacific region, it is important the Australia make a special effort to maximise attendance at the Kyoto meeting to show solidarity for the region and ensure continued HL7 support for these meetings being held at suitable international venues.

Value of IHIC attendance

The IHIC (International HL7 Interoperability Conference) is where HL7 implementation experience and issues are shared among the HL7 community with a strong emphasis on practical aspects of HL7v3 CDA and v3 Messaging. Attendance at the IHIC 2009 meeting in Kyoto is strongly recommended for those who would value contacts and information that would be directly relevant to the implementation of CDA and v3 in Australia.

Proposal to hold May 2010 WGM in Australasia

Some Affiliates, with little or no consultation with HL7 Australia, have proposed that the May 2010 international Working Group Meeting be held in "Australasia" as their first choice or, alternatively, South America, as the second choice.

There was some justifiable concern among those responsible for HL7 Finances as to whether the likely attendance could justify a meeting in Australia or New Zealand, given the relatively high costs and time involved for most delegates in travelling to this part of the world.

Australian delegates at the Vancouver Meeting diplomatically expressed their surprise at the suggestion but agreed to facilitate any further investigation. If the suggestion does come to fruition, it will be a major commitment for all those involved in the local Australian and NZ health informatics communities (including government, the health sector and IT industry) to ensure that the event is successful and that the Working Group Meeting can actually progress the standards work needing to be done.

This matter was discussed in some depth and it was noted that the HL7 Finance Committee had recommended that the HL7 Board NOT proceed with an Australasian venue unless the

financial prospects significantly altered within 60 days (i.e. by mid-November). It was proposed that HL7 work with the Australian and NZ Affiliates to determine whether high local attendance or cheaper venues made the proposition worthwhile – but there has been no further contact.

Proposed action. HL7 Australia to monitor and keep NEHTA, IT-014 and other local interests informed of any further developments.

HL7 Interoperability Pilot May Impact Regional Interests

HL7 was successful in obtaining a $US 348,000 Rockefeller Foundation grant for a one-year project on *"The path to eHealth Interoperability for the Global South"* which commenced in July with a one-week problem identification and strategic planning workshop in Italy, co-convened with the WHO. A second stage is involves piloting a sustainable model for reporting and re-use of laboratory data with a view to having a capability demonstrator that demonstrate a clear business case for large-scale deployment of the relevant standards-based solution. HL7's technical partners in the "sustainable model" are all US-based agencies (ONCHIT, CCHIT) and the California Foundation for Healthcare.

NEHTA, MSIA members and the Australian health informatics community may all wish to inform themselves of the technical standards and approach HL7 is promoting and the implications for compatibility with their various recommendations for Australia, remote communities our Asia-Pacific neighbours.

1. Meeting Program

The September 2008 HL7 Annual Plenary and Working Group Meeting (Vancouver Meeting) was held in the Sheraton Vancouver Wall Centre Hotel, Vancouver, British Columbia, Canada from 14 to 19 September 2008.

The full program was extensive and is summarised in Attachment A with an indication of Australian interest and involvement in the various activities.

2. Australian Participation and Strategy

The following delegates from Australia attended the Vancouver Meeting with support from the Australian Government Department of Health and Ageing:

Richard Dixon Hughes	Health informatics consultant & managing director, DH4 Pty Limited. Member of HL7 Inc Advisory Council; Member of Standards Australia Board of Directors and IT-014 Health Informatics Committee, Chair IT-014-09; Liaison Officer from ISO/IEC JTC1 to ISO/TC215; Member ISO/IEC/HL7 JWG; Head of official Australian Delegation to Vancouver Meeting
Heather Grain	Executive Officer, Austin Centre for Applied Clinical Informatics. Academic research & teaching as international health informatics consultant. Chair, Standards Australia IT-014 (Health Informatics) Committee; Co-chair HL7 Inc Vocabulary WG. Convener ISO/TC 215/WG3 (Semantic content). Chair Standards Australia Committee IT-014-02.
Jane Gilbert	Director Australian Health Messaging Laboratory (AHML), University of Ballarat; Co-chair HL7 Inc Compliance WG
Elizabeth Hanley	Health Informatics project lead Standards Australia; Secretariat for ISO/TC 215 WG9 (Health Informatics SDO Harmonization) Joint Working Group, which met at the Vancouver Meeting. Also Secretary to ISO/TC 215/WG8 (EHR Business Requirements)
Richard Harding	Independent consultant (until recently employed by Queensland Health). Co-chair of HL7 v3 Publishing Committee. Active member of IT-014 Working Groups in the areas of Laboratory and Collaborative Care Messaging
Dr Ken Harvey	Adjunct Senior Research Fellow, School of Public Health, La Trobe University. Specialist physician with background in development of therapeutic guidelines, pharmaceutical policy and clinical decision support
Dr Vince McCauley	Managing Director, McCauley Software. Emergency medicine specialist and clinical informaticist active in IT-014-06 (Messaging & Communication) Working Groups
Dr David Rowed	Director, Ocean Informatics Pty Limited. General practitioner and clinical informaticist active in IT-014 Working Groups and chair of referral message working group.
Klaus Veil	Chair of HL7 Australia; Recent Member of HL7 Inc Board of Directors; Co-chair of HL7 Patient Administration WG and HL7 v2 Publishing Committee

The following delegates were separately funded by either themselves or their employers:

Grahame Grieve	Health Informatics Consultant, Jiva Medical. Many different senior technical leadership roles within HL7 Inc including Member, Architecture Board and Co-chair HL7 Infrastructure & Messaging (InM) Work Group. Currently leader of international work producing updated logical data types standard for harmonized adoption in ISO, CEN and HL7.
Dr Andrew McIntyre	Managing Director, Medical Objects Pty Limited. Clinical informaticist and active participant in IT-014-06 (Messaging & Communication) Working Groups
Eleanor Royle	Clinical Information Architect, NEHTA – clinical information program.
Max Walker	Max Walker, Manager, Information Systems & Services, Department of Human Services Victoria. Co-chair HL7 Community Based Collaborative Care WG. Active member of IT-014 Working Groups.
Dennis Nguyen	Medical Objects Pty Limited
Dr Peter Scott	Medical practitioner and health informatician working with Medical Objects Pty Limited on Clinical Terminology and Clinical Decision Support.

While the size of the officially funded Australian delegation on this occasion (9 persons) was much closer to that needed in order to represent Australian interests effectively, there were still some occasions at which adequate coverage was problematic and, on one occasion, a critical quorum needed to pass some Australian resolutions was only achieved when another person could be prevailed upon to attend a meeting briefly.

The following table is based on the final registration figures for the Vancouver Meeting and shows that 41.6% of the total attendance was from outside the US.

Canada	98	US- Government	45
UK	28		
Japan	17	US- Consultants	49
Australia, Netherlands	15		
Germany, Korea	11	US- IMS & Services Vendors	88
France	7		
Brazil, Singapore	4	US-HL7 Staff & Other	23
Italy, Switzerland	3		
New Zealand	2		
Argentina, Finland, India, Ireland, Israel, Rwanda, Spain, Taiwan, Uganda	1	US-Health - inc health providers, funders, prof bodies, Pharma &c	114
Total Non-US	227	Total – US	319
		Grand Total	546

As this was an international meeting held outside the US, albeit still in North America, the proportions of attendees differed somewhat from working group meetings that are held in the US with a somewhat smaller US contingent and over three times the normal Canadian attendance.

The attendance from within the US has been analysed in terms of the sectors represented – with the largest group (35.7%) being providers of healthcare services or

healthcare products (other than health information systems) and healthcare funders. The second largest sector (27.6%) was vendors of information systems and services, then came consultants (15.4%), the US Government and its agencies (14.1%) and finally, HL7 personnel and some from other SDOs and miscellaneous types of organisations (7.2%).

Non-US attendance has not been analysed in the same detail but appears to reflect a different pattern, with a smaller proportion coming from the healthcare services, products and funding sector and a much greater proportion coming from national eHealth programs and associated consultants, with the proportion of vendors of eHeath systems and services being similar.

These proportions raise interesting questions about the ability of international HL7 meetings outside North America to attract the same numbers - to do so, they will need to attract large numbers of participants from health service provider organisations.

3. CEO Report to Business Meeting

The CEO of HL7, Dr Charles Jaffe MD PhD, presented a brief report to the Annual Business Meeting held at breakfast on Wednesday, 17 September 2008, during which he commented on progress and some pleasant surprises during the preceding year.

1. The HL7 Roadmap has progressed to the stage where it is ready for general publication and release on the HL7 website. The Roadmap was developed as a business plan for delivery of HL7 products and services designed to meet the growing business needs of HL7 members and stakeholders. It is supported by a detailed technical plan with clearly defined objectives, milestones and success metrics for completion of HL7's work. The Roadmap is a significant achievement and has involved collaborative effort on the part of HL7 members, government and non-government agencies, and other standards development organisations [see section 4 below for more detail about the Roadmap and Technical Plan].

2. Development of an Office of Outreach and Marketing is an area I have been keen to develop since taking over as CEO. The aim is to build a team of experts in the domain of public relations, media, outreach and resource development charged with developing a marketing plan that integrates with and supports the Roadmap's strategies and objectives. Naturally, this initiative should fully integrate with the activities of the Marketing Council and also support the growth initiatives being progressed by the Education Committee. HL7's marketing activities now need to reach out to the global marketplace (not only the US) and create a sustainable revenue stream to support the growing need for HL7 products and services.

3. HL7 has been successful in obtaining a Rockefeller Foundation grant for a project on *"The path to eHealth Interoperability for the Global South"*. This one-year grant is for developing an eHealth interoperability program that defines the character and components of interoperability and how they may effect change in the Global South (i.e. the developing nations of Asia, South America, and Africa).

   HL7 commenced the activity by co-sponsoring with the World Health Organisation a series of keystone activities at a four-week conference program being run by the Rockefeller Foundation in Italy. HL7 is also partnering with the American Medical Informatics Association to develop an international program for informatics training.

[More information on the Rockefeller Foundation's Making the eHealth Connection conference series is available at: www.ehealth-connection.org]

4. With the cooperation and generous support of the American College of Physicians, HL7 has commenced a pilot to have relevant HL7 Working Group activities recognized as part of physician Continuing Medical Education, driven by new requirements of the Council on Accreditation. It is proposed to explore a similar arrangement for Continuing Nursing Education credits. It is expected that there will be a small fee for certifying relevant credit but HL7's goals is for the its CME/CNE activities to be highly cost-effective.

5. The activities of the Clinical Interoperability Council are predicated on the need to bring clinical expertise into HL7's development processes and for HL7's product developments to reflect needs of domain experts rather than technologists. The Council's role is being developed in cooperation with professional societies, academia and the business community.

Finally, Dr Jaffe indicated that he looked forward to meeting everyone again at forthcoming working group meetings in Orlando, Florida (Jan 09), Kyoto Japan (May 09) and at the Plenary in Atlanta, Georgia (Sep 09).

4. HL7 Strategic Roadmap

The HL7 strategic Roadmap first evolved from the actions needed to realise the goals of the HL7 Inc Strategic Initiative and Transition Task Force. An initial priority of the new CEO, Dr Charles Jaffe it was workshopped widely with the Board, the Advisory Council, key stakeholders and with HL7 at large, resulting in many additional contributions. By early 2008, the draft Roadmap had become far-reaching and detailed, spanning a window of 18 months to three years and providing guidelines for many aspects of technical and process development. While it still embraced the strategic vision of the Board and key stakeholders, it was burdened in many places with specific tactical requirements and deliverables.

It was decided that a broader overview of management and business objectives was required. The resulting (Version 2) of the strategic initiatives and their ultimate outcomes was developed by the HL7 Board, again with input from the Advisory Council and some key stakeholders. Version 2.1 was reviewed at the HL7 Board Retreat in late July with:

- Minor edits being identified and corrected
- A Roadmap Task Force being appointed to continue efforts with the Roadmap and its maintenance
- The Board approving publishing of the Roadmap to the membership
- Annual refresh of the document being set as a target

The roadmap was created as a "living document", designed to reflect growing needs and an ever-changing landscape. It is framed by five overarching strategies that broadly defined the direction for HL7 and is supported by a detailed technical plan with clearly defined objectives, milestones and metrics for measuring success.

The strategic initiatives and outcomes are summarised in the Roadmap Strategic Overview, which outlines the following five major strategic imperatives:

1. Expand, reinvigorate and streamline HL7's production, processes and technologies

2. Evaluate HL7's competitive environment and define HL7's roles, positions and actions

3. Enhance communication and outreach: make HL7 more useable, useful and understandable and share the ideas worldwide

4. Embrace the Electronic Health Record (EHR)/Electronic Health Record System (EHR-S)/Personal Health Record (PHR) as the focal point of technical development of health informatics standards

5. Connect to the clinicians, an essential HL7 community.

A copy of the updated Roadmap Strategies (v2.1.1) as approved by the Board for publication is provided in Attachment C to this report. Attachment D contains a summary that lists completed and current tasks as they appear on the Roadmap Technical Plan. This document is to be actively maintained on a regular basis.

The Roadmap is to be managed and maintained by the Roadmap Task Force, which plans to meet regularly in order to incorporate the changes and refinements inherent in HL7's global communities, exercising the following roles and responsibilities:

- Prioritising Roadmap projects
- Reviewing and adjust due dates for tasks
- Triage Roadmap comments/suggestions from the membership
- Determine disposition on each comment/suggestion
- Develop future versions of the Roadmap

The members of the Roadmap Task Force are:

- John Quinn, HL7 CTO
- Ed Hammond, HL7 CTO, Duke University Medical Centre
- Linda Fischetti, HL7 Board Member, US Veterans' Health Administration
- Becky Kush, President & CEO CDISC
- Don Mon, incoming HL7 Board Member, CEO
- Wes Rishel
- Ken Lunn
- Jill Kaufman

with administrative and managerial support from Mark McDougall and Karen Van Hentenryck.

Its first meeting was at the Vancouver Meeting (Wednesday AM).

Strategic issue for Australia

In his brief address to the Affiliates' Council, the HL7 CEO described the Roadmap as:

- an evolving, living, non-static document, but more importantly;
- a promise of what we will deliver, in what timeframe.

If it is to achieve these ends, the Roadmap (and its task list) should become a very important element of HL7's overall strategy, which will determine what is on HL7's actual agenda and what is not. Australia an other Affiliates may need to influence this from time to time; however, it is noted that the HL7 Roadmap Task Force (RTF) includes only one person from outside the US (Dr Ken Lunn) and is far more US-centric than is the HL7 Board of Directors.

While all but one of the RTF are also on the Board of HL7, it may be appropriate to see if Australia could argue for at least one more independent member with an international perspective – if not an Australian, someone like Don Newsham (Canada) the convener of the HL7/CEN/ISO JWG. In the first instance, this might be put on the agenda at the Affiliates Council.

5. HL7 Services-Aware Enterprise Application Framework (SAEAF)

Of the things which happened at the September 2008 HL7 meeting in Vancouver, one of the more significant was the first release of the draft HL7 Services-Aware Enterprise Architecture Framework (SAEAF) to the wider HL7 community.

NEHTA and jurisdictions, HIS suppliers and consultants in Australia need to be aware of this work, which is expected to set the broad directions for further work within HL7, a revised HL7 Development Framework and the use of a more integrated, domain-by-domain approach to capturing and delivering HL7 interoperability solutions.

To address the cornerstone issue of reconciling HL7's evolving approaches to services, documents, messages, workflow and domain analysis, the Architecture Board (ArB)

held three out-of-cycle meeting between the Phoenix WGM in May and the Vancouver

Meeting in September. Each of these meetings ran for three days and was hosted in Rockville, Maryland by Booz Allen Hamilton with facilities for external participation by teleconference and web-based document sharing – with all members of the ArB and several other key experts contributing.

Led by a group of highly talented and experienced HL7 experts working with CTO, John Quinn and ArB Chair, Dr Charlie Mead and near full-time effort by John Koisch and some other key contributors, the HL7 Architecture Board (ArB) released the initial draft of the HL7 SAEAF (pronounced "safe") in Vancouver, with the full agreement of all participants in the process.

While still a first step, it goes a long way toward answering the questions: Where should HL7 be going? and How should its various products relate to each other?

It is considered a superior piece of work - driven by major client needs - such as the NCI in the US, CHI and NHS - and informed by some of the best consulting expertise available in the field.

SAEAF is already changing the HL7 landscape and is expected to drive the way in which HL7 develops specifications for standard messages, documents and services; it will underpin efforts to establish integrated open tooling to support specification, development and implementation of HL7 and is providing the signposts for redesign and realignment of the internal organisational structures used for HL7's technical work.

The workshop meetings considered what the focus of their work should be, noting that the resulting outputs needed to accord with the following guidelines:

- Focus - to be on Services first, before other interoperability paradigms but trying NOT to exclude existing artefacts, processes, etc.
- Motivation - responding to internal and external stakeholders who are asking for a SOA Strategy
- Addressing potentially critical questions/relevant issues
    - Definition of a Dynamic Framework for specifying the semantics of *interactions*
    - Definition of a Conformance Framework? How do HL7 standards help us achieve interoperability? What does it mean to be conformant?
    - Alignment of HL7 to other SDOs in an SOA world
    - Guidelines for provisioning resources to adopt HL7 standards

It was based on the premise that HL7 Service Specifications should address the needs of two or more users or groups of users (at national, enterprise or individual level) interested in collaborating and sharing healthcare/ life science data or information using computer systems across an interconnected communications medium (communications “cloud”) and that the specifications should have the following characteristics:

- *Computable Semantic Interoperability (CSI)* – Measurable goals; Plug and play; Incremental Benefit
- *Implementable* Specifications - including governance as modeled, testable specifications
- Conformance/Compliance Model
    - Fitting with the way organizations model, use, and test components
    - Implementation Guides (“Are you ready? How does this work with our new ABC Interface Engine?”)
- Services (and service realizations) that reflect the “…ilities” - scalability, composability, etc

The deliverables were required to include (but not be limited to)

- Strategic vision for service identification and specification
- Required infrastructure (e.g. Behavioural Framework, Conformance/ Compliance Framework, etc.)
- Legacy artefacts (e.g. RMIMs, ADTs, Vocab, etc.) integration strategy

- Operationalisation of service specifications Including Work Group organization, governance, etc.

The expectation is that SAEAF should work well with HL7 Services, V3 and CDA, and map to V2. The challenges are likely to reside in the "outlier" standards (e.g. CCOW, Arden), for which the architecture may need to be adjusted.

In developing the framework, attention was given to work in Europe and other parts of the world on service architectures, with a final reconciliation being undertaken against Bernd Blobel's Health Information Systems Interoperability framework, which seeks to achieve synchronicity by

- Combining RUP, MDA, RM-ODP, HL7, and SOA [see notes in box below]
- Aligning with the DoD's Enterprise Architecture Rubic's Cube
- Aligning with many of the findings from the out-of-cycle 2008 meetings through explicit instantiation of components (SOA, RM-ODP, MDA)

The main "delta" between Blobel's work and the ArB's work is his addition of RUP to provide a concrete intersection between a Software Engineering Process and these other influential components; however, the ArB did not believe that it should advocate *any particular* Software Engineering Process, only that *traceability* must occur.

Notes on Software Architectures and Design Methodologies

Model-driven architecture (MDA) is a software design approach for the development of software systems. It provides a set of guidelines for the structuring of specifications, which are expressed as models. Model-driven architecture is a kind of domain engineering, and supports model-driven engineering of software systems. It was launched by the Object Management Group (OMG) in 2001.

The Reference Model of Open Distributed Processing (RM-ODP, ITU-T Rec. X.901-X.904 | ISO/IEC 10746) is a joint effort by ISO, IEC and ITU-T, which provides a co-ordinating framework for the standardization of open distributed processing (ODP) which supports distribution, interworking, platform and technology independence, and portability, together with an enterprise architecture framework for the specification of ODP systems.

The Rational Unified Process (RUP) is an iterative software development process framework created by the Rational Software Corporation, a division of IBM since 2003.

Progressing the work

The timeline and activities planned for progression of SAEAF through the next few stages is as follows:

- September 2008 – Vancouver Meeting – Introduce SAEAF to HL7 membership and "socialise" (present to key WGs) – get feedback and engagement

  (Included: SAEAF peer review, outline SAEAF reference implementation, plan further communication, identification of artefacts)

- Nov/Dec 2008 – Three out-of-cycle (OOC) ArB meetings to finalise comment version, including one face to face and two teleconferences to address:
  - SAEAF validation

  - Service artefacts (behavioural framework / service classification scheme)
  - Community vetting - engagement and validation with HL7's Foundation SD work groups (artefacts and methodologies)

- January 2009 – Orlando WGM. Provide education on SAEAF; Manage impact, drafts for comment.
  - Impact: agree organisational responsibilities; hold education sessions
  - ArB outreach for early adopters (e.g. deep dive for any workgroup that wants to put Drafts for Comment into the Ballots)
  - TSC Issue list re-contextualized through the SAEAF Lens
  - Work with MnM and Publishing to deal with Conformance, Ballot Governance, Notion of parallel ballots
- May 2009 – Kyoto WGM. Implementation Starts. Work through organizational impacts and responsibilities, changes to ballots. Provide "draft for comment" samples of services artefacts with the ballot
- January 2010 – Phoenix WGM. All ballots meet SAEAF criteria.

Further information

Included in the files accompanying this report is a report on the development of SAEAF (as at September 2008) – and also a slide deck used in detailed presentations on SAEAF to some of the HL7 Work Groups in Vancouver. The first 20 or so slides are almost identical to the smaller executive overview.

John Quinn made the point strongly that those wanting a good understanding of SAEAF should make the effort to read the report and not only rely on the presentation slide decks.

All out-of-cycle minutes, documents and in-process slide decks are being made

available on the ArB Wiki.

As a member of the ArB and expert on HL7 tooling and implementation, Grahame Grieve was a significant contributor to this work and is probably the Australian most equipped to explain its significance more fully.

6. Tooling

All of HL7's standard specifications are underpinned by a complex series of information models that have to be maintained using automated tools.[1] HL7 must now address the tooling used to support development and publication of its specifications (in particular, v3 and CDA) and production of implementation guides (IGs) because the tools and processes being used are now outdated, leading to problems such as:

- Every year it is a struggle to publish the normative ballot – an off-the-shelf publishing environment is needed

[1] Current tools include: Rational Rose (old version), RoseTree Viewer, Vocabulary Harmonization Submission, Visio R-MIM Designer, Publications Database, V3 Generator

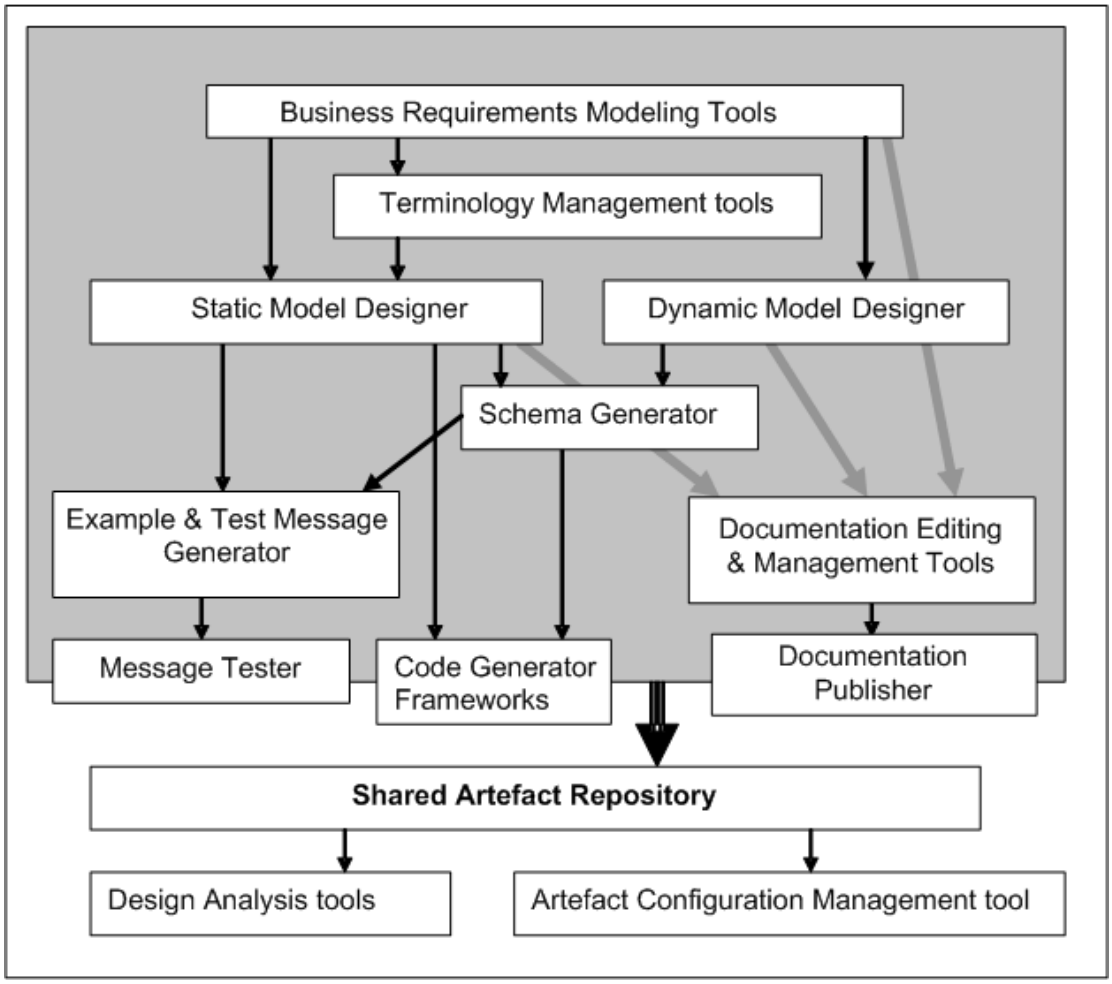
- Also difficult also to define/create IGs
- Vocabulary harmonisation to the RIM is another challenge –an active Vocabulary repository integrated with the other tooling is needed.

The original Visio tools underpinning v3 RIM models no longer run with current Microsoft products and require a high level of manual intervention – which occurs independently during document preparation in a WG and at the final publication stage – with the risk that errors may be introduced and material has to be re-balloted.

A tooling upgrade project has been underway with a view to meeting the following pre-requisites:

- All specification artefacts to be submitted for publication need to be in MIF compliant XML
- All specification artefact versions managed in formal source control environment, with associated bug reporting and change request tracking
- Consensus on specification quality criteria required for acceptance for ballot
- Automated quality checking both within and across specifications with error reports directed to responsible Work Groups
- Consensus on publication structure and format consistent with emerging standards (DITA)
- Validate Dynamic Model Framework to ensure it is harmonized across Messaging, Documents and Services interoperability paradigms
- Determine governance and processes for registering Templates

The problem is how do we get to this? The plan is to move to an Open emerging standard (DITA) with help from IBM and the Open Health Tools (OHT) consortium supporting the following future environment:



Tooling design principles

Another objective is for the same tooling and artefacts to be able to support implementation activity. Overall, the new tooling needs to be able address all of the following design principles:

- Artefacts output from one tool can be input to a related tool using standard interfaces
- Model Interface Format reflects HL7 V3 modeling rules and is the basis of tool interchanges
- Tools are supported either as commercially tools or Open Source with formal change management and open bug reporting
- Tools can be operated either as online or offline tools but permit ongoing change management of all specification artefacts
- Traceability can be maintained from requirements through to deployment
- Tools are designed to be interoperable but run on multiple client platforms
- Development and tool integration projects share resources across SDOs and HL7 affiliates wherever possible to optimize consensus on requirements and reduce both development investment costs and ongoing operational and enhancement costs

HL7 Priorities

There is a considerable amount of development work to be carried out. HL7 and its partners cannot achieve everything at once, so priorities must be set, with the following being seen as High Priority Tooling Issues from HL7's perspective.

- Vocabulary Harmonization Submission tool inadequate – significant upgrades are required to increase ease of use and generate MIF compliant output or seek an alternative tool and process
- Upgrade Publication Database to become "Facilitators Workbench" that includes all publishing transforms to increase ease of use and ballot quality prior to submission
  - consider alternative authoring and review tools
  - generate MIF compliant XML
- Enable Static Model Designer to capture additional constraint types and output transformations to support Template designing for both CDA and Message Static Models
- Need Vocabulary repository based on MIF compliant XML with improved User Interface that supports searching and value set design
- OID Registry User Interface needs improvement
- Participate in cross-SDO initiative to leverage DITA standards into new Publishing Tools

Tactical Tool Migration

Moving this forward involves the following:

- Plan release strategy to align policy & process change, tooling development, testing & training and specification conversion and quality checking
- Replaced Rational Rose with Rational Modeler
- Integrate Publication Database and pre-submission publication processes into a Facilitators Workbench in near term
- Actively seek Vocabulary Repository and harmonization change management solution that is CTS II complaint
- Visio R-MIM Designer to be replaced by NHS sponsored Static Model Designer, but phase 2 enhancements still needed
- Consider opportunity to enhance both the NHS Static Model Designer and the IBM/VA HL7 Modeling Tools to enable additional constraints modeling to support Template Design
- Initiate Publication Process requirements analysis and collaborate with other SDOs in leveraging DITA standards

Short-Term Implications for HL7

- Release strategy must plan to align: policy & process change + tooling development + testing & training + specification conversion and quality checking.
- We must define and document the methodology for vocabulary harmonization because it will still require manual processing
- We will provide training on any new tools and process changes prior to their roll-out.
- We will support Work Groups for their use of Source Control for specification development.
- We need to focus on existing automated quality checking and any that are developed and/or adopted as a result of related tool initiatives (eg. NHS, Infoway).
- We now have an opportunity to create and execute automated cross-specification quality checking before rolling out ballots and published standards.
- We believe that introducing new tools will require increased training and support.

7. 2008 Plenary

The 2008 plenary session focussed on the theme "The Role of IT in Healthcare Policy" and featured a program of seven keynote speakers, who shared considerable insights about the challenges of implementing IT in ways that deliver significant benefits in the provision of healthcare to the community.

7.1 Canada's vision for healthcare IT

Richard Alvarez, President and CEO of Canada Health Infoway (CHI) made the following points in presenting on *"Canada's vision for healthcare IT"*.

The easy part is developing a "vision" – the real challenge is achieving outcomes - leading the changes required for successful implementation. This was the challenge that he faced when he first arrived at CHI some four and a half years ago.

The development of electronic health records (EHRs) is rapidly becoming a worldwide phenomenon (e.g. Rockefeller Foundation, national e-health programs) and requires new e-health capability, which must be based on good health information standards and globally harmonised standards processes.

The promises of national e-health programs must be tied to real business needs in order to justify the required investments. In Canada, key drivers for e-health include:

- an ageing population with an increasing incidence of chronic conditions placing increasing pressure on existing resources – with patients often re-entering the health system through an unplanned arrival in emergency care
- changing care settings and care delivery models – doing it smarter, better and supporting health care providers 24/7
- growing consumerism, increasing the focus on: personal health records (PHRs), personal health/wellness tools and emerging requirements for interoperability between clinical applications and PHRs

Benefits of EHR technologies are sought in the three key result areas of: Access, Quality and Productivity: more specifically:

Access

- reduced waiting time and improved availability of services
- reduced wait times for diagnostic imaging services
- improved availability of community-based health services
- reduced patient travel time and cost to access services (e.g. telehealth)
- increased patient participation in home care

Quality

- improved interpretation of diagnostic and laboratory results
- decreased incidence of adverse drug events
- fewer prescription errors
- increased speed and accuracy in detecting infectious disease outbreaks

Productivity

- increased access to integrated patient information
- reduction in duplicate tests and prescriptions
- reduced physician prescription call-backs
- reduced patient and provider a travel costs

To achieve these potential benefits, Canada has developed the following vision for the role of information in health care

> *"A high quality, sustainable and effective Canadian health care system supported by an infrastructure that provides residents of Canada and their health care providers with timely, appropriate and secure access to the right information when and where they enter into the health-care system. Respect for privacy is fundamental to this vision."*

In the broadest terms, the overall business case is that a capital cost of CAD $10 to $12 billion on establishing information systems infrastructure is estimated to yield benefits of $6 to $7.6 billion annually.

To bring about the Canadian e-Health vision, Canada Health Infoway was created in 2001 as an independent, not-for-profit corporation with CAD $1.6 billion in federal funding. It is accountable to the 14 federal/provincial/territorial governments with the goal that, by 2010, every Canadian will benefit from the implementation of modern health information Systems and at least 50% of Canadians will have an electronic health record accessible by authorised health-care providers.

"Smart" Strategies

Moving from the vision to successful implementation has required smart moves, which have included:

1. Collaboration and strategic alliances with health ministries in jurisdictions and other partners
2. Co-investment - leveraged investments with jurisdictions on a 75:25 basis
3. Strategic co-investment in targeted projects - providing 50% of funding upfront and 50% on successful demonstration of uptake
4.. Each targeted program of work being based on, and led by, standards – always with the view of ensuring pan-Canadian interoperability of EHR information
5. A real focus on privacy - which required harmonising legislation around the country to provide a sound privacy framework – which is enforced
6. Working closely with end users to secure their adoption through team building and investing in end-to end support
7. Measuring benefits and adjusting the approach based on the outcomes (led by Dr Sarah Muttitt)
8. Piloting of solutions, followed by progressive rollout to other jurisdictions.

Outcomes

By following these strategies, Canada has achieved significant progress, including:

- Four years ago 50 projects had been approved for a total outlay of CAD $25 million. Today some 263 projects have been approved with $1,500 million having been allocated (and matched by local funding)
- Planned capability is now operating at various locations and includes: telehealth, an end-to-end drug information system, interoperable EHR (iEHR) modules - client registration, provider registration, repositories for PACS/DI reporting, laboratory, pharmacy and EHR, and public health surveillance (PHS)
- EMRxtra (Ontario) - prescription information available to pharmacists led to improved communication - a 94% increase in previously undetected drug problems, better communication with clinicians and 246% increase in active medication management
- In Alberta, online chronic disease registry now captures 97% of required data surrounding treatment – revealing actual 8% prevalence compared with 4.4% indicated by administrative systems. 63% of diabetic patients on the registry have optimum treatment compared with national average of 51%.
- The use of teleradiology for diagnostic imaging services is proving to be low-hanging fruit:
  - 25-30% improvement in radiologists' productivity; a capacity increase equivalent to 500 additional specialists across Canada
  - 10,000 to 17,000 patient transfers each year eliminated
  - 39% of radiologists now reporting for new remote sites – enabling support of care delivery and improving access for remote populations
  - 30 to 40% improvement in turnaround times (clinical decisions and treatment occurs 10 to 24 hours sooner)
- WebSMR (Synoptic Medical Record) is improving outcomes for Cancer surgery patients in Alberta with 99% of specified data elements being captured in the record versus 49% in a dictated report. 81% of cancer surgeons would recommend it to their colleagues and it is now being introduced in British Columbia, Ontario, Quebec and Nova Scotia.

EHR Architecture

These achievements are based on a pan-Canadian EHR architecture, which has been progressively developed and is now relatively stable with buy-in from all jurisdictions. Major suppliers (IBM, Telus/Emergis, Sun Microsystems, Oracle) are now building their health solutions in lockstep with the model.

Many foreign interests have identified the Canadian approach as being a world-class model on which to build their solutions and it is also the primary reference implementation for both Open Health Tooling (OHT) and HL7 SOA.

Standards Collaborative

CHI identified standards as vital to the achievement of these goals and formed the Standards Collaborative (SC) to bring together all of the disparate groups working on e-health standards in Canada. The SC is a globally unique, “common-sense” Canadian

solution to accelerate standards-based implementation of electronic health information solutions through four strategies

- increasing awareness and understanding of pan-Canadian health information standards and how they enable interoperability of health IT
- engaging a broad spectrum of stakeholders throughout the standards life cycle to ensure ongoing relevance of standards for all
- stimulating market demand to facilitate uptake of pan-Canadian health information standards, while influencing, leveraging and aligning with international standards, and
- reducing risks and costs associated with uptake.

The SC coordinates, maintains and supports EHR standards activities across Canada, providing maintenance, implementation support and conformance services for supported standards including HL7 and SNOMED CT. Infoway hosts the secretariats and supports participation in relevant international SDOs including: HL7, IHTSDO (for SNOMED CT) and ISO/TC215.

More than 20 standards initiatives have been completed or are underway for an investment totalling around CAD $33 million and covering:

- Demographic information (client, private provider, service locations)
- Clinical information (drugs, lab, DI, encounters, clinical notes, referrals, conditions),
- Public health; Physician systems; Clinical orders; Claims administration,
- Clinical terminologies and nomenclature.

Experience with HL7 v3 Messaging

Canada's smallest province, Prince Edward Island (PEI) was the first to implement the national Drug Information System based on common HL7 Version 3 messages. It is an important step toward the creation of a pan-Canadian interoperable electronic health records system covering all facets of patient care. Pan-Canadian HL7v3 standards are now developed or being developed for Saskatchewan, British Columbia, Newfoundland and Labrador, Quebec and Alberta but, while it is now essential for our success, it has taken a lot of money, too long and far too many bright people to achieve the results. It was tough move getting HL7v3 messaging working - let alone the proposed move to SNOMED CT.

HL7 and its standards provide an invaluable channel for advancing interoperability and the EHR but there remains a need for:

- greater harmonisation of work, at an earlier stage, within HL7, across SDOs, and across national/regional initiatives - capitalise on the work of the ISO/ CEN/ HL7Joint Initiative
- a more prominent role for HL7 overall to: rationalise work programmes, drive consensus, and support implementation uptake.
- Pragmatic application of standards by vendors – and vendor uptake
- Enhanced tooling and support services from HL7 for the HL7 community
- Broader promotion, use and adoption of HL7v3.

Challenges in Achieving Strategic Goals

Key challenges to be addressed and overcome in moving the CHI program forward to a sustainable future include:

- standards harmonisation and alignment
- improving functional capability, usability and interoperability of vendor systems
- developing and maintaining jurisdictional capabilities to apply and manage the technologies
- clinician adoption
- patient engagement
- delivering and demonstrating tangible benefits to the community - improved access, reduced wait times and improved safety
- recapitalisation and update of the technology base as the program achieves its goals

Immediate Goals

By March 2010, the collaborative approach led by Canada Health Infoway expects:

- The patient and provider registries to be completed
- 80% of publicly funded digital images captured and shareable
- Lab Information Systems holding 75% of patient test results in readily accessible form
- 75% of all prescriptions handled by the Drug Information Systems, and
- 50% of all Canadians having an EHR

Questions

Question (Ed Hammond): How has Canada engaged with consumers?

Answer: Consumers were consulted through focus groups. Initially, 85% to 90% of consumers were in favour, but passive. Consumers won't fight for e-health unless they come to believe that it is not going to happen. To address this, Canada has developed an advertising campaign around the theme "where is your health information?" They are also working with Google and other online providers to make it easier for individuals to interact with their health information. The idea of a PHR has been around for a while but now it is taking off. The program is very open with much information having been published in both bard-copy and online. Anyone can register at the Canada Health Infoway web site for detailed information about the program: (See: http://www.infoway-inforoute.ca and register for a “passport” for more detail).

Question (Mike Henderson): Making radiology and imaging information available through a PHR poses major infrastructure challenges due to high data volumes. How is Canada addressing this?

Answer: Canada has been fortunate in that most facilities now have access to PACS systems. Our repositories sit between the PACS systems and we have a network that interconnects the repositories to provide access to the information from its source repository when required.

7.2 Healthcare IT in British Columbia

Elaine McKnight is the Assistant Deputy Minister, Health Sector IM/IT Division, British Columbia Ministry of Health and she presented a paper on *"The Status of Healthcare in British Columbia"* a copy of which is available on the HL7.org website at: http://www.hl7.org/documentcenter/public/plenary/2008/presentations/The%20Status%20of%20Healthcare%20I.T.%20in%20British%20Columbia%20-%20Elaine%20McKnight.ppt

The following are some of the key points that she made during the presentation:

- Health care represents 50% of the British Columbia (BC) provincial budget. Integrated, interoperable, electronic information systems are seen as essential components to support health-care decision-making, health system sustainability (including management of health resources) and personal health care initiatives. Because of the size of the investment, political scrutiny is high.
- BC has a long, proud history of successful health care information systems projects, notably:
  - PharmaNet, providing access to medication profiles, drug-interaction and prescription insurance claims processing from points-of-service across the Province since 1995 – handling 50 million transactions p.a.
  - Client registry for all who receive health services in BC – also facilitating basic health insurance eligibility checks
  - A common provider registry application also used by the three other western provinces – now the basis for the international standard on provider registry interaction, and
  - A broad portfolio of IT applications and infrastructure supporting shared core services (e.g. networks, HR payroll), First Nations health services (e.g. telehealth), local health authorities (acute care administrative/ clinical applications and integration with the primary, community-based, residential, home and personal care sectors), Health Ministry reporting functions and, increasingly, the pan-Canadian EHR agenda led by CHI.
- The right balance must be struck between accessibility, security and privacy protection – and be backed by legislative protections
- BC has been a strong supporter of HL7 since 1992, when it adopted HL7v2 for PharmaNet and other major projects.
- In 2003, the transition to HL7v3 messaging began, involving much effort and great expense but with little demonstrable benefit to end users and those who provide the funds. Collaboration with others enables some sharing of cost
- The Province has a broad portfolio of applications established and being extended under an integrated plan developed collaboratively with relevant players - local health authorities, the Ministry, provider organisations, and, through Canada Health Infoway (CHI), other provinces, national agencies, suppliers and international interests
- With financial support form CHI, current BC initiatives are aimed at establishing provincial EHR facilities based on pan-Canadian standards, supporting the interoperable EHR (iEHR) and strengthening Canada's health system. HL7v3 is a key foundation standard for these initiatives.
- Major initiatives focus on: common infrastructure, information repositories and point-of-service systems. These have big price tags over and above maintaining

current health information capability; therefore, BC is seeking to share as much of the cost as possible and avoid reinventing the wheel.

- Common infrastructure initiatives to allow secure access to an individual's EHR include:
  - A consistent, secure front door to EHR services for both health and social welfare applications (based on HL7v3 messaging)
  - A series of integrated secure health networks supporting message-based electronic health services for the Province
  - Developing and implementing identity management standards, policies and practices for both citizens and providers – facing major challenges from emerging trends toward data vaults, PHRs etc – and involving many big stakeholders, both across Canada and internationally.
- Establishment of information repositories to support iEHR input and access by some health authorities in 2009 and all by 2010, including:
  - Repositories for collecting and presenting lab results (underway), immunisations, diagnostic images and results
  - Rebuilding PharmNet to enable new features such as fully electronic prescribing - this is a big challenge as it is a leader in its field and, despite its age, has already delivered many of the available benefits
  - Eventually, enabling electronic order entry throughout all services -- but this is still a vision.
- Supporting the point of service, BC is:
  - Developing and piloting implementation of a new pan-Canadian public health surveillance application (PHS) in partnership with Canada Health Infoway to facilitate management of disease outbreaks, communicable disease cases, immunisation and vaccine inventories, health alerts and related workflow.

    While the longer-term benefits are great, there is much short-term pain in realising this huge initiative with broad collaboration being essential.
  - Implementing new public health point-of-service applications for surveillance, family health and health protection, all integrated into the provincial EHR infrastructure
  - Working with local health authorities to integrate provincial EHR services into their clinical and lab information systems
  - Supporting the standardisation of EMR applications used by physicians and their proposed integration into the provincial EHR infrastructure. Six systems have been selected and one has passed all its tests. Physicians have only just begun to adopt these applications
  - Working with existing software providers on integrating EHR services into their point-of-service products (e.g. hospital applications)
  - In collaboration with Alberta, Quebec and the Atlantic provinces, building an integrated browser-based viewer, to enable access to the EHR where this is not supported by a point-of-service application.
- Looking to the future, BC wants to:
  - enable BC citizens to access their EHR information directly (some limited capability is already being trialled – e.g. child immunisation)

  - use technology to engage patients directly in managing their own care, particularly for those with chronic conditions
  - produce information that "closes the loop" to enable assessment of outcomes and improvement across the full range of care delivery

- Some of the challenges and issues include:
  - Consumerism is on the rise. Some already want to move to the next steps, including patient to patient care
  - Changing clinical processes to facilitate and benefit from improvements in health information systems and better information management
  - Educating and training a heavily loaded clinical workforce in new information-based approaches and producing sufficient trained personnel to ensure that initiatives are adequately supported
  - Given the level of investments there is huge expectation of success and continual political scrutiny
  - Actually realising (and demonstrating) financial benefits, greater efficiency and improved quality of life by keeping people out of the acute care system and supporting them better in their homes and communities
  - Mapping IT investments to improved clinical outcomes and demonstrating what we are getting is difficult, but essential, if the programs are to continue being supported.

- With respect to the role of standards:
  - Standards are critical -- but they must be developed collaboratively to enable information to be brought together seamlessly in different contexts - hospital, primary care, community-based care
  - Pan-Canadian and international alignment is important but needs to inform local development and implementation activity and take into account implementation experience.

Question

When should we celebrate success?

Answer: Ten years is too long to wait. It is important to deliver incremental benefits and celebrate key milestones.

7.3 US – The McCain HealthCare Policy

Stephen T. Parente PhD, McCain Campaign Healthcare Volunteer and Associate Professor at the University of Minnesota presented on the topic *"Enabling Market Forces to Achieve Quality Metrics and High Performance"*.[2]

The main elements of the McCain healthcare policy were:

- Making healthcare more affordable by:
  - Removing barriers to competition between drug companies, insurers, providers etc in meeting consumer demands for their services

[2] Note. The US Presidential Election was held between the time of the Vancouver Meeting and the completion of this report. Given that Barack Obama was successful, the McCain policies have been summarised in a historical context.

  - Rewarding quality, promoting prevention and delivering health care more effectively and efficiently to reduce the overall cost of healthcare.

- Giving Americans more choice and access to good quality, affordable coverage (including the option of keeping their current coverage)

- Changing the rules to improve portability and security of healthcare cover – providing continuity through change of employers and/or circumstances

- Strengthening the quality of health care by promoting research and development of new treatment models, promoting wellness, investing in technology and making better information on service quality available

A key incentive to encourage competition and customer focus among healthcare insurers was to encourage citizens to take up their own health insurance by giving them an upfront, inflation-indexed, annual tax credit of $2,500 per individual or $5,000 for a family. The cost of this to the Government would be paid for by reductions in employer tax exemptions on healthcare plans – currently some $250 billion p.a.

This choice package would have needed to be accompanied by a guaranteed access plan for those who cannot afford or obtain insurance, to include:

- Providing funded assistance to join existing state-based health insurance plans (still seen as a highly problematical area)

- Assisting those who are turned down for insurance because of chronic illnesses or other conditions

- Policy measures to ensure this assistance can be delivered in a fiscally responsible manner, recognising that significant cash injections are involved

He proposed moving toward full portability of health insurance, to allow families to purchase health insurance nation-wide across state boundaries. This would require nation-wide consensus and regulatory reform to move away from state-based restrictions that followed US Supreme Court decisions on state rights in 1945. Nevertheless, there are so many inequities and imbalances in the current system that most commentators agree that something drastically different is needed to address the problems, which include:

- Unreasonable cost differentials - a package equivalent to one costing $4,800-$5,400 in Pennsylvania costs $11,000 to $12,000 in neighbouring New Jersey, with care provision likely to be of a similar cost

- Small employers were exempted from the mandatory health care provisions because they are unaffordable – but this potentially leaves many Americans uninsured and means big corporations are increasingly less competitive

- The field is far too complex for large employers and health plans (such as Blue Cross Blue Shield) which have operations crossing many state borders

- Health care costs cannot continue growing in relative terms to exceed 20% of GDP.

McCain also proposed that incentives should be given by way of credits for staying healthy which could be applied to insurance costs or health savings accounts. Consumers should have simple health care cards linked to their plans that operate like a credit or debit card. Tort law reforms were also proposed to reduce costs of medical

malpractice insurance, which has become an unreasonable proportion of the costs of delivering healthcare

With respect to Health IT, Parente considered that it is a politically neutral issue as both sides believe it essential that investment at current or increased levels of healthcare IT is required.

The McCain proposed that there should be greater use of IT to reduce costs in the healthcare sector by promoting "*the rapid deployment of 21st century information systems and technology that allows doctors to practice across state lines*". Parente also highlighted that significant additional investment in IT will be required to manage healthcare tax credits, payment entitlements and information sharing (e.g. quality statistics) needed for the new approach. Much of the required data is already there; the challenge is connectivity – bringing it together to achieve the overall objectives.

Questions

Question: Only a few (15%) of private physicians maintain electronic records. Where will the patient data come from? Answer: laboratory and acute care, plus increasing consumer demand for physician health information to be available online.

Question: How do tax credits work for the poor who are not paying tax? Answer: an equivalent amount would be advanced: as a payment toward the cost of cover.

Question: Under the current administration we have the National Coordinator for Health IT (NCHIT) but this role lapses and there is no on-going program health IT with funding. How is it proposed that this be addressed under a new administration? Answer: the details are not yet clear but support for health IT is a political reality and there would need to be an open discussion with bipartisan support on the best way of taking forward the work done by AHIC, ONCHIT, CCHIT and the NHIN initiatives. As a health economist I would personally be surprised if there were any less support for health IT among a new administration.

The McCain healthcare plan is still online at:
http://www.johnmccain.com/content/default.aspx?guid=8475c713-a541-4b97-a2aa-800e35da37bb (Accessed 2008-12-19).

7.4 US – the Obama Health Care Plan

Blackford Middleton MD, MPH, MSc, Chairman Centre for IT Leadership and Director Clinical Informatics R&D for Partners HealthCare System, Assistant Professor Harvard Medical School and a spokesman on health issues for the Barack Obama campaign presented on the topic *"The Senator Barack Obama Health Policy; An Opportunity for HealthCare Changes".*

The meeting papers contained a copy of the Obama health care policy (as then current) entitled *"Barack Obama's Plan for a Healthy America: Lowering health care costs and ensuring affordable, high-quality health care for all*". A PDF version of this document has been sourced and has been provided as an accompanying document to this report. The current version of the Obama-Biden health care policy (which is a little shorter and more critical of the health insurance industry) may be downloaded from:
http://www.barackobama.com/pdf/issues/HealthCareFullPlan.pdf

While both the Middleton presentation and the Obama plan are well researched and contain many useful insights, it is extremely significant

> *"(1) INVEST IN ELECTRONIC HEALTH INFORMATION TECHNOLOGY SYSTEMS. Most medical records are still stored on paper, which makes them difficult to use to coordinate care, measure quality, or reduce medical errors. Processing paper claims also costs twice as much as processing electronic claims. Barack Obama and Joe Biden will invest $10 billion a year over the next five years to move the U.S. health care system to broad adoption of standards-based electronic health information systems, including electronic health records. They will also phase in requirements for full implementation of health IT and commit the necessary federal resources to make it happen. Barack Obama and Joe Biden will ensure that these systems are developed in coordination with providers and frontline workers, including those in rural and underserved areas. Barack Obama and Joe Biden will ensure that patients' privacy is protected. A study by the Rand Corporation found that if most hospitals and doctors offices adopted electronic health records, up to $77 billion of savings would be realized each year through improvements such as reduced hospital stays, avoidance of duplicative and unnecessary testing, more appropriate drug utilization, and other efficiencies."*

In his presentation, Middleton reviewed the problems with US health care system from the perspective of providers, purchasers and consumers – discussing how health IT could make improvements within the context of the Obama health plan. The following are some of the key points made in his presentation.

Provider dilemmas

US health care is vexed by unexplained variation in service cost, quality and outcomes, disparities in access and utilisation, medical error, patient safety, quality issues. Within this context:

- 18% of medical errors are estimated to be due to inadequate availability of patient information – a study in one clinic indicated that required patient data is missing in 81% of cases, with an average of 4 missing items per case.
- Medical error is the eighth most common cause of death in the US
- Treating physicians are unaware of 1 in 4 four prescriptions being taken by their patients
- 1 in 5 lab and x-ray tests are ordered because original results could not be found
- 40% of outpatient prescriptions are unnecessary
- Patients often fail to receive recommended care due to miscommunication

Paper-based medical care is prone to error, does not enable the capture and re-use of information and cannot be transformed in ways needed to overcome these difficulties; whereas, health IT offers the following benefits (including real money savings):

- Use of appropriate clinical (EHR) systems:
  - more complete and correct patient records
  - support for decision support, formulary and brand to generic substitution
  - reductions in duplicate/redundant medications and tests
  - online display of cost/charges at time of order

- workflow support, messaging (patient-provider), referrals, electronic billing and account management, care team communication

For IT-enabled chronic diabetes management (just one condition), estimated net savings through basic diabetes registry at USD $8.3 billion[3].

Advanced EHR offers net savings a further $17 billion if is also used.

- CPOE (Computer Physician Order Entry). Reduction in hospitalisation and length of stay due to adverse drug events, improved clinical decision support

  Estimated saving from Ambulatory Computerised Order entry
  - USD $44 billion nationally or $29K per provider per annum

- HIEI (Healthcare Information Exchange & Interoperability). Reduction in unnecessary and redundant tested procedures and labour costs saving an estimated USD $78 billion per annum

- Telehealth. Reductions in patient transport, utilisation of hospitals and physician office visits estimated to save over USD $20 billion per annum

- Use of PHR to hold and provide access to relevant health information. Potential savings of approx USD $20 billion through savings in administrative time; reductions in hospitalisation and physician visits, improved medication safety reduction in redundant laboratory and other diagnostic tests

In combination, CITL Health IT Value Assessments indicate that the US could save a net amount of $150 billion through widespread adoption of Health IT in care provision – equivalent to approximately 7.5% of overall US health-care expenditure.

Controlled studies of Health IT implementation impacts within organisations such as the US Veterans Administration have demonstrated reductions in cost and improvements in quality of clinical care from investments in Health IT.

The cost to providers is the biggest factor inhibiting their uptake of Health IT and achieving these benefits. When providers consider the time, money and resources required for them to implement and use more advanced Health IT – there is no net benefit. The big problem is that while these costs are borne by providers, 89% of the benefit goes to other others, including a significant public good. For a national Health IT strategy to work, a significant proportion of the savings must be given back to the provider community to justify their investing in Health IT. The Obama Health Plan seeks to address this fact.

Purchaser dilemmas

US health-care now costs payers/purchasers USD $1,700 billion p.a. or 16% of GDP – compared with 1963 when it was 5%. This is also much greater than the average across all industrialised societies, which is still less than 10%. In addition:

- Costs are rising at 7% to 9% per annum an are expected to double in 10 years
- 25% of insurance premiums are for administrative overhead - which contributes little value
- Public expenditure is now 43% of the total health spend (up from 33% in 10 yrs)
- Health care cover now costs GM $1500 /car produced - and is the most expensive single component

[3] All based on CITL (Center for IT Leadership) Health IT Value Assessments

The challenge for the future is: “where can additional value be found? or costs taken out of our health system?"

Consumer dilemmas

On average the American consumer pays USD $6,240 /year for health-care or $12,200 for a family and health insurance premiums have risen four times faster than salary over the past six years. In addition:

- 50% of personal bankruptcies are due to health-care costs
- 42% of the public have experienced medical errors themselves when their family (24% with serious consequences
- 45 million Americans lack health-care insurance and this figure gets as high as 80 million at some point each year
- The health-care system is fractured and “unwired".
    - Medicare beneficiaries see between 1.3 and 13.8 different providers each year, the average is 6.4.
    - 90% of health-care transactions every year conducted by mail, fax or phone
- Consumers lack reliable, transparent data about quality and value of increasingly complex “tiered” pharmacy plans – without such information rational choices based actual value are not possible.

The Barack Obama Health Care and Health IT

Health IT has been portrayed as the lynchpin to success for each component of the Barack Obama Health Plan, which has the following major planks:

1. Universal health care – Health Care Exchange with private and public payers
2. Health care reform
    - Affordability, cost control approved quality, efficiency
    - Helping patients receive better care: investment in coordination of care, disease management, and quality measurement reporting initiatives
    - Helping providers deliver better care: expanding research to understand what works
    - Reforming reimbursement systems to align financial reward with quality and not quantity of services, with good health outcomes, keeping Americans healthy and reducing disparities
3. Promoting prevention and strengthening public health by:
    - promoting healthy lifestyles at home, school and workplaces
    - improving public health infrastructure for community health and wellness and for disaster preparedness

Benefits Claimed for the Obama Health Plan

- Investments in information technology - savings estimated at between USD $78 billion (RAND) to $150 billion (CITL)
- Reduced insurance industry overhead. Commonwealth fund estimated to save between USD $32 and $46 billion per year. Reduce uncompensated care to <1% of private premiums
- Improved disease management, care coordination, clinical effectiveness research, and payment excellence
  - Enable comparative purchasing based on effectiveness and value
  - With additional savings through active disease management
- Net potential savings of the Obama Health Plan within the Health Care Industry estimated at USD $120 billion to 200 billion
- Insurance costs to decline by $2,500, on average, for a typical family -- private insurance premiums reduced by 5%
- 98 to 99% of all Americans having health-care coverage including 10 million more with employer-based coverage
- A more rewarding practice environment for providers and patients – with a lot less administrative hassle and expense

Given the size of the IT investments and standards needs implied by the Obama Health Plan and an expected urgency for demonstrable results, it is likely that HL7, as an affected US organisation will be keen to respond positively and collaboratively with the new organisational groups, structures and political influencers concerned with health and e-health under the Obama Administration. Rapidly meeting emerging US requirements can be expected to even more imperative for HL7 management – which may lead to significant reductions of HL7's interest in meeting the needs of its international Affiliates and stakeholders. Australia needs to stay abreast of developments.

7.5 EU eHealth Strategy

A presentation entitled *"European Union eHealth Strategy in Support of Member State Health Policy Priorities"* was presented by Dr Veli N Stroetmann MD PhD and Dr Karl A Stroetmann MBA PhD, both of empirica Technology Research. Their presentation addressed the following:

- The diversity of the EU in terms of languages, health service organisation and health service payment models
- The shared common values of EU Member States (MS) in relation to health – universal coverage, access to good quality care everywhere, equity and solidarity
- The evolving responsibility for provision of healthcare services, with citizens increasingly gaining the right to access healthcare services throughout the EU, and, also, rights such as confidentiality/privacy of medical records
- Since 1994, the ICT for Health Unit within EC Information Society and Media DG has pursued the vision of *"eHealth unlabelled citizen-centred care"* through three main activity streams:

  - Supporting research & development. Through Framework programmes some 450 projects worth over €1 billion have been supported, focussing on concept validation, exploitation and impact assessment.

    Research is increasingly focussing on technology support for individuals leading to genomics-based personalised medicine in the longer term
  - Supporting eHealth deployment (eTEN and the Competitiveness & Innovation Programme)
  - Development of eHealth policy - reviews & research, major events, stakeholder engagement, producing recommendations & statements

- A key policy outcome, the European eHealth action plan, approved in 2004, provides a central political focus for eHealth strategy and interoperability. It seeks the commitment of MS to work together in implementing eHealth and developing common interoperability approaches and standards through:
  - Development and sharing of national/regional eHealth road maps
  - Seeking common approaches to patient identification and identifiers
  - Interoperability standards for EHR and messaging
  - Boosting MS investments in eHealth and the deployment of health information networks
  - conformity testing and accreditation
  - legal frameworks and certification of qualifications
- The EC currently places strong emphasis on interoperability, including:
  - Interoperability Standards. DGEI Mandate M/403 seeks collaboration between SDOs on standards for patient identifiers, health practitioner identifiers, patient summary and emergency datasets
  - Evolving policy and guidelines under the EC Recommendation on (Cross-border) Interoperability of EHR Systems
  - A large-scale pilot of cross-border interoperability (across 12 MS) using smart open services to demonstrate safe, secure and efficient medical treatments for citizens travelling in Europe – initially focussed on a European Patient Summary and ePrescribing.
  - Create consensus and community building through CALLIOPE – web-based forum on interoperability of eHealth services.
- The current relatively low penetration of PC applications in primary care and acute care settings provides little incentive for interoperability and little opportunity for exchange of medical data other than laboratory results

Impact Assessment, Conclusions and Lessons Learned

- Evaluation of European eHealth projects demonstrates that eHealth works and is worthwhile
- National/regional health information networks and services can improve quality efficiencies and also realise cost savings:
  - The Danish Medcom network is saving €80 million per year
  - IZIP in the Czech Republic is saving €60 million per year

  - In Sweden, ePrescription saves €70 million per year and improves patient safety

- Personal Health Systems and Telemonitoring for heart patients in the UK deliver care at the point of need and reduce hospitalisation by 20% to 40%

- The "NHS Direct Online" information service in the UK was found to empower patients, avoid unnecessary hospitalisation and support lifestyle choices, as well as saving an estimated €110 million per year

- Nevertheless, European evaluation studies have found very little evidence of the huge savings being claimed for Health IT in the USA and . European the benefits in European projects have rarely been able to be realised as direct cash savings directly as cash savings as cash savings

Other lessons learned have included:

- Optimal results are obtained when eHealth tools are combined with proper organisational skills

- Avoid the big-bang approach based on grand designs. Programs that take an incremental approach with smaller steps are more effective and cost-efficient (NHS Scotland and MedCom in Denmark are examples)

- The European social model and citizen mobility are necessitating faster progress in intra- and cross-health systems interoperability

- Benefits of eHealth are high for patients, public health, clinical research, third-party payers and health systems

- Slow progress in realising effective interoperability remains a key barrier to realising these benefits

- Individual health service providers often have little interest or capacity to invest in "external" interoperability - therefore incentives are needed

- To be more successful, eHealth strategies must be integrated into and support health policies - the pursuit of separate eHealth strategies is less effective

- 20 years of successful R&D and concrete eHealth road maps provide both the European Commission and EU member states with the strong leadership and commitment needed to realise basic pan-European eHealth interoperability

- Building on [claimed] global leadership in ICT use by European health service providers, the strategy is to focus on a few key pan-European applications (patient ID, basic patience summary, medication record/you prescribing this)

- The key policy goals are: - patient safety, quality and access

- eHealth is not a panacea – the key is optimal redeployment of freed resources to improve quality, service delivery and productivity - rather than delivering expenditure reductions.

A copy of the presentation is available on the HL7.org website at:
http://www.hl7.org/documentcenter/public/plenary/2008/presentations/European%20Union%20eHealth%20Strategy%20in%20Support%20of%20Member%20State%20Health%20Policy%20Priorities%20-%20Veli%20N.%20Stroetmann,%20MD,%20PhD%20and%20Karl%20A.%20Stroetmann%20MBA,%20PhD.pdf

More information on the ICT for Health Unit and its activities may be found at:
http://ec.europa.eu/information_society/activities/health/index_en.htm

7.6 Interoperability Standards in Emerging Countries

Beatriz de Faria Leão, MD, PhD of Zilics Health Information Systems and Co-Chair of the HL7 Brazil Advisory Council presented on *"The Role of Interoperability Standards for Emerging Countries"* concentrating on developments in South America and providing an overview of:

- Health status and challenges in developing countries of South America, noting the wide disparity in the types of services and their needs – with some first-world capability alongside the need to service cost-effectively large disadvantaged communities in both urban and remote rural settings
- Standards and National eHealth Policies in Uruguay, Argentina, Chile and Brazil, and
- The growing role of HL7 and its Affiliates in South America and, potentially, in many other developing countries – a role that is much wider than just participating in standards development, with the potential to provide and share the information, education and expertise needed to support highly distributed health services with eHealth solutions suited to the global "South".

The full presentation is available on the HL7.org website at:
http://www.hl7.org/documentcenter/public/plenary/2008/presentations/The%20Role%20of%20Interoperability%20Standards%20in%20Emerging%20Countries%20-%20Beatriz%20de%20Faria%20Leao,%20MD,%20PhD.ppt

Some of the points noted by delegates included the following.

Uruguay

By South American standards, Uruguay is a relatively small country with a compact population of 3.46 million, of which 1.7 million live in greater Montevideo metropolitan area. Uruguay has been actively pursuing eHealth goals for over 5 years, including:

- Passing legislation in Sep 2003 for an EHR for all citizens and suggesting the use of international standards, such as HL7 and DICOM
- In March 2006 - the elected Government presented its plans for a national integrated health system under which sharing of information among all HC providers became mandatory from 2007.
- The Uruguayan Society for Standardization, Interchange and Integration of Health Service Data (SUEIIDISS) (at http://sueiidiss.org), which was founded in 2005, is the local HL7 Affiliate with 46 members and a mission of promoting, developing, and providing training and capacity building on interoperability standards to share health information for patient care and health care management – with a focus on HL7v3, CDA and IHE.
- Interoperability Standards being used in Uruguay include: IHE profiles (with digital security certificates based on national PKI infrastructure), a consistent time service (provided by SUEIIDIS), HL7 CDA for document sharing, Uruguay national identification standards, OIDs for object identifications and a common WSDL defined and shared among all participants

Argentina

Argentina has a population of around 40 million, a relatively large land area and a GDP of around $US 6,550 per capita.

HL7 is not a national Standard for Argentina, but there are several developments involving the use of HL7 standards for e-claims and interdepartmental interoperability (mainly using HL7 V2.x and CDA r2)

The main focus has been on training and dissemination of the HL7 standards – with HL7 Argentina (http://www.hl7argentina.com) having developed the HL7 web-based learning platform now being adopted internationally - already used to train over 600 people in the Spanish version and 200 in the English version.

Chile

Chile has a population of around 16.6 million, long distances and rugged terrain and a GDP of around $US 9,880 per capita. HL7 Chile (http://www.hl7chile.cl) is a relatively small organisation focused on education and training. The country is in the process of developing its eHealth program.

Brazil

Brazil is an emerging world giant with the world's 5th largest population (around 190 million), a huge land mass and a GDP of around $US 3,640 per capita. SUS, the Brazilian public health system, provides full coverage to all and is free of charge; however, it is very fragmented with funding and management being spread across the federal, state and municipal levels of government. Around 50 million people pay for supplementary private health cover, which is provided by some 1,600 health maintenance organisations.

Brazil is a fragmented and uncoordinated market for e-health with many small, badly connected players and little investment in management reform and IT. As a country, Brazil faces the following healthcare challenges:

- Increasing demand for health care (ageing population, emergence of new diseases, resurgence in diseases that had been suppressed for many years)
- Skyrocketing healthcare costs (often driven by new Health Technologies)
- Inefficient, paper-based, uncoordinated health system with multiple formularies and poor resource allocation
- Silo systems - one for each health program (of which there are many)
- Lack of adequate information to support decision making, quality of care evaluation and to monitor disease management programs;
- Few common health and healthcare information standards

Nevertheless, Brazil has implemented national standards in the following areas:

- Unique health care identifiers for – 160 million individual consumers, 180,000 healthcare providers and 1.4 million other health sector workers
- Record Systems (for content and vocabulary), including
    - Essential Encounter Dataset

  - Diagnostics (ICD-10), Procedures
  - Immunization Charts
  - National Registries of Births and Deaths (in place for over 50 years)
  - Notifiable Diseases (OH&S, communicable diseases, external causes)
  - Hospital Discharge Summaries
  - High Complexity Utilization Reports
- Interoperability:
  - TISS – a Private Health Information Exchange using XML and web services technology for communication of billing/claims information, referrals, hospital discharge summaries and statistics, laboratory and other diagnostic transactions. In May 2007, its use became mandatory.
  - Laboratory integration (based on LOINC + HL7 Brazil)
- Security – based on national PKI infrastructure
- Software certification – through the Brazilian Health Informatics Society and the Federal Medical Council (www.sbis.org.br/certificacao)

A National TeleHealth Project is being piloted in 9 states - supporting some 900 health clinics and 2,700 Family Health teams serving a population of around 11 million. The objective is to promote the use of technology by Family Health teams to improve the quality of primary care and decrease the number of patients unnecessarily sent for secondary level care. Different technologies and methodologies and the associated costs are being evaluated; however, preliminary estimates indicate savings of up to one-hundred-times the costs.

HL7 Brazil (http://www.hl7brazil.org) has 10 individual members and 15 corporate/government members and is working on harmonising Brazil's national eHealth standards with HL7; training programs (including eLearning) and conducting working groups focussed on CDA, LOINC, SNOMED and support.

SIGA Saúde, the integrated, distributed system for managing the São Paulo City public healthcare system (serving close to 20 million people), was described. Among other things, it has been credited with reducing waiting times for consultations by 30% and is based on application of the following standards:

- National Health Card Number - Patient Identification
- National Registry CNES - Healthcare provider and worker identification
- XML schemas, datatypes and WSDL for TISS Messaging
- HL7 v3 (tags translated) - Lab orders and results information content
- HL7 v3 pan-Canadian Messaging Standards
- LOINC (Logical Observation Identifiers Names and Codes) – Vocabulary

Laboratory integration within SIGA Saúde is based on HL7v3, which was selected following detailed evaluation of alternatives including HL7v2, because v3 has much richer information content for laboratory orders and results. Nevertheless, HL7v3 messages are too big, because too much information about application events is included in the message and a modified, stripped-down message was developed (see slide deck on HL7 website for details). CDA documents are part of the current solution – enabling a mix of free-text and LOINC-encoded information.

Although they faced considerable challenges and considerable resistance to v3, which was perceived as being too "scary" and the tools too complicated, these problems were overcome with solid training and education in both HL7 and LOINC. The advantages of having a standard are now clearly understood.

HL7 and developing countries

It was suggested that HL7 is uniquely placed as "THE" organisation best placed to foster health informatics standards development, education and innovation in emerging and developing countries to enable interoperability in health information systems. To do this it was suggested that consideration should be given to:

- Promoting South to South collaboration
- Re-thinking of v3 (v4?) - to be more efficient on the wire, less complex and more services-aware
- Learn from international examples (Brazil drew heavily on pan-Canadian standards, Canadian experience with HL7v3 and the Argentine web-based training programs)
- Promote full interoperability with ISO 13606 – including data types alignment
- Better tools based on open source environments
- Free Distribution of HL7 standards according to country HDI
- Ensuring that HL7 remains and grows as a friendly, open environment, where people can work together and feel comfortable to think "outside the box" in order to improve health care everywhere.

7.7 eHealth in Singapore

Sarah Muttitt MD, FRCPC, MBA is the Chief Information Officer, MOH Holdings, a wholly owned subsidiary of the Singapore Ministry of Health, responsible for delivery of public health services in Singapore. A copy of her presentation *"IT Integrating Healthcare and Empowering Patients"* is available on the HL7.org website at: http://www.hl7.org/documentcenter/public/plenary/2008/presentations/Integrating%20Healthcare%20and%20Empowering%20Patients%20-%20Sarah%20Christine%20Muttitt,%20MD,%20FRCPC,%20MBA.ppt

Dr Muttitt provided an overview of:

- Singapore, its population and their health,
- Availability and financing of public and private sector facilities in Singapore for primary care, secondary/tertiary specialist care and step-down/Long-term care
- Government investment in healthcare and the associated drivers
- Organisation of public healthcare delivery, including:
  - The two healthcare clusters responsible for frontline service delivery – National Healthcare Group and SingHealth
  - The supporting role of MOH Holdings (MOHH), with its mission of being a multiplier to Singapore's public healthcare system by providing support in the areas of financial and corporate governance, information systems, human capital and branding and marketing

A key role for MOHH is Health IT master planning in order to support the national agenda for an Electronic Health Record by 2010. To arrive at this point some challenges have had to be addressed:

- Both healthcare delivery clusters had adopted IT extensively and have their own EMR systems
- Before 2004, there was no mechanism to allow patient clinical information to be shared across the two public healthcare clusters electronically
- Pursuing the vision: *"One Singaporean, One Medical Record"*, in 2004, the Ministry of Health (MOH) implemented EMRX (EMR Exchange), starting with in-patient discharge summary sharing between the two clusters
  - Today, over 100,000 clinical documents are shared through EMRX each month, with the major types of shared clinical information being:
    - Hospital Discharge Summaries
    - Laboratory Test Results and Radiology Reports
    - Medication information
    - Immunisation Records
    - Drug Allergy, Medical Alerts and Adverse Drug Report
    - Operating Theatre and Endoscopy Reports

There are still gaps to be addressed in order to achieve the current strategic EHR goals, these include:

- Technical Performance
  - Improved responsiveness, scalability and robustness
  - Support for non-text EMR data (e.g. diagnostic images)
- Clinical Performance. Interoperability profiles for clinical workflows to support areas such as: - case management, e-referrals, basic disease management, clinical quality monitoring, and adverse drug reaction surveillance
- Standards. Data, message & document standards for semantic interoperability
- Analytics. Support for performance measurement, public health surveillance and clinical research
- Reach. Access for the non-public sector (GPs and institutional LTC)
- Privacy & Security. Establishing a robust fframework to govern the usage, collection, storage, analysiss and dissemination of EMR information

Then next steps toward delivery of the shared EHR by 2010 (as at April 08) include:

1. Meeting the requirement for a national integrated electronic health information system based on a common enterprise architecture, data standards and privacy and security guidelines.
2. Broad stakeholder engagement - the EHR is not an IT project but a business and clinical transformation project.
3. Governance and accountability needed to align strategic intent with implementation, encompassing:

- National strategy and implementation plan
- Funding mechanisms to encourage consistent, coordinated and continuous investment in health IT
- Skilled resource capacity

4. Establishing a benefits evaluation framework by which success of the national EHR with regards to health care quality, safety, and productivity can be measured.

Some specific measures include preparation of a clinical informatics roadmap with defined strategic focus areas, a Clinical Advisory Group to set roadmap directions and oversee a broadening of engagement with mid-tier clinical taskforces for each focus area defined by the roadmap [see presentation for details]. The end result is an Enterprise Architecture for the Health Informatics initiative.

Health informatics standards will be an essential component within this framework as foreshadowed in a 2007 Innovation Week address by Ms Yong Ying-I, the Permanent Secretary for Health in Singapore:

> *"The Government will identify and set nation-wide standards for our healthcare IT infrastructure. This common backbone should include standardized data definitions and formats for medical records to be shared. It will be cheaper and more effective for everyone if Government designs the common backbone that everyone can use – both our public sector clusters, primary care GPs, private hospitals step-down care institutions and the charity sector."*

The standards strategy is based on:

1. Global Standards Engagement with HL7, including formation of local Affiliate, (completed June 2008), IHTSDO (joined as a full member and participating fully in SNOMED CT development), ISO/TC215 and IHE.
2. Develop a framework for the coordination of Health Informatics standards activities at the national level – including a governance process and methodologies for the evaluation, development & maintenance of standards
3. Use of International Classification of Diseases (ICD) & Diagnosis Related Groups (DRG) for statistical measures

8. Health Informatics SDO Harmonisation

The 5th meeting of the Joint Working Group on SDO Harmonization (constituted as ISO/TC215/WG9) was held at the Vancouver Meeting on Sunday, 14 September 2008 from 1530 to 1800 hours.

This was the first meeting of the JWG held at an HL7 Working Group meeting; therefore, the HL7 mirror group, the HL7-ISO-CEN Coordination Group, which is chaired by Mark Shafarman and normally meets after the International Affiliates meeting at each HL7 Working Group Meeting, did not meet in Vancouver.

Minutes of the JWG meeting are available and have been provided as an accompanying document to this report.

The JWG meeting was co-chaired by Charles Jaffe (CEO of HL7), Don Newsham (Canada, representing ISO/TC215) and Melvyn Reynolds (UK, representing CEN/TC251) and attracted just over 100 attendees from 13 different countries.

Joint Initiative Council (JIC)

Don Newsham reported on activities of the JIC, which consists of the chairs of the three participating SDOs and governs the harmonization process. He noted that the JIC had met regularly since May to advance discussion of harmonization issues and approve processes, including processes for admitting new SDOs to the JIC and harmonise their activities with those of other SDOs working on Health IT.

CDISC (Clinical Data Interchange Standards Consortium) has now been admitted to provisional membership of the Council, having been sponsored by HL7 and being accepted by the other members as a global SDO.

IHTSDO has expressed interest in becoming a member of the JIC, which will be discussed further at the next meeting in Istanbul.

The JIC have approved the policy and procedures for establishing a Joint Initiative task Group (JITG), which will accord with the following principles:

- *The JIC determines the need for any JITG through assessment of received proposals and through unanimous agreement to proceed with an SDO hosted JITG. JIC can also determine to use present in-place agreements for proposed work.*
- *The target deliverable for any joint initiative work is, at minimum, an ISO standard and can also be a standard of any other Joint Initiative SDO.*
- *The standard and its intellectual property (IP) will be owned, marketed and maintained by each SDO that ballots the standard successfully.*
- *The JIC will dissolve the JITG upon the unanimous agreement of the Joint Initiative SDO's.*

SDO Work Program Harmonization

Joint SDO work program inventory, version 2.1, now has over 200 work items currently active across the four participating SDOs.

[Note: Maintenance of the inventory is a significant task which must be carried out by the JWG Secretariat – hosted by Standards Australia]

It continues to be a challenge for JI/JWG to understand the active work items on the inventory, and to assess these for overlaps, issues, problems and gaps. At previous meetings, two different approaches had been put forward (classification of standards; and use cases) and were considered further in light of:

- Practical experience of the European Mandate M/403 task force, which had used keyword classification;
- The Canadian Standards Map project, which had combined a Zachman architecture with a profiling classification; and
- Bernd Blobel's research work on a health information systems component architecture.

It was agreed that the JWG would establish a taskforce to explore these issues and propose next steps for standards analysis and to consist of Don Newsham, Melvin Reynolds and Charlie McCay, and other volunteers.

Progress of Joint Work Program

13606 Electronic Health Record (EHR) Communication, parts 1 - 5

Parts 1 to 4 of the EN 13606 Standard are at publication stage in CEN/TC 251 and at an advanced stage in ISO/TC 215. The attention now is on Part 5 and the HL7 V3 implementation guide project with harmonization of 13606 and HL7 Version 3 being the goal. It was noted that:

- Dr Dipak Kalra has found reconciliation of the two abstract models very complex - so he is working on use case approach, based on contributions from Brazil, Austria, Netherlands, and England.
- A JI task group template for joint development of the IG has been submitted to JIC for approval.

ISO 21090 Harmonized Data Types

Graham Grieve reported that the joint project is now at DIS ballot in ISO/TC 215, with both the HL7 and CEN ballots already closed. Reconciliation of the HL7 ballot was done at the Vancouver Meeting, with 33 major technical issues to be discussed [See section 10 below]. Matters of potential concern for the JWG included:

- Intellectual Property (IP)– it was confirmed that the aim of the Joint Initiative is to develop a singular data types standard jointly balloted, co-owned, co-branded but separately published by the three SDOs
- The potential for the final definitive versions in ISO and HL7 to get out of step if HL7 publishes joint document as a DSTU, which is subsequently altered on becoming normative
- The potential need and role of a maintenance agency, particularly in relation to update and versioning of value sets

Charlie McCay agreed to raise the outstanding issues relating to final versions and on-going maintenance with the HL7 TSC.

Pharmacovigilance - Individual Case Safety Report project

The ICSR project had demonstrated the major problems and challenges in taking a singular standard to ballot in CEN, ISO and HL7, given the very different paradigms for publishing and cross-referencing related standards material. Further discussion among project leads is required (including Lise Stevens (US) and Ian Shepherd (UK), convenor of ISO/TC 215 /WG6 Pharmacy and Medicines).

Health Informatics Standards Glossary

Heather Grain reported that the project (with ISO/TC 215/ WG3 lead) aims to achieve a harmonized and consistent approach to definitions used in any health informatics standard. The deliverables are a document on structure and process, and harmonization of definitions using the Standards Knowledge Management Tool (SKMT). Currently 718 defined terms, including duplicates, are being for discrepancies: linguistic and semantic. JWG noted that:

1. A Joint Initiative task group template has been submitted to JIC for approval of the Glossary as a joint project.

2. Heather Grain would forward to JWG Secretariat details of the process for registration and entry of terms to the glossary via the SKMT and this would then be circulated to the JWG.

Entity Names Harmonization

This project will address harmonization between HL7 name identifiers, and ISO identification standards for subjects of care and provider.

Units of Measure

There is a project underway in ISO/TC 215 /WG6 Pharmacy and Medicines on Units of Measure which needs to be harmonized with the informal publication produced (and made freely available) by the Regenstrief Institute, which are the Units of Measure mandated for use with HL7v3.

Harmonization Issues

Some of the previous discussions on and work within HL7 on EHR-S Functional Model Release 2 and Common Terminology Services Release 2 (CTS2) highlighted questions about on-going development and maintenance of standards that have supposedly been harmonized through JI processes, in particular:

- How to manage ballot cycles where one SDO is balloting / publishing release 1 and another SDO has already started to develop release 2
- How to consider and handle ballot comments that arise when a released standard is balloted in a second SDO
- How to handle negative votes that may arise when an earlier “release x”, that has been passed/published in an originating SDO, is subsequently being balloted in other SDOs – does there need to be a further ballot of release x.1 in all SDOs (including the first)?
- Who is responsible for maintenance?
- What are the additional requirements of the earlier HL7 / ISO project agreement (if any)?

The JWG Convenor (Don Newsham) agreed to raise these issues with the JIC for discussion and decision.

Next JWG Meetings

It was noted that these were planned for:

- Istanbul, Turkey on 12 October 2008, 8am to11am - in conjunction with the joint meetings of ISO/TC 215 and CEN TC 251.
- Orlando, Florida on 11 January 2009, at the HL7 Working Group Meeting after the international Affiliates Council meeting (location and time to be confirmed)

9. Affiliates Council

HL7 has approved recognition of international Affiliates in around 30 countries:

Argentina (AR)	Finland (FI)	New Zealand (NZ)
Australia (AU)	France (FR)	The Netherlands (NL)
Austria (AT)	Germany (DE)	Singapore (SG)
Brazil (BR)	Greece (GR)	Spain (ES)
Canada (CA)	India (IN)	Sweden (SE)
China (CN)	Ireland (IE)	Switzerland (CH)
Colombia (CO)	Italy (IT)	Taiwan (TW)
Croatia (HR)	Japan (JP)	Turkey (TR)
Czech Republic (CZ)	Korea (KR)	United Kingdom (UK)
Denmark (DK)	Mexico (MX)	Uruguay (UY)

Of these, some are still in the process of completing, renewing or revising their affiliate agreements with HL7.

The HL7 Affiliates Council met from 0900 until 1515 on Sunday, 14 September and was attended by close to 100 participants, with 15 national Affiliates being represented for the purposes of voting.

Michael van Campen (Canada), who took over in January 2008 as one of the two directors on the HL7 Board elected by the Affiliates, led the proceedings for most of the meeting, assisted by Kai Heitmann (Germany), whose lengthy period as an HL7 director elected by Affiliates expires in January 2009.

Copies of the draft minutes of the meeting may be sourced from the HL7.org website at: http://www.hl7.org/library/committees/intl/minutes/MIN_HL7%20AC%20Plenary%20Mtg_YVR%20WGM_20080914%20Draft%201d.zip

Similarly, the main business presentations may be downloaded from: http://www.hl7.org/library/committees/intl/HL7%20AC_Business%20Presentations_YVR%20WGM_20080914%20v1.0.zip

The following are among the matters discussed.

9.1 Committee and Council Reports

International Mentoring Committee (IMC)

The International Mentoring Committee (IMC) assists potential Affiliate organizations and struggling Affiliates with guidance and education to permit them to improve their processes and procedures to become more viable. It may also provide assistance and education to strengthen support for the work of the Affiliate from government agencies in the Affiliate's home country. The IMC report was presented by IMC Co-chair John Ritter) with the following being noted:

- The HL7 Board and Marketing Council have been examining the possibility of HL7 setting up a tax-deductible charitable foundation. IMC is encouraging HL7 to do this in a way that supports IMC activities but this becomes very complicated if any activities are funded outside the US

- It would be desirable for IMC to have one or more co-chairs from outside the US. Affiliates were asked to consider people who could assist.
- HL7's Ambassador's Briefing program can serve as a powerful IMC-outreach tool but more Ambassadors are needed who can work with nearby Affiliates
- IMC is working with HL7 Brazil on the upcoming Medical Informatics conference. The Brazilian Plenary presentation will be videotaped to provide feedback to USTDA (US Trade & Development Agency), HL7 HQ/Board and HL7 Brazil.
- IMC was meeting jointly with the Marketing Council in Vancouver with a view to jointly advancing HL7 in new Affiliates and emerging economies

Implementation/ Conformance

Frank Oemig provided an update on IC Work Group activities, noting:

- The previous Implementation Guide (IG) Project has been suspended due to a lack of funding and having been overtaken by other events
- Little feedback was received from the implementers survey – it is now out-of-date
- An NLM Project is looking to accelerate tooling to create IGs, including vocabulary binding; Canada also has some standard language, and there is the "Guide to Guide" from Germany
- Several IGs were put up in the last ballot: IHE, HITSP, and IA's
- See HL7 Wiki (Implementation FAQ) for major components of the Implementation FAQ Project: http://wiki.hl7.org/index.php?title=Implementation_FAQ [See HL7 Australia Members Website for Usercode/Password]
- Implementation case studies/presentations are being given for CDC, RIMBAA, pan-Canadian standards, Gaselle/Cypress and, in the Netherlands, GP2GP.
- DSTU testing project is focussed on drafting documents for sample test plan and test scenarios.

HL7 Marketing Council

Dr Jill Kaufman reported on the following notable activities of the Marketing Council.

CDA Product and Services Guide

The CDA Product and Services Guide is being piloted as an online resource by the HL7 Marketing Council in collaboration with the EHRVA (EHR Vendors Association).

Phase 1 was completed for the Vancouver meeting (printout of contents were distributed and feedback sought)

Phase 2 is due for completion in Q4/2008 and involves: - simplified data entry (to address user feedback); recruitment of more entries and giving online access via the HL7 website - www.hl7.org. While this directory is in its pilot stage with 7 product vendors and 8 service vendors being listed, parties in Australia interested in implementing CDA and, also, potential suppliers need to be aware of it.

The Marketing Council is now asking Affiliates to assist with the CDA Product and Services Guide by:

- Helping get local participation in the guide
- Putting links to the guide on the Affiliate website

Phase 3 is scheduled for Q1/2009 and is focused on recruiting other organisation collaborating with HL7 under an MOU to participate (e.g. IHE).

Other registers are under development/consideration for HL7v3 messaging, SOA, EHR-S Functional Model and PHR-S Functional Model.

It is proposed that the next pilot will be an HL7 Product Services Guide for V3 messaging. This is scheduled for Q1/2009.

Question (Kai Heitmann): Did you consider gathering information through interviews? Comment: The Product and Services Guide should be a useful tool for each Affiliate – i.e. a marketing tool to use to help recruit new members.

Potential Australian action is canvassed in the introduction to this report [see p.7]

HL7 Ambassador Program

The Ambassador Program aims to equip selected members involved with HL7 with the messages and information needed to represent the organisation effectively to executives and decision-makers in a range of different contexts – including presenting at specialist conferences and meetings.

Material presented in the Affiliates Council on the Ambassador Program has been consolidated into section 12 below.

Question (Martin Entwhistle, NZ) - Can non-Ambassadors have access to this material? Answer: That was not planned. You could get access though, by participating – i.e. by helping to write a guide.

University Project for 2009

The University Project is a targeted initiative aimed at:

- Increasing the number of Universities teaching HL7 Standards as part of Healthcare Informatics programs, globally
- Defining HL7 benefits for Universities as members
- Increasing University, faculty and student HL7 participation in HL7 and Affiliate activities

Affiliates were particularly invited to participate in the Marketing Council meeting in Vancouver and contribute suggestions as to how universities should be engaged and which universities might be appropriate.

EHR Work Group

See section 18 below for information on relevant activities of EHR WG.

9.2 Report from Affiliate Representative to TSC

Charlie McCay presented the report as Affiliate Representative to the TSC and also in his role as Chair of the TSC.

Navi Natarajan, of the NHS CfH Programme in the UK, is taking over from Frank Oemig (HL7 Germany) as the second Affiliate Council representative on the TSC in January 2009 for a two-year term.

Charlie summarised the new structure of Board (on which he serves as Chair of the TSC), then TSC, Steering Divisions and Architecture Board (ArB) and Work Groups. [See Attachment B below for more detail].

The main responsibility of the TSC can be summarised as:

- Ensuring visibility and oversight of projects, Work Group activities and HL7 product releases
- Common processes and coordination across the Work Groups in carrying out their technical activities – requiring roll out of governance, architectural and tooling changes
- Providing a focus for HL7 resources – *"Best Value for membership dues"*

9.3 CEO and CTO report to Affiliates

CEO Report – Dr Charles Jaffe

Charles Jaffe gave a brief CEO presentation touching on the following points (most of which were covered in more depth at other points in the week's agenda, including the Business Meeting on the morning of Wednesday, 17 September).

1. He thanked the Canadian hosts for their support of the Vancouver meeting – commending the agenda, initiatives & excellent attendance

   International WGMs are an essential part of HL7's outreach strategy to get further penetration and acceptance of HL7 across the broader world community. These efforts must not only continue, but intensify and require:

   - Cooperation and all participants being proactive for effective interchange
   - Continuing to work with the Affiliate Chairs in identifying the local agencies, groups etc which offer the best opportunities for engagement

2. Roadmap – promise of what we are going to do for the broader community. [See section 4 above for more details on the HL7 Roadmap, its maintenance and potential strategic implications for Australia and other Affiliates].

3. How to evolve the organizational structure to make HL7 into a more successful organization.

   In particular, the difficult issues surrounding the formation of a US Affiliate, One Member One Vote and the associated implications for the business model and financial sustainability of HL7 and also its Affiliates.

CTO Report – John Quinn

In presenting his address to the Affiliates' Council, John Quinn reported on:

- Activities of the Architecture Board (ArB) - in particular, the three sets of three-day workshops facilitated in Rockville MD by Booz Allen Hamilton (with remote access for external participants) to progress the question of integrating HL7's activities with its work on SOA – resulting in the first draft of the Services-Aware Enterprise Application Framework (SAEAF) (see section 5 above)
- The HL7 tooling initiative – which is essential to address the following problems:
  - Obsolescence of current tools used to maintain HL7's underlying information models and to publish them in standard specifications
  - The annual struggle to publish the normative ballot – an off-the-shelf publishing environment is needed
  - Efficient definition and creatioin of
  - Harmonisation Vocab to the RIM is another challenge
  - Excessive workload on both WG publishing facilitators and HQ publications personnel for each ballot cycle due to inefficiencies and incompatibilities

  The Tooling Initiative is reported more fully in section 6 above.
- His other activities since May WGM
  - ISO /TC 215Gothenburg Meeting
  - Leading development of the HL7 Roadmap
  - Board Retreat
  - US SDO Summits
  - US National Center for Biomedical Ontology (NCBO) in Dallas

Question (Beverly Knight, Canada) – What are next steps and timing?
Answer: To look at gaps, developing the short-term strategy and obtaining funding. The Board and Executive Committee believes that tooling and its impact on HL7 operations is the highest priority issue to deal with.

Comment (Bernd Blobel, Germany): Previously we focused on hospital systems (primarily one domain) but now we need to include many other domains, services and devices. If we integrate genomics, etc. we need to be considering many other components. We are on track but have not arrived yet.

9.4 Affiliates Council – Elections & Office Bearers

The following results in relation to HL7 Directors and Affiliates Council Office Bearers elected by the Affiliates were noted:

HL7 Board Members elected by the Affiliates

The new (2007) constitution reserves two positions on the HL7 Board for directors elected by HL7 Affiliates. The current two directors are:

- Michael van Campen (HL7 Canada) – initial term from Jan 2008 until Jan 2010

- Dr Kai Heitmann (HL7 Germany) whose term expires after 5 years in Jan 2009

It was announced [on Wednesday] that Catherine Chronaki, a senior software engineer at the FORTH Institute of Computer Science in Greece and former Chair of HL7 Hellas, had been elected to the HL7 Board of Directors by the Affiliates, taking over from Dr Heitmann in January 2009 for an initial 2 year term until January 2011. Catherine is the principal organiser of the IHIC 2008 conference that took place in Crete in October.

Dr Robert Stegwee (HL7 Netherlands) ran against Ms Chronaki but was not successful.

Affiliates' Council – Co-chairs

Originally there were four Affiliates' Council co-chairs each having responsibility for one of the portfolios: Affiliate Liaison, HQ Liaison, Technical and Secretary. The following appointments were confirmed at Vancouver following co-chair elections:

- Catherine Chronaki, HL7 Hellas (Greece) - Affiliate Liaison,
- Dr–Robert Stegwee, HL7 Netherlands - HQ Liaison,

Sam Forou–i (HL7 Canada) also ran for the position of Co-Chair (Affiliate Liaison) but was unsuccessful.

There was originally no candidate for the Council Secretary position but Helen Stevens Love (HL7 Canada) subsequently volunteered and was elected Secretary at the subsequent Affiliate Chairs' meeting.

At the meeting of Affiliate Chairs on Thursday it was resolved to discontinue the position of Co-chair (Technical) as the new HL7 organisational structure has two Affiliate representatives on the TSC.

Affiliate Representatives on the TSC

The new HL7 structure reserves two positions on the Technical Steering Committee (TSC) for representatives elected by HL7 Affiliates. The current two representatives are:

- Charlie McKay (HL7 UK) (also Chair of the TSC) - term ends December 20–9
- Frank Oemig (HL7 Germany) - term ends December 20–8

Incoming Affiliate Representative on the TSC, replacing Frank Oemig, is Ravi Natarajan (HL7 UK), starting in January 2009

Appreciation to retiring and former Co-chairs

Dr Heitmann's five years of outstanding service to the Affiliates' Council and his more recent service on the HL7 Board of Directors was recognised.

The Affiliates' Council also noted the significant contribution of Jane Howarth (retiring Secretary), and former co-chairs: Klaus Veil, Miroslav Koncar and Laura Sato.

9.5 One Member One Vote

The One Member One Vote (OMOV) issue relates to the fact that organisations and individuals participating in HL7 through local Affiliates do not have a direct vote in HL7 matters, even though they may be organizations that pay significant fees to belong to the Affiliate. Instead, each Affiliate receives a quota of votes that relates to their relative size; management of those votes is then a matter for each Affiliate according to its rules. Michael van Campen reported back at some length to the Affiliates' Council on the background and progression of this contentious issue.

- OMOV originated through a "plea" from Charlie McCay and René Spronk in January 2007 based on a position paper that attempted to inform the HL7 organization through the Strategic Review Task Force of a proposal for parity amongst members of HL7.
- The HL7 Board set up an OMOV Task Force with members: René Spronk, Ed Hammond, Charles Jaffe, Klaus Veil, Michael van Campen, Robert Stegwee, Rik Smithies, Charlie McKay, with Wendy Huang (HL7 Canada) as secretary
- There is an OMOV "wiki" (currently accessible to OMOV Task Force members) to document the workings of the Task Force
- Prior to the May 2008 Phoenix WGM, the OMOV Task Force met 4 times by teleconference to consider the two main approaches that had been suggested:
    - Securing "low hanging fruit" by focusing on OMOV in standards ballots (as distinct from voting on governance issues). As summarised in the *"Equality on Global Membership for Balloting"* document, this has been put forward as the first step on a transition path to a new HL7organisation.
    - There is another perspective which addresses the issue of the best path forward by considering the question *"If HL7 was created today as a global health informatics SDO, what would it look like?"*
- During the Phoenix WGM, the OMOV Task Force put forward a "straw dog" model at the Affiliates' Council meeting, which was subsequently refined through discussion at that meeting and at several teleconferences through the (Northern) summer. the preferred model is One where:
    - Dues are paid centrally to HL7 International and redistributed to Affiliates, including a US Affiliate
    - Members would allocate % to specific Affiliates
    - HL7 would provide a global directory, seen as a must to allow for transparency in voting and member rights
- At Vancouver, Affiliates were invited to contribute thoughts to the OMOV Task Force when it met on Wednesday there was some discussion including comments from:
    - Ed Hammond – Thinks this discussion needs to be resolved soon and would hope that a recommendation would come to the Board by the Jan WGM. The Board has set aside some time at this WGM, on Tuesday night, to discuss this as well. This relates to many other topics and issues … and, lastly, we are interested in "unification" as opposed to "rights of states".
    - Hugh Glover (on Benefactors) - the level of ballot i–terest from UK members has fallen away due to influence of CfH, a Benefactor member.

9.6 May 2010 WGM Planning

Michael van Campen (Affiliate Council Co-chair and Board Member) gave an update on planning for the May 2010 Working Group Meeting.

Of concern to Australian delegates was the fact that some Affiliates, with little or no consultation with HL7 Australia, had proposed that the May 2010 international Working Group Meeting be held in "Australasia" as their first choice or, alternatively, South America, as the second choice. Michael summarised the lengthy considerations given to this topic at by the Board and HL7 Administration, noting that:

- Four WGMs have been held outside of the US: Toronto (Canada), Noordwijkerhout (Netherlands, May 2005), Köln (Germany, May 2007), Vancouver (Canada, September 2008)
- The next non-US WGM is planned for May 2009, Kyoto, Japan. IHIC 2009 is also planned to be held in the two days prior to the WGM
- HL7 Board has committed to one non-US meeting per year - on the expectation th–t they are financially viable and strategic, or, at worst, any financial losses are acceptable (and do not put the organization at financial peril)
- Affiliates have participated in the past few months to help identify possible WGM meeting locations for May 2010
    - 1st step - identify a re[gi]on - A–stralasia (Australi– / New Zealand) was selected, with South America coming in second
    - 2nd step - identify a ci[ty] withi– the region - this activity is pend–ng
    - 3rd step - HL7 HQ to wor[k] with A–filiate to confirm venue, cost estimates, logistics, etc. This activity is pending
- While the Vancouver meeting was expected to attract over 500 attendees, the attendance at the last two non-North American based WGMs were
    - 372 in Köln, Germany (May 2007)
    - 431 in The Netherlands (May 2005)
- For 2009 budgeting purposes, the Finance Committee (FC) believes that fewer people will attend the Kyoto WGM than attended the Köln WGM in 2007 - from a conservative b–dgeting perspective, the FC recommends budgeting Kyoto on the basis of 250 attendees
- Given all the costs of producing the meeting and assuming 250 attendees, the budget shows a loss of $162K. This equates to a $228k negative variance to the <u>average</u> surplus earned ($66K) at the two most recent WGMs.
- With other projected expenses for 2009 budget (e.g. including a new Marketing Director), the Finance Committee is now projecting a reduction in HL7's cash reserves from 9.7 to 7.1 months. The target is >6 months
- The variance for Kyoto ($228K) is significant. Australasia does not, at present, suggest a more significant increase in attendees and/or lower venue costs (compared to Kyoto)
- The Finance Committee, and indeed the HL7 Board, are expressing concern over the financial impacts to HL7 for non-US WGMs; however, both remain committed to the idea but careful consideration of venue and/or frequency of non-US WGMs must be a strong consideration

- HL7 HQ needs to commence planning May 2010 before end of calendar 2008

Proposed approach:

1. Promote Kyoto to increase attendance and reduce loss
    - Work with Japan Affiliate to promote and attract local interest
    - Work with all Affiliates to bring numbers to Kyoto that will help offset any reduction in attendance (from US members)
2. Hold off (postpone) May 2010 international WGM
    - Recommend to Board to NOT proceed with the Australasia venue options for May 2010, unless the financial prospects significantly alter within 60 days
    - Work with Australia/New Zealand to confirm if other factors in this region would change the financial equation (e.g. significantly higher local interest, lower venue costs, etc.)

There was considerable discussion, with the following points being made:

- The May WGM has always had the lowest number of attendees, regardless of where it is held – the impacts should be averaged over the whole of each year
- Ed Hammond would be happy if the May WGM approaches “break-even”.
- Why not consider holding the non-US meetings when numbers are up - during January, or, i– September, with the plenary meeting?
- Meetings have a strategic value and also contribute to local interest – the overall business value may still be greater, even if there is a loss on the event
- Klaus Veil - it is vital for HL7’s–credibility to have meetings outside the US
- Weather may be factor supporting high attendance figures in January. Consider favourable climatic regions for a WGM outside of the US in January.
- The host country might consider putting monies saved on their travel costs of their delegation towards the costs of the WGM meeting.
- There certainly was not much of a local presence in Köln [the clash with a major public holiday was noted as a possible cause].
- Consider a rotating schedule of regions for one meeting per year outside of the US – the Affiliates Council has considered this previously when planning IHIC meetings and some potential non-US WGMs - synergy with other in–ernational SDO meetings and/or national Standards meetings is also a factor.
- Audrey Dickerson – Has there been consideration to holding the meetings in conjunction with Fall & Spring ISO TC 215 meetings?
- Michael van Campen – We need more information about projections for Kyoto
- Klaus Veil – Agree we need more discussion about this including having an annualised view of revenue from all 3 WGMs within a year.
- Ed Hammond – Let’s look to see how creative we can be to offset some of the costs to achieve at least “break-even”.

Australian delegates at the Vancouver Meeting diplomatically expressed their surprise at the suggestion that the May 2010 WGM be held in Australasia but agreed to facilitate any further investigation of the options.

9.7 Update from HL7 Board Retreat - July 2008

Michael van–Campen summarised the various activities that had been considered at the HL7 Board Strategic Planning Retreat, which had been held on July 30-31st, 2008 at the Inn on Biltmore Estate, Asheville, North Carolina.

The annual face-to-face meeting of the HL7 Advisory Council had been held at the same venue on Tuesday, 29 July with the outcomes being reported to the Board's strategic planning retreat. [Richard Dixon Hughes from Australia attended this, his third, face-to-face Advisory Council meeting].

Matters considered by the Board at the retreat included:

1. Feedback from Advisory Council. Sam Brandt, Chair of the Advisory Council, recapitulated comments on its vision statements developed the day before.

   By 2010:

   - Position HL7 as accountable and purposeful
   - Roadmap that addresses marketplace problems
   - All projects to have goals, implementers and linked to marketplace requirements
   - Work with other organisations – accept a brokering role
   - Establish process to lead SDO engagement in US Realm

   By 2014, HL7 should be:

   - Perceived as global organisation
   - Free and open
   - With secure funding stream

2. Marketing. The new marketing position is scoped with supporting the financial growth of the organisation - from a global perspec–ive (CEO).

3. The future of messaging - How to close the gap –etween v2 & v3? Is HL7 only about messaging? (dealing with perceptions out there). Rigorous specifications (supported by tooling) are necessary (Ed Hammond).

4. Roadmap - Further updates and refinements [Discussed under its own heading at the Affiliates' Council and separately covered in section 4 above]

5. Competitive Landscape (Ed Hammond)

   - Includes (but not limited to) ISO TC215, IHE, X12, NCPDP, ASTM, CEN, IEEE, all laying claim to some part of the health informatics standards landscape
   - SDO Summit recently held in the US, but not focused and missing some key participants Many of these organizations need to be coordinated
     - Bodies such as NHS (UK) & *Infoway* (CA) are coordinating this effort in their respective realms
     - No such organization exists in the US or many other countries

  - Delineation of SDOs (e.g. HL7), Enforcers (e.g. NHS, *Infoway*) and Implementers
- Mergers and Acquisitions need to be considered

6. Tooling. John Koisch is leading work on tooling for balloting and for implementation of RIM-based standards, which is starting to become a critical issue for the organization. The preferred strategy is to working with OHT on a common platform to address these issues.

7. Financial Model. The CEO has lead responsibility for developing a viable financial model tied to the Roadmap, with more information to be presented at HL7 Board meeting in Vancouver. [This was done – but the work is still at the conceptual stage. Nevertheless, there is a theme emerging that HL7's main customers (and beneficiaries) are the national eHealth programs, and their equivalent in regional and health provider networks - and that this should – ecome a central plank of HL7's global business model.

In response to presentation of this topic at the Vancouver Meeting, Richard Dixon-Hughes commented that he was a bit disturbed that HL7 is sending very mixed signals by portraying the collaborative landscape as a "competitive environment" – noting that HL7 is a member of the Joint Initiative. Hammond responded that competition is good and does not preclude collaboration. Several others supported Richard's concerns, with HL7 management noting the issue.

9.8 Other "business" at Affiliates' Council

HL7 Roadmap

Michael van Campen provided an update on further development of the HL7 Strategic Roadmap (or Business Plan) and progress in achieving its milestones. Progress with the Roadmap was also reported in other sessions by Ed Hammond (HL7 Chair), Charles Jaffe (CEO) and John Quinn (CTO) and is covered in section 4 above.

The earlier versions of this document were substantially rewritten at the Board Retreat and Advisory Council meeting – being simplified and separated into a set of Strategies and a Plan setting out the tasks to be completed.

An updated copy of the Roadmap Strategies (v2.1.1) is provided in Attachment C to this report while the completed and current tasks on the Roadmap Technical Plan are summarised in Attachment D.

Status of Affiliates

There are no new Affiliates to report and no lapsed Affiliates. The Singapore Affiliate commenced operations in June.

New Affiliate Chair for HL7 Hellas – is George Patoulis, MD, the Affiliates Council webpage has been updated with his details.

Budget/Planning for international projects

There were no new funding requests for 2009; however, the HL7 Taiwan Affiliate had previously foreshadowed funding for the 2009 Asia-Pacific meeting, which was to be considered by the Affiliate Chairs at their working lunch meeting

Affiliate Chair Lunch Meeting

As usual, there was an Affiliate Chairs' working lunch meeting, which was held on Thursday, 18 September. Topics foreshadowed included:

1. Fulfilling the mandate of the Affiliates' Council to maintain relationships with "Liaison Organizations" – including ISO, CEN, IEEE, OMG … and others. Since the work of the Joint Initiative began, the informational reports traditionally delivered by Yun-Sik, Kees Molenaar and others have "slipped through the cracks". Feel it is important that these general overviews of overarching standards work items (which are of great interest to many delegates) be re-instated in either the AC meeting OR the ISO-CEN-HL7 meeting
2. Arrangements for replacing Jane Howarth as Secretary.
3. Funding for the HL7 Asia-Pacific Conference in Taiwan.

HL7 e-learning course

Diego Kaminker reviewed progress to date and the plans proposed for the HL7 e-learning course, the Spanish version of which he developed for HL7 Argentina and which has now been translated and piloted in English, under the auspices of the HL7 Education Committee.

At the Affiliates' Council, Richard Dixon Hughes contributed to discussion of the course, questioning some of the success metrics and suggesting reforms; on request, he agreed to participate in further discussions at the Education Committee.

Progress, plans and issues related to the e-learning course are covered more fully in section 11 below.

9.9 HL7 around the World

Argentina

Diego Kaminker, Chair of HL7 Argentina, presented on behalf of HL7 Argentina, reporting that:

- Membership and income have been growing slowly. Membership has grown from 9 members in 2004 to 25 members in 2008
- In line with its vision of: *"More members, more money, more conference participation …"* HL7 Argentina has been active, running and participating in local and regional conference/seminar programs and events, including:
  - April 2008. Seminar on *"Healthcare Interoperability in Argentina - What is available? What do we need?"* Mead Walker was invited to speak at this event, which HL7 Argentina co-sponsored with Argentina Medical Association (AMA), SADIO and Microsoft.
  - September/October 2008. Working with SUEIIDISS (HL7 Uruguay) running:
    - 3rd Iberoamerican Congress of Standardized Medical Informatics.
    - 2nd Iberoamerican Connectathon in the Spanish Language

Two HL7 Argentina speakers: Dr. Fernán Quirós, and Diego Kaminker with Mark Shafarman also invited.

- October/November 2008. Supported IMIA INFOLAC 2008 Conference: "Advances in Medical Informatics and their impact on Healthcare Systems", held in Buenos Aires with HL7 speakers and activities:
  - Diego Kaminker – Full day HL7 Introductory Tutorial
  - Bob Dolin - Present and Future of CDA R2
  - Ed Hammond - Solving the interoperability dilemma
  - Robert Jenders - Standards for CDSS
  - Participate in IHE roundtable

- First CDA R2 Certification in Buenos Aires
- The HL7 Argentina web site has been improved with forums (both open and reserved sections for the Working Groups) and secure document access restricted to members.
- HL7 Argentina Working Groups: are focusing on interoperability solutions:
  - WG#4: ADT – produced ADT Implementation Guide for v2.5
  - WG#3: Structured Documents – produced Implementation Guide for CDA (translated CDA Quick Start.DOC)
- Education - Two more editions of HL7 introductory virtual eLearning course were provided in Spanish attracting over 230 participants - jointly with HL7 Spain and all Latin-American HL7 Affiliates wanting to participate.

  [Information on the English-language pilot of the eLearning course, which is likely to expand to Canada, China and Singapore, is covered in the main eLearning presentation reported in Section 11 below]
- HL7 Argentina is currently able to sustain itself on revenues from its training and other activities and could afford to remit 100% of membership fees received for its offerings

Australia

As Chair of HL7 Australia, Klaus Veil reported briefly, tabling an overhead presentation for inclusion in the minutes and highlighting that:

- Australia was again pleased to have a full delegation in attendance this WGM thanks to the support of the Australian Government
- It has been business as usual for HL7 Australia running education events and working with Standards Australia on standards development
- eHealth activities are again under review. NEHTA had a change of leadership in April and since that time, dialogue has increased and the organisation has become more active and responsive.
- Volunteers from HL7 Australia set up IHE Australia, which successfully ran the first Australian IHE Connectathon in July 2008 (in Canberra) and the fourth Interoperability Showcase at the annual Health IT conference held in Melbourne in August 2008.

His overhead presentation also indicated that NEHTA (National eHealth Transition Authority) work is intensifying:

- March 2007: the (NEHTA) approved HL7 as the national standard for the electronic messaging of health information in Australia.
- February 2008: NEHTA revises Work-Plan
- Since the change in NEHTA's leadership in April 2008, there is increased focus on HL7 Standards, vendor engagement and practical implementations.

Brazil

Marivan Abrahao, Chair HL7 Brazil presented briefly on behalf of HL7 Brazil, reporting:

- Membership (Dec 07) is 25 – 10 individuals and 15 corporates
- Activities carried out by HL7 Brazil since it commenced operations in 2005, have included:
  - Support for Brazilian representation at Vancouver Meeting
  - 10 activities in 2007 – mainly participation in conferences, tutorials and courses (70 persons x1 day)
  - So far, 6 activities for 2008 including courses (40 persons x2 day)
  - Formation of a working group to harmonise CDA with Brazilian code sets and data structures (in Portuguese)
  - Production of a newsletter
- A forum established using open source tools based on the Argentinean experience - but in Portuguese) for - Technical Support (phpBB); Free distribution list (phpBB); Training and Learning (Moodle)
- Provision of input and advice to major projects:
  - SIGA Saúde - HL7v3 Lab Integration System (order, results), handling 2.7M exams/month
  - TISS - Brazilian National Health Electronic Data Interchange in Private Health Insurance Market – using CDA
- Continuing strong relationships and collaboration with Affiliates in Argentina, Chile, Uruguay - particularly for education.

Canada

Michael van Campen, Chair of HL7 Canada and one of the two international representatives on HL7 Board, presented a report on behalf of HL7 Canada, noting that:

- The *Infoway* Standards Collaborative continues to develop, maintain and integrate pan-Canadian message & terminology standards. Current plans are to publish a new Release of pan-Canadian specifications (profiles) for March 2009 to include
  - Lab, Pharmacy, iEHR, Client Registry, Provider Registry, eClaims
  - Infrastructure (e.g. wrappers, data types, CMETs)
  - Common terminology (e.g. SNOMED, LOINC, etc.)

- A refined Standards Life Cycle – needed for dealing with SFU to formal standard (similar to DSTU to Normative). Policy in draft form now deprecated.
- Implementations of HL7 v3 continue to progress - Pharmacy, Registries and Chronic Disease Management

Colombia

Diego Kaminker, presented briefly on behalf of Fernando Portillo, Chair of HL7 Columbia, reporting that:

- Membership has grown from 16 to 38 in the 12 months since the Affiliate was formed
- Training has been provided to improve knowledge among the local membership, to promote participation in the Technical Committees and, also, use of the standard
- Promotion of HL7 is strong:
  - At least 200 hundred people are participating in forums conducted by HL7 Colombia
  - Newspapers, publications, radio, news are mentioning the use and promotion of HL7 in Colombia
- Four (4) Technical Committees have been established focussed on: - Four (4) Technical Committees have been established focussed on: - General Technical; OID; CDA; Laboratory Orders
- Centro Médico Imbanaco (CMI) is a pilot institution for HL7 work in Columbia. It is a leading health institution with high level technology and very qualified personnel. The focus areas will be: Laboratory, imaging and clinical orders
- HL7 Colombia is working closely with the Ministry of Communications on their "Connectivity Agency" program, which is leading the e-government strategy, and defining the interoperability platform for different government agencies

  The government is considering using HL7 in their interoperability platform (GEL-XML) and an official from the Ministry of Communications attended the HL7 course.

Finland

Juha Mykkanen, presented briefly on behalf of HL7 Finland, reporting:

- Finland is currently rolling out three major eHealth initiatives nation-wide.
- ePrescription (eResepti), the first initiative; was launched in Kotka and Turku in the second half of 2008 and involves:
  - National ePrescription Centre
  - National Pharmaceutical (Drug) Database
  - Prescription summary and uniform ePrescriptions throughout the service provider systems (public and private)
  - Initial implementation in the two main EPR and pharmacy systems
  - CDA R2 header + digital signatures

  - 15x CDA R2 document templates,
  - 4x non-CDA documents for logs and summaries
  - 26x HL7v3 interactions (Finnish realm, based on v3 Medical Records)
  - 5 different transport models

- eArchive (eArkisto), the second initiative, to be introduced in 2009 for use throughout the service provider system, encompasses electronic archive and search of patient records, a national central repository, consent management, release and access logs.
- e-Access (eKatselu), the third initiative, is being introduced simultaneously with ePrescription and eArchive and allows citizens over 18 to view personal medical information stored in the archive over the Internet
- Implementation and deployment of these 3 initiatives required the following supporting activities:
  - New legislation: *Electronic Prescriptions Act* and the *Electronic Healthcare Patient Records Act* – (Acts 61/2007 and 159/2007)
  - National cluster projects for integration to central systems used by health professionals
  - Certification criteria development (first versions for ePrescription and eArchive available)
  - Project office to support the deployments
- Other National IT Services forming part of overall national infrastructure include:
  - National code server up and running (Stakes)
  - National service for professional attributes and certificates under development (TEO)
  - National coordination for projects related to citizen eServices
  - Appointment scheduling (national guidelines, shared services design), self-care and portal services
- HL7 Finland has 78 members and strong following in the national health IT community, and:
  - Very active monthly technical committee activities including active SIGs for CDA/Structured Documents, IHE (new), Common Services
  - An agreement with the Ministry of Social Affairs and Health – as a key player for connectivity and integration of national eHealth solutions
- Across Finland
  - HL7 v2.3 is routinely used in many applications
  - HL7 v3 Medical Records + v3 Web Services Transport is used for ePrescription and eArchive messaging
  - CDA R2 is used for ePrescription, EPR documents (for archive), electronic forms
  - HL7 v3 Messaging is used for Appointment Scheduling, death notifications, others

- International SDO activities involving HL7 Finland have included:
  - Revitalization of national de jure standardization linkages with CEN and ISO, including approval votes in ISO for CDA R2, EHR-S functional model, HL7 CTS Release 1, Harmonized data types etc.
  - Recent revitalization of ISO/TC215 and CEN/TC251 meeting participation
  - Initial work with IHE and Continua groups exploring potential activities, to create models for Finnish use and involvement
  - October: several participants at IHIC 2008 / Crete
  - November: 2-day education event with HL7 UK and NHS / England (v3 and archetypes) - Helsinki

France

The report from HL7 France (officially: Association HL7 France – HPRIM) was given by Nicholas Canu and addressed the following matters.

Potential merger of HL7 France and IHE France

Possibly the most interesting development from an Australian viewpoint was the move by IHE France and HL7 France to operate as a single organisation with a single membership and a single budget. The new organisation would host three technical committees and, possibly, produce common documents.

[Note (Richard Dixon Hughes): there is a cautious tone in the material presented – the reasons for this are unclear but may involve IPRs of the parent organisations, avoiding conflicts of interest in the IHE activities, or wishing to continue having two voices].

DMP Project

The flagship French DMP project (Dossier Médical Personnel = PHR) is still delayed as the Government decides what the business architecture for the project might become in the future, with the key issues being

- The extent to which the information in a subject's Dossier will be controlled by the subject of care. Originally the consumer had almost total control but the value of such an approach has now been questioned by clinicians and the future approach may well be less "personal"
- Need for a critical mass of participants, more engagement with the clinical care community, better management of laboratory results and unfavourable impact on clinical workflow. There has apparently been a negative reaction among over-worked clinicians, which has been picked up by the new conservative national administration.

Notwithstanding, work continues on the standards required for interconnectivity.

Dossier Pharmaceutique (DP) – HL7v3 Case Study

The pharmaceutical record (DP) project (see information in box below) is far beyond a vision on a Powerpoint presentation – it is a real system that has now been developed, implemented, deployed and tested in hundreds of pharmacies – with a view to fully generalised rollout in 1999. The project is understood to be regarded as a success.

Note: an abstract on NLM/NCBI PubMed Database includes the following brief outline of the DP project:

This professional tool, which the National Council of Pharmacists is currently developing, aims to centralise data on all medicines dispensed to each patient, and, subject to strict confidentiality conditions, to make it accessible from any pharmacy. The DP should allow pharmacists to meet the objectives set by the law: fighting drug induced accidents and redundant healthcare.

The project has adopted HL7v3 messaging and CDA throughout, with HL7v3 adoption being considered to have made the project simpler and faster.

Germany

Thomas Norgall, Chair of HL7 Germany, briefly presented a verbal report on behalf of HL7 Germany, reporting that:

- This is the 15th year that HL7 Germany has been in existence and it has around 270 members, with an annual conference held every October, and a magazine issued twice a year.
- Electronic German citizens' health card about to be rolled out nation-wide, supported by new health informatics infrastructure and generating lots of standards activity. This has resulted in many of the health sector players only just becoming aware of health informatics standards for the first time as many of the Bundesländer (States) have previously used their own specifications.
- IHE activity in Germany is still mainly focused on diagnostic imaging (DICOM) and needs to progress further as in other countries.
- There is a lot of ongoing involvement in standards development, implementation and related activities on national, European and international levels, including:
    - Unique Identifiers
    - Scores for assessments – with strong collaboration between Germany and the CDC in the United States
    - Handling of terminologies – national OID registry – 500 registered
    - 2 new ISO work items for XML exchange of OIDS
    - Support use of LOINC and ICD-10; with working proceeding on a German translation of LOINC
    - Healthcare records – being specified and developed in harmonisation with other nations in the EU – with a view to a European approach
    - Support for European e-Health initiatives
- Emphasis and awareness of interoperable devices – standards not widely used … but needed for personal health records

India

Pradip Kumar Parida, an HL7 certified v2.x expert with IBM India, presented on the current status of healthcare IT and HL7 in India, reporting that:

Healthcare IT in India

India is a big country with a wide range of hospitals (over 5,000), clinics, hospices and nursing homes ranging from small to large paper-based institutions to modern facilities, such as those operated by the Apollo Hospitals group, which have world class healthcare IT. The market for healthcare IT is fuelled by the growing trend toward Health Tourism, Medicities (20+) and cities which have increasing numbers of medium to large hospitals.

There is some use of HL7v2 standards-based systems in the Medicities and major hospitals and the Government of India through the Ministry of Health and Family Welfare (and also Department of IT) has been involved eHealth standards activities, including producing a draft document on Health IT Standards in India.

There is strong healthcare IT capability in India with over 150 universities and over 1000 colleges teaching IT at tertiary level – with some teaching institutes specialising in healthcare IT. These provide personnel who are well qualified that join an IT sector that supports over 5,000, of which, over 100 specialise in healthcare IT servicing both domestic and international markets.

HL7 Opportunities in India

There is already significant interest and participation in HL7 activities in India today as evidenced by:

- India having more than 200 HL7 Certified individuals – the highest number among any Affiliate country
- 87 Students having undertaken or are in the queue for the HL7 eLearning program (across English language pilots No 1, 2 and 3)

There is significant potential for HL7 to play a much greater and influential role, provided that current barriers to participation are addressed. This is based on:

- There being hundreds of people interested in HL7 currently working for healthcare IT vendors and service providers, healthcare providers, government organizations and universities – all are potential HL7 India members
- In India, face-to-face training in HL7 has been very limited due to a lack of training activities being conducted by HL7 India
- The formal HL7 India Affiliate organisation has only 5 members and new members have been unable to join for over 3 years. There is a website [but with limited content]

Next steps

- Allow new members to join HL7 India and gain the benefits of belonging to an HL7 Affiliate (publications, discounts etc)
- Hold regular meetings (in India) to exchange ideas [organised by HL7 India, HL7 Inc, or others?]

- Establish local programs to promote & educate healthcare organisations, healthcare IT vendors, government and healthcare IT academics and informaticians in India in the use of HL7 Standards.

Japan

Dr Michio Kimura, Chair of HL7 Japan, gave a brief presentation on HL7 Japan's activities, focussing on:

- the May 2009 HL7 Working Group Meeting in Kyoto (at the International Conference Center) to be held on 10-15 May 2009; and
- IHIC 2009, being run as a shoulder event at the same venue on 8-9 May.

For more information about these two events, see section 13 below.

With regard to other activities in Japan of interest to HL7:

- HL7 Japan celebrated its 10th anniversary in July and has around 250 members
- The Japanese Government Ministries' are running an interoperability promotion under which major HIS vendor products are being equipped with HL7 data export capability

  [Note (RDH): It has previously been reported (Jan 08) that support for HL7 in Japan has been enhanced by national projects requiring everything to be reported in CDA R2]

- The Japanese Government is starting to face a capital funding problem as subsidised EMR systems that were installed in 2002/03 under an earlier health IT program come up for replacement and now also require investments of many ¥ millions for conversion of data.

Korea

No report from HL7 Korea was given at the Vancouver Meeting.

The Netherlands

Robert Stegwee gave a brief presentation on behalf of HL7 Netherlands (HL7-NL) noting that it has been "business as usual" and that:

- The Netherlands had a delegation of 15 at the Vancouver Meeting
- HL7-NL has over 220 organisational members. It does not have individual members but does have 473 "interested persons" according to the website
- The focus in the Health Care and Clinical messaging area is on Lab, with HL7-NL working jointly with IHE and NICTIZ on national access to lab results. A joint workshop with IHE on lab interoperability is being planned for March/April next year (2009)
- Pharmacy – aligned with requirements arising from NICTIZ Medication Information Exchange projects
- Patient Care / Templates - Participating in joint Detailed Clinical Models work

- Administrative Management/ Registry Services - Ongoing work regarding regulatory changes - current Implementation Guides may need to be changed
- Infrastructure Management / Datatypes - Ballot reconciliation of a Dutch CMET underway. Datatype Implementation Guide is also being produced
- RIM Based Architecture / Service Oriented Architecture. There is much enthusiasm, with several participants attending the Vancouver Meeting
- New Developments include
  - Work toward a Dutch EHR-S FM profile for Behavioural Health
  - Work on specifications for Public Health Reporting
- This year's National HL7-NL Standardization Conference will be held on 10 December 2008

New Zealand

Martin Entwhistle provided a brief presentation on behalf of HL7 New Zealand, highlighting:

- There is a new Chair for HL7 NZ, Dr David Hay, who has a strong interest in CDA for shared clinical documents from his role as an Enterprise Architect with Health Alliance, the major health service in the Auckland region
- The current position of NZ health IT vendors on adoption of HL7v3.0 and/or CDA remains negative, because:
  - They perceive the technology as being too complicated with significant vendor costs and a steep learning curve for adoption – who pays?
  - HL7 v2 and/or XML [?self-made schemas] are considered sufficient
  - Perception that: "There's no evidence of successful use - It's still all theoretical"
  - They have a block and do not acknowledge the benefits of standards - the value of interoperability and the "law of increasing returns" as people move to and build on a standard
- Membership of HL7-NZ is trailing off – strategies for retaining and growing membership are focussed on compelling reasons to belong:
  - Making day-to-day work easier; Relevance;
  - Added value for members over non-members through access to resources, tools and assistance
- Key Initiatives relevant to HL7
  - e-Pharmacy
  - Referrals / Discharges
  - IHE, where HL7-NZ is now discussing how IHE Australia might assist.

  CDA is being adopted for all relevant new initiatives – this is a challenge!

- Skills, Training and Support
  - Several students from NZ participated in the English-language pilot of the HL7 eLearning program developed in Argentina
  - Focused training needed to provide NZ with a level of practical knowledge and expertise on CDA and HL7v3
  - IHIC 2007 was successful plus CDA training in 2008 – but need more and need international assistance
  - Need advice on adoption, use and implementation of CDA
  - Direct input to MoH on these issues
  - Increased level of resources on www.hl7.org.nz

Mark Shafarman noted that HL7 needs a centralised web site for the CDA resources.

Singapore

Choon Khin Fong, Chair of HL7 Singapore, provided a brief verbal report on behalf of HL7 Singapore, noting that:

- HL7 is a very new Affiliate, having been formally in existence for just over 2 months. It has around 30 members.
- On 27 June, the first CDA/CCD training was held, attracting 140 people
- HL7 Singapore is looking at how the HL7 eLearning program might be adapted/delivered locally in Singapore.

Spain

Jesus Villagrasa Fornos spoke briefly to his presentation on behalf of HL7 Spain, with the following highlights being noted:

- HL7 Spain was established in 2004. In 2007 it had 67 members and this has grown to 79 in 2008.
- Demand for Tutorials, Seminars and Certification exams continues with agreements in place with the some Spanish Healthcare Authorities to promote HL7 standards with HL7 Spain providing some of the training.
- Engaged in e-Learning Program with HL7 Argentina and this continues to be well patronised
- Three (3) active subcommittees – V3 CDA, e-Prescribing, ADT
- V3-CDA Subcommittee:
  - Statement about proposed Electronic Medical Record by Spanish Healthcare Department
  - Working with the Spanish Healthcare Department about a technical proposal for EMR using CDA.
- Pharmacy Subcommittee - Published: e-Prescription Implementation Guide
- ADT Subcommittee - Statement about v2 implementation guide for “Servicio Salut Castilla y Leon” (health authority)

Taiwan

Dr Jin-Shin Lai, Chair HL7 Taiwan (Jslai@ntu.edu.tw) provided a brief report on behalf of HL7 Taiwan, highlighting:

- "Good News" – CDA favoured as Taiwan's National Standard instead of (home-grown) TMT
- "Bad News" – DOH will probably not give financial sponsorship for 7th Asia-Pacific conference.

  This Conference will be held conjointly jointly with MIST 2008, NIST 2008 and MISAT 2008, November 21-23, 2008. See website: http://mist2008.ym.edu.tw.
- Funding Request – HL7 Taiwan is requesting support for ~USD $2,000.00 for the 8th Asia-Pacific HL7 Conference, to be held in Taipei, November 2009.

United Kingdom

Rik Smithies, Chair of HL7 UK gave a brief presentation on HL7 UK activities, reporting that:

- The UK NHS reports CfH deployment statistics on the web at: www.connectingforhealth.nhs.uk/newsroom/statistics/deployment
- Many v3 messages have now been operating for well over 12 months, interconnecting a variety of systems across England and without significant problems. As of September 2008:
  - Over 10 million (a milestone!!) electronic bookings/referrals have been placed – all using V3 messages (up from 5 million in August 2007)
  - 116 million electronic prescriptions have been issued (using several V3 messages per prescription)
  - 240,000 complete electronic medical records have been transferred from one GP to another, via V3 message (up from 100,000 in March 08)
  - 160,000 medical summaries uploaded to the NHS central record

  HL7v3 messaging is now well established as a core component of day-to-day operation of the NHS in England and the volume of messages processed will now continue to grow with time.
  -
- With the main HL7v3 messaging applications now operational, the need for new message creation is slowing down – it seems that the message development curve has now peaked. Has this been experienced elsewhere?
- Upcoming domains are more document-like – based on CDA. These involve a different development paradigm with more profiling of existing models, less message-based modelling, less development of core standards – and less core HL7 technical work.
- Document development is mainly undertaken by clinical people and analysts and requires less message modelling and standards development – once the technical frameworks are in place, implementation is becoming easier!

Impact on HL7 UK

- As a result of the shift in emphasis in the NHS from technical message development to deployment and implementation by propagation, HL7 UK has changed its focus and is having fewer of the technical working (standards development) meetings that we used to have.
- HL7 UK looking at fostering innovation and implementation - and promotion.

Upcoming events

- Next meeting is the annual 2 day conference HL7UK2008 being held in London on 22-23 October and featuring over 20 speakers from around the world – aimed at sharing experience and planning for the future – a less technical event
- Also planning a series of outreach "Roadshows" in early 2009. This was last done in 2007 and got a far larger attendance (>100) compared with the technical meetings (<30).
- Bringing in an introductory level back-to-basics "How can HL7 help you?" program aimed at broadening the base.

Examples of other HL7 Activity in UK

- Despite the NHS and HL7 UK placing less emphasis on the technical aspects, there is still a lot of detailed work going on (e.g. a good UK attendance at the Vancouver Meeting)
- Development work now in progress to move to Lab messaging using the HL7v3 balloted standard
- NHS CFH activities of particular note:
  - On-going content modelling and templating work (for EHR)
  - Logical Record Architecture (LRA) programme – establishing a common model to which existing systems can be mapped (for interoperability)
  - Sponsoring development of new HL7 "Static Model Designer" based on OHT to to replace Visio RMIM tool (demonstrated Tuesday evening).

Request for sample messages

Diego Kaminker (Argentina) requested that international Affiliates provide examples of developed messages to demonstrate how useful they are to our students on the eLearning program.

10. ISO Harmonized Data Types Standard

At the Vancouver Meeting, Graham Grieve presented and led work on ISO 21090 (*Health Informatics -- Harmonized data types for information interchange*) which is being jointly balloted within ISO, CEN and HL7 with a view to common adoption of a single co-branded standard for the next generation of abstract data types for use in Health Informatics. It builds on the previous CEN data types and on the HL7 data types, Revision 1 of which are already widely used in HL7v3 messages and CDA documents. The harmonisation effort also involves an attempt to achieve maximum reconciliation with the *open*EHR data types which are the de facto standard used

where the *open*EHR and the ISO/EN 13606 EHR communication standard are being applied.

While HL7 has a relatively short ballot period (30 days), a 5-month ballot period was required for the 21090 specifications to pass the Draft International Standard (DIS) stage in ISO and the Public Enquiry (ENQ) stage in CEN. This long ballot period is aimed at allowing member bodies to translate the documents, discuss them and submit informed comments. The time for the HL7 ballot of the draft datatypes standard was extended to correspond with the five-month cycle used in ISO and CEN but commenced several weeks earlier, with the results being available for the Vancouver Meeting. Because of publication delays, the ISO ballot closed a few weeks after the Vancouver Meeting – but all member bodies had been asked to submit their comments in time for Vancouver, if possible.

Final consideration of the work from the ISO and CEN perspectives was planned for their joint meeting in Istanbul in mid-October 2008.

Graham Grieve led consideration of issues related to the data types in several different sessions at the Vancouver meeting, including:

- Overview of progress and process issues at the JWG for Health Informatics SDO Harmonization. As set out in the notes on the JWG above, discussion encompassed completion of the ISO ballot, intellectual property rights in the final product, publication format issues, on-going maintenance of the standard without loss of harmonisation, and requirements for final approval balloting as well as a summary of the technical issues arising in the HL7 ballot.
- Jointly with Vocab and INM - vocabulary issues (Tue Q3)
- With INM – implications for HL7 abstract data types; entity names (Wed Q2)
- At ITS (Wed Q3 & Q4) – main reconciliation of HL7 ballot comments

The previous major face-to-face discussion had taken place in May at the ISO/TC 215 meeting in Gothenburg, Sweden, at which useful progress had been made on: localisation issues including Japanese concerns over the required use of Unicode; Framing and introductory issues; and Entity Name (EN) harmonisation.

The main HL7 ballot reconciliation was done at the Vancouver Meeting, noting that 213 individual comment lines had been received; these were split about 50:50 editorial to technical with 33 major technical issues to be discussed. While the ballot could be considered to have "passed" several of the negative votes had raised persuasive questions leading to substantive change. Under HL7 rules, a re-ballot is required – with the leading question for the TSC to consider being: *"should this be another DSTU ballot, or would it be better to bring this to full normative ANS status in parallel with the final ISO FDIS ballot?"*. Richard Dixon Hughes lobbied heavily for the second option on the grounds that the existing HL7v3 data types standard is already widely implemented, this is an update rather than a completely new standard and it would be far better to have the same version of the standard reach final normative form in all three SDOs at around the same time to avoid potential loss of harmonisation (which could occur if HL7 adopted the DSTU route, thereby requiring it put the specification to a further normative ballot within two years).

Vocabulary issues

- The HL7 vocabulary WG noted that harmonised data types are an important foundation and indicated that specific rules controlling changes to them needed to be published – along with a commitment in writing to maintain the joint IP.

- CD (Concept Descriptor) and SC (Coded String). Can they be equal? When each should be used needs to be differentiated more clearly.
- Value Set naming and versioning
- QTY/QSET.OriginalText – correct coding and usage with QTY.value when there is only text. Whether should be allowed with uncertainty.
- Code rules for use of OTH within CD

HL7 adoption issues

- ISO datatypes include architectural changes that are causing push-back
- Backwards compatibility issues. Although incompatibility has been minimised, existing implementations remain concerned about changes that are not backwards compatible but harmonisation and compatibility with XML tooling are not possible without some backward incompatibility.
- There is pressure for CDA and SPL to adopt enhancements proposed for HL7 R2 datatypes. With many of the R2 enhancements required for CDA R3 having been picked up in the ISO 21090 harmonised data types standard – it moved too far for some in HL7 (who wanted more consideration/debate of these changes) and not far enough for others (who want most/all of R2 now).
- Future of the new HL7 ITS is unclear – the adoption framework for HL7 datatypes R2 (and related aspects of ISO 21090) is therefore unclear. Some would prefer to await these developments before committing to a longer-term data types standard.

Some specific topics under review following ballot

- Revised proposal for EN (Entity Name) harmonisation (considering HL7 and ISO approaches to identifiers and identification practices).
- Schema versions
- AD (Address) and EN (Entity Name) models
  - Named elements or not?
  - Delimiter representation
  - Initials
  - TN (Trivial Name) representation
- TEL (Telecommunications Address) usage issues.
  - Equality and the canonical form (why have a canonical form if not used to define equality?)
  - TEL.PERSON and TEL.PHONE
- Handling of precision in REAL, PQ (Physical Quantity) and TS (Time Stamp) data types
  - Should full Date Time allow milliseconds?
  - General fix up of PQ/PQV proposed
- Flavors
  - How are flavors represented in XML? flavorID and xsi:type
  - Simplifying main data types model diagram by removing flavors?

- CO.translation. Clarifying where a Coded Ordinal (e.g. 1:Low, 2:Medium, 3: High) must retain its ordering when translated to a different language to ensure safety of clinical computation.
- GTS (General Timing Specification) – use of codes to be reviewed
- Values for primitives - are they allowed when null?
- Structured text - XML or not?
- How to manage reference with compression?
- Exclusion of integrity check on text?
- IsNotOrdered - default value is "false"?
- SLIST (Sampled Sequence) – update operations
- CS coding rationale
    - change to CS not SET(CS) ?
    - Need for bodies issuing CS values to be identifiable and take responsibility for proper definition and ongoing maintenance
    - Dangers of inventing code sets to be highlighted

Those with queries or contributions should contact Grahame Grieve.

11. Education – Web-based Distance Learning Project

HL7 Argentina has developed and implemented a 10-week interactive internet e-learning training program *"Introduction to HL7"* providing practical skills needed to successfully implement HL7 v2, v3, and CDA. The course has been successfully delivered to several intakes totalling over 500 students from across the Spanish-speaking world. The online content includes team assignments with online tutorial support from instructors experienced in HL7 implementations.

Detailed information on this training program was provided as Attachment A to the report of the Australian delegation to the September 2007 Atlanta Plenary and WG Meeting. In Atlanta, HL7 agreed to form a project team to pilot delivery of the program in English.

A further update was provided in Australian report on the January 2008 San Antonio Working Group Meeting, at which arrangements for piloting the e-learning course in English were announced with an initial intake limited to 100 students to be drawn from: China and India (at a price of $US100 per seat) and Australia, NZ, USA, Canada and Sweden (at a price of $US350 per seat). The mix deliberately included students both native English-speaking and NESB students. Around 10 students took the course from Australia, including a colleague of Richard Dixon Hughes with considerable HL7 background.

The expansion of this activity on a global basis is being sponsored by the Education Committee with the initial translation into English being provided by HL7 Argentina, edited and reviewed by a panel comprising: Rene Spronk, Virginia Lorenzi, Mark Shafarman and Mike Henderson. Argentinean tutors supported the first two English-language editions (with assistance from the edit/review panel).

At the Vancouver Meeting Diego Kaminker presented an update on progress and the outcomes of the English language pilot to the Affiliates' Council (on Sunday), the

General Meeting and to the Education Committee, where potential changes and enhancements were discussed. Key points from his presentation included:

- The GOALS of the eLearning program are:
  - OPPORTUNITY: To create a cost effective and affordable way to give opportunity for healthcare IT professionals, globally, to learn about HL7 standards so that they can use them in their implementations.
  - OUTREACH: To allow HL7 to reach countries where there is limited HL7 education available and therefore bring them into the HL7 community.
  - FLEXIBILITY: To enable the students to undertake the course from work or home irrespective of their geographic location it is offered in the form of a ten-week virtual course.
- In 2008 alone, HL7 will train a total of almost 400 hundred students from 15 countries using the eLearning program
- Structure. The e-Learning course is Divided into the folllowing10 units or modules – with one unit being released each week:
  - Unit 01: Interoperability and vocabulary
  - Unit 02: Intro to HL7, Data Types
  - Unit 03: ADT, Orders and observations
  - Unit 04: HL7 V2 Implementation, Messaging Profiles
  - Unit 05: Intro to XML, V2.x XML
  - Unit 06: Intro to V3
  - Unit 07: Reference Information Model
  - Unit 08: V3 Data Types and domains
  - Unit 09: From the model to the message
  - Unit 10: Intro to CDA R2
- The course focuses on practical healthcare IT issues and “learning by doing”, so that students learn basic healthcare interoperability using HL7 standards, and are able to read/write and understand V2.x and V3 messages and CDA R2 documents.
- The English editions (as pilots) are part of HL7 Project #207, sponsored by the Education Committee, with the first pilot edition (in English) being taught to approximately 100 students from USA, Canada, Australia, India, China, New Zealand and Sweden – 88 students completed the course in mid-2008.
- Since almost 500 students registered for the first pilot, the HL7 Board agreed to roll out two more English-language pilots, in order to fulfil expectations. The second pilot involved 66 students (9 from ANZ). The third English pilot began on 6 October 2008 with an expected enrolment of 85 (≤ 11 from ANZ).
- Evaluation was via anonymous feedback surveys (pre-course, mid-course and post-course) with questions about expectations, clarity of material, basic understanding of HL7 concepts, activity completion, tutor coordination and weekly dedication. Based on feedback:
  - the e-learning team recommended a review/edit of the English materials in order to make them clearer – Chuck Meyer won the contract for this work, which was to be completed by the end of September

  - More tutors are to be engaged (initially in India and China – with others being sought) – to provide better communication with local students from the perspective of both time zones and language.

- For 2009, the concept of HL7 Affiliates running their own HL7 e-learning courses will be piloted with the first expected to be HL7 Canada and HL7 China. HL7 Singapore will be in the second wave of pilots for 2009.

- The course may also be translated into other languages, such as Mandarin Chinese, a task which would be undertaken by HL7 China.

- Estimated total revenue for the first three English editions was $US 65,380 with HQ and co-tutor expenses of $14,584. 50% of the balance ($50,806 x50% = $25,403) was paid to HL7 Argentina for hosting the content, the initial English translation and tutorial services. The balance was retained by HL7 Inc with some being reinvested in the further review/edit by Chuck Meyer. [It was noted that HL7 Inc ended up clearing about US $21,000 for very little effort or risk – by contrast, HL7 Argentina copped 50% of all overheads plus 100% of the significant costs of providing the primary tutors and the website hosting!!]

- It was noted that HL7 Canada had put forward a general proposal for management and exploitation of IPRs arising in Affiliates and then exploited more widely by HL7 Inc and other Affiliates.

At the Affiliates' Council meeting, Richard Dixon Hughes noted that:

- The course was reputed to be very difficult and excessively demanding in its present form - a highly competent interface engineer had found it unnecessarily demanding in places – requiring near full-time commitment, with the relevance of some mandatory material being questionable.

- Enrolments is the major success metric currently in use; given the demands of the course, information be provided on completion rates (not just enrolments) – it was agreed that these should be reported in future.

- Given the apparent workload and the fact that not all students have the same needs or time, it might be desirable to separate the offering into two or three components.

The originators seemed proud that the course was found to be difficult.

By invitation, Richard Dixon Hughes assisted in reviewing comments and strongly suggested to the Education Committee that the content be re-cast into a common foundation element – to be followed by separate specialist modules on v2, v3 and CDA.

HL7 Australia and relevant Australian interests (including NEHTA) need to consider how this course should be used in Australia. It is considered vital that local experts review and contribute to the development of the content to ensure that it meets Australian needs, noting that the current concept has already been refined significantly and that HL7 and HL7 Argentina have significant IPRs in the material.

12. HL7 Ambassador Program

The Marketing Council has established and runs the HL7 Ambassador Program on behalf of the Board. The Ambassador Program aims to equip selected members involved with HL7 with the messages and information needed to represent the

organisation effectively to executives and decision-makers in a range of different contexts – including presenting at specialist conferences and meetings.

Each Ambassador Program module consists of a short standardised presentation to promote awareness of key HL7 work on a particular topic. The presentation is usually first piloted at an HL7 Working Group Meeting and then adjusted in line with feedback received from the pilot presentation before release.

HL7 Global Ambassadors

- Are authorised to deliver a module following a formal application and review process (and authorizations must be renewed annually)
- Are authorised by topic (and most current Ambassadors are actually the leading experts on their topic's subject matter)
- May, as part of their authorisation, be required to demonstrate their capacity to deliver the module at a Working Group Meeting and respond to questions, and
- Must, in relation to a topic, have personally participated in recent HL7 WG meetings, Affiliate events or other activities with equivalent standing.

Much was achieved during 2008. The core Ambassador modules were created, an initial list of Global Ambassadors was established, processes were developed for managing the program and a series of conferences were targeted for presentations and others sought them

The current modules, lead author and authorised ambassadors for each topic are:

- SOA (Jan 08): Ken Rubin. Other: Juha Mykkänen
- CDA/CCD (May 08): Keith Boone
  Others: Bob Dolin, Liora Alschuler, Calvin Beebe, René Spronk, Hui Nar Quek, Frank Oemig, Diego Kaminker, Kai Heitmann
- EHR-S Functional Model (May 08): Lenel James
  Others: Pat Van Dyke, Don Mon, John Ritter, Corey Spears, Gora Datta, Bernd Blobel
- PHR-S Functional Mode (Jan 08): Pat Van Dyke, John Ritter
  Others: Don Mon, Ana Estelrich, Gora Datta, Bernd Blobel
- Clinical Genomics (Sep 08): Grant Wood. Other: Amnon Shabo
- Intro to V3 (Sep 08): Virginia Lorenzi, Mark Shafarman, Gora Datta, Kai Heitmann, René Spronk, Jill Kaufman.
  Others: Frank Oemig, Diego Kaminker, Pierre-Yves Lastic, Bernd Blobel
- HL7 101 (Sep 08): Mark Shafarman, Gora Datta, René Spronk, Kai Heitmann, Jill Kaufman, Dan Russler. Others: most of the above (plus others)

One of the key roles for Ambassadors is to be available to speak at conferences being organised by Affiliates in their countries. Presentations have been given, or are planned at the following:

- IHIC 2008, Crete, October 2008
- International Medical Informatics Assoc Latin and Caribbean, Buenos Aires, Argentina, October 2008
- Georgia Health Information Association, Atlanta, August 2008

- Singapore HealthCom, July 2008
- Scottsdale Institute, CDA, CCD via telecourse, Feb 2009
- Scottsdale Institute, V3 via telecourse, 2009
- Plus: Early bird sessions at all HL7 WG meetings

Next steps for the Ambassador Program include recruitment of more appropriately qualified individuals to be authorized as HL7 Global Ambassadors (please consider applying if you are a regular participant in HL7 Working Group Meetings) and adding new briefing modules, with the following modules currently under development:

- HL7x3 102 (An introduction for more technical audiences)
- HL7 RCRIM standards
- HL7 Security

HL7 members are being asked to consider contributing to the Ambassador Program in the following ways:

- Helping to write a new Ambassador Briefing
- Applying to be an Ambassador
- Looking for conferences where Ambassadors can present on HL7 topics

Australian delegates noted that, at present, there are no Australians authorised as Global Ambassadors on any topic – and there is a shortage in the Asia-Pacific region.

13. Kyoto WG Meeting, May 2009 – Information

The May 2009 HL7 Working Group meeting is to be held in Kyoto, Japan and for the first time ever, the International HL7 Interoperability Conference (IHIC 2009) is to be held as a shoulder event to an HL7 Working Group meeting. Key points presented by Dr Michio Kimura, President of HL7 Japan, include: -

- IHIC 2009 dates: Fri, 8 May and Sat, 9 May – website to be set up – deadline for submission of papers: 15 February 2009, for earlybird registration: 15 March 2009.
- HL7 Working Group Meeting dates: Sun, 10 May to Fri, 15 May 2009.
- Both events will be held in the Kyoto Convention Center (where the Kyoto agreement on climate change was negotiated). The Convention Center is about 20 min from the centre of Kyoto on the Karasuma subway line.
- Unlike HL7 Working Group Meetings in North America, HL7 has not contracted with a resort hotel in Kyoto to provide accommodation for delegates as well as meeting rooms. HL7 Japan has recommended that delegates book their own accommodation near the centre of Kyoto, with the aim of getting a better deal than is normally available.
- Three (3) hotel venues were identified for around AUD $140 per night.
- The nearest international airport to Kyoto is the Osaka Kansai regional airport (73 minutes by Japan Rail express).

- Kyoto is also 2 hours 22 minutes by bullet train from Tokyo Station (but requires a change of train if arriving/departing from Narita).
- There is the local Aoi festival parade on Friday, 15 May, which may be of interest to anyone not committed to HL7 meetings (TermInfo, DCM, Vocab etc) on that day.

Reports on Work Group & Committee Activities

14. Clinical Decision Support

The following comments draw heavily on a report from Dr Ken Harvey that focussed on several issues including Clinical Decision Support (CDS) – his full report has been provided as an accompanying document.

In addition to Dr Harvey, Dr Andrew McIntyre and Dr Peter Scott, both from Medical Objects Pty. Ltd in Queensland participated in the CDS Work Group sessions at the Vancouver Meeting.

The Clinical Decision Support Work Group (CDS WG) aims to support patient-focused health care decision making by making use of formal systems of clinical logic, specifically:

- The rules-based Arden Syntax, an HL7 standard
- Standards for representation of clinical guidelines such as GLIF (GuideLine Interchange Format), and
- GELLO – an HL7 (and ANSI) standard query and logical expression language for CDS that can interact with an EHR (or a virtual medical record (vMR)).

Many other methods and tools exist that can support the computerisation of clinical practice guidelines.

Arden Syntax is a formal procedural language that represents clinical algorithms as reusable medical logic knowledge modules. While the logic is portable the linkage with EHR elements is vendor specific. A number of vendors have implemented Arden Syntax in their own environments.

GELLO is an object-orientated query and expression language for clinical decision support. It is used for expressing logical conditions and computations in the GLIF guideline modelling language and is capable of extracting and manipulating data from EHRs. The data model is compatible with the HL7 Reference Information Model (RIM).

Discussion first involved problems identified by Medical Objects with the implementation of GELLO BNF. Problems had been found in implementing GELLO (an OCL2 grammar problem). After reworking the grammar GELLO was proven to work. A GELLO implementation guideline guide had been produced and an authoring tool (based on Grahame Grieve's data type OCL) was also available. This enabled RIM classes to be explored and the tool could also dynamically load a vMR. In short, this work brought the GELLO V1 standard up to implementation. It was not OCL compliant because the GELLO standard is not OCL compliant. It was agreed that these developments should be reballoted to produce GELLO V 1.1

Next, GELLO-GLIF implementation was discussed. GLIF 3.5 was published 2004, it mentioned GELLO but was never implemented. There was also an overlap between GLIF & GELLO with respect to logic. In a Medical Objects lymphoma example, GLIF was integrated with CEN 13606 Archetypes, and logic encoding was removed from GLIF resulting in a simplified GLIF with didactics embedded in XML and a single XML GLIF executable file. In short, the use of GELLO and Archetypes (or HL7 templates) reduced GLIF complexity and was implementation agnostic. GLIF 4.0 was suggested based on the above experience.

Guideline representation was then discussed. Bob Greenes (CDS Co-chair from Arizona State University) noted that a definitive Guideline model was yet to be anointed. There were many other models apart from GLIF such as PROGIDY, PRO*forma* and EON. It was felt the time was right to review the feasibility of doing a project reviewing guideline representation.

While there was no lack of need there had been past problems in reaching agreement about a preferred approach. In addition, guidelines ranged from making useful narrative available to clinicians, to implementing and monitoring specific clinical work flow for chronic disease management, such as diabetes. It was suggested that an initial approach would be to collect more use cases (the vMR project was driven by use cases).

Potential Action. Dr Harvey committed to discussing the possibility of putting up some Australian guideline use cases with the National Prescribing Service (NPS) &/or Therapeutic Guidelines Limited. Robert Dunlop (InfoMed, UK) was also interested.

There was also a useful presentation / discussion on the vMR concept led by Robert Dunlop InferMed, UK, and Barbara Mckinnon, McKinnon Associates, faciltator. There was a need to coordinate with the Public Health and Emergency Response (PHER) group (about immunisation data), continue work adding genomic / pedigree data and then pilot test the vMR / Care Record. There was also a need for a comparative analysis of HL7 vMR with CEN vMR (CHIME).

A final discussion involved the goals for future work on ARDEN, GELLO, GLIF, etc. There was a need for an authoring environment to assist knowledge engineering (via flow charts, decision tables, trees, etc); logic implementation (compilers, interpreters) and messaging standards (HL7 V3). Functional requirements for decision support were that the clinical information is computable (made explicit); supports a changing knowledge life cycle (separate knowledge from logic) and is readable and self documenting. It was felt that GELLO with a vMR might be the way ahead.

Potential Action. Dr Harvey noted that the personnel from Medical Objects in Australia had a practical, working implementation of GELLO-GLIF and there may be some benefit in them linking up with the NPS and/or Therapeutic Guidelines Limited to look at some test cases. The Medical Objects team said they were happy to demonstrate their work to the NPS if this could be arranged.

15. Clinical Genomics

The following comments draw heavily on a report from Dr Ken Harvey that focussed on several issues including Clinical Genomics – his full report has been provided as an accompanying document.

Co-Chairs: Kevin Hughes, Partners HealthCare System, Inc. Boston Massachussetts; Philip Pochon, CDISC; Amnon Shabo, IBM Research Laboratory, Haifa, Israel; Mollie Ullman-Cullere, Partners HealthCare System, Inc.

An introductory lecture was provided by Grant Wood of Intermountain Healthcare. The aim of the Clinical Genomics (Clin Gen) WG is to facilitate communication of clinical and personalized genomic data between interested parties. The focus of clinical genomics work is the personalization of genomic data by identifying differences in an individual's genome and the linking this to relevant clinical information. Data to be communicated includes a family history of disease and genetic data from testing such as BRAC2 genes (for breast cancer), genetic loci, alleles or genetic sequence data. If these are standardised then risk stratification algorithms can be applied and clinical decision support given. The family history, genetic data and risk analysis can then be stored in the HL7 EHR (which is being modified to accommodate this additional data).

The HL7 Family History specification is already a normative ANSI/HL7 standard

HL7 Version 2 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Genetic Variation Model, Release 1 passed its informative ballot.

The *HL7 Version 3 Standard: Clinical Genomics; Genetic Variation, Release 1*, which formalises the v3 genetic variation model, failed the normative ballot on this occasion but will hopefully be accepted as an ANSI/HL7 standard in 2009 after amendment and re-balloting. Incompatibility with the Clinical Statement pattern and other Lab/OO/PC models was the main issue.

Clin Gen WG activities at the Vancouver Meeting were concentrated into sessions on the Wednesday and Thursday (thereby clashing with the CIC meeting on the Thursday) and focussed on:

- Genetic Variation V3 Ballot – Overview, detailed reconciliation of ballot comments (over several sessions) and, in particular, amending the payload message to comply more closely complies with the Clinical Statement patterns and models from Lab, PC and OO WGs
- Concerns on the part of Clin Gen WG that attempts are being made to shoe-horn too much into v2 messages for Genetic Variation. A gap analysis is to be carried out to highlight areas which cannot be adequately conveyed using v2 and v3 information structures.
- Considering impact of new topics in clinical genomics practice and research (e.g. specimen handling, cytogenetics, representation of whole genome)
- Genetic Security - what security & privacy challenges are unique to genetic data?
- Discussion of vocabulary/coding and modelling issues: Act Class codes, LOINC efforts and pre-LOINC review processes, terminology for anatomical location, specimen collection information and specimen type codes, and the need for Clin Gen Domain Model and related update of information models
- Update on US HITSP Personalized Medicine Use Case - system to system interactions based on CCD (even if CCD not well suited to Clin Gen information), plans to include Pedigree in CCD model, relationship of Genetic Variation to HITSP CCD model
- Update on Family History standard implementation project and Implementation Guide development

- Status of Gene Expression Array Project and plans for its progression at the January WGM for May 2009 ballot

The Covance company has many affiliated organisations interested in passing genetic information with drug submissions to FDA. FDA has set up a voluntary submission of genetic information associated with the drug application with the idea of FDA gaining experience with genetic data becoming part of the normal submission process.

The Hughes riskApps developed by Massachusetts General Hospital and Newton Wellesley Hospital identify and manage women at high risk for hereditary cancer. This software is currently in use at seven breast and risk assessment clinics and is in the process of being implemented at several others. It is available on an open source basis. The system allows the patient to input her own family history and risk data using a Tablet PC or a clinician or staff member can enter data into the system through a desktop PC. The data is then analysed for breast/ovarian or colorectal risk, and a printout of risk information is generated [see: http://www.hughesriskapps.com/].

Australian implications. Several Australian research institutes are involved in genomic research and testing and should be interested in the standards and applications being formulated. There are also pharmacogenomic implications for drug development and deployment, both with respect to better targeting patient populations and minimising adverse effects of drugs.

16. Clinical Interoperability Council (CIC)

The Clinical Interoperability Council met throughout Thursday, 18 September with Dr Vince McCauley, Dr David Rowed and Max Walker being present in the meeting for most of the day and Grahame Grieve presenting at one session.

A total of 46 people attended at least one of the four quarters, with 18 being present all day with the average attendance being 2.7 quarters – indicating significant sustained interest in the CIC's activities.

CIC – Background

HL7 established the Clinical Interoperability Council in 2007 to bridge the gap between HL7's acknowledged technical expertise in clinical informatics and those who practise in various clinical domains.

The CIC mission includes collaborating with the clinical community to define requirements necessary for development of robust health data standards in various clinical domains. It is responsible for providing clinical expertise and defining clinical requirements – with a focus on clinical content, not the technology of standards.

It is also intended to provide outreach beyond HL7 and the ability to mentor new clinical groups as they come into the organization.

Specific aspects on which CIC may advise include: the flow of data in clinical settings, query characteristics from a clinical perspective, EHR content and trigger events, clinical guidelines, disease management protocols, decision support rules and focus, and other clinical issues.

A potentially significant but controversial element of the CIC's charter is a requirement that it establish processes whereby a master set of clinical data elements and their

attributes will be defined and maintained, to include for each data element: a name, a unique and unambiguous definition, units, data type and complete value sets. The stated aim was that (1) these data elements would eventually encompass the entire set of data elements required for all aspects of clinical care and the management of that care; (2) only one definition per term would be permitted; and (3) no one group is likely to use all data elements, but any data elements used would come from that master set.

The following observations are largely based on notes supplied by Dr Vince McCauley and Max Walker.

Co-chair Election

At the commencement of the Vancouver Meeting the CIC had three co-chairs – Ed Hammond (HL7/Duke – up for re-election), Brian McCourt (Duke Clinical Research Institute) and Crystal Kallem (AHIMA). The CIC voted to add a fourth co-chair position before holding the required election – with Ed Hammond and Dr Sam Brandt MD, PhD of Siemens Medical Systems, who is also a practising physician, being elected.

Clinician Participation – Outreach

While the CIC is well attended by clinicians already active within the HL7 community, it has yet to secure significant levels of outside interest and has developed an outreach plan to improve clinician engagement by identifying communities of interest with which engagement is being sought. Specific approaches proposed in the outreach plan, which were debated at some length included:

- CIC Public Web Site for publicity (rather than as a work area) – regularly updated, with event calendars, RSS feed, and navigable by the types of user interest e.g. Clinicians, professional societies, related standards groups, informaticists, academic programs, vendors
- CIC Canned Content – press kits, RSS feed, monthly articles to support professional societies and associations communicating CIC involvement and activities to their membership.
- Include CIC segment in the HL7 Ambassador Program for use with clinical groups and their academic conferences, meetings etc.
- Workshops and presentations at other professional meetings
- Personalized CEO visit

Cardiovascular (CV) /Tuberculosis (TB) data collection project

Anita Walden provided and update on the CV/TB data collection project, which is sponsored by the US National Institutes of Health and has been underway for some four years with the primary objectives of:

- Developing and publishing a set CV/TB-specific data standards and common data elements (including terminology, definitions and permissible values)
- Developing and documenting methodology for creating and implementing common data standards for Disease/Therapeutic specific disciplines
- Demonstrate that data collected for patient care can support multiple re-uses, including research and surveillance activities

Work is well advanced, with the following key activities having now been completed:

- Create stakeholder group 2004-5
- Create master data element list from healthcare and related secondary uses

  Since 2005, some 2000 candidate elements have been identified – most are general medical record items with significant overlap and similar elements appearing at different levels of granularity in different collections.
- Refine this into a set of data elements according to the ISO 11179 (metadata) standard along with clinical definitions for each of the data elements:
  - For CV examination – 21 data elements have been defined;
  - For TB, Release 1 had 90. Release 2 now has 137.
- Create a dynamic model of the domain represented through an activity diagram, using the UML standard – this was facilitated by Mead Walker
- Create a research representation of the data elements in the CDISC Study Data Tabulation Model (SDTM) form
- Make the resulting standards available to the public through an ANSI accredited balloting process; this was completed
  - For CV in May 2008
  - For TB in Sep 2008

The activities remaining to be completed related to the sharing of this information and its implementation in data collections and other relevant standards:

- Making the data elements and their definitions freely available via the National Cancer Institute (NCI) Enterprise Vocabulary Services (EVS) and CaDSR Tool – this activity was planned for completion in Oct/Nov 2008
- Representing the CV data elements in the HL7 CDA model that supports the *Quality Reporting Document Architecture (QRDA)* project.

The overall approach has been to:

- Standardise at source – where the data element arises in the healthcare process
- Regard each data element as unit of exchange – and to define it with sufficient specificity for semantic interoperability – working with HL7
- Include all Stakeholders with: CDISC representing research; CDC representation for, public health; professional societies for quality improvement and HL7 providing the healthcare information perspective.

The resulting standards (as balloted) address the following aspects:

- Section 1: Use cases and patient scenarios (Healthcare)
- Section 2: Data elements and clinical definitions (Universal)
- Section 3: Domain Class model (Healthcare) - model, classes, attributes, descriptions
- Section 4: Domain Activity diagram (Healthcare) – showing clinical processes within the CV and TB domains
- Section 5: Data collection forms (Research)
- Section 6: Suggestions for SDTM representation (Research) (TB)

HL7 Project scope statements are in the process of being revised (for CV) and reviewed (for TB) and need to reflect proposed governance and maintenance by HL7 in partnership with the CV and TB Global Stakeholders
Australian delegates noted that there do not appear to be any linked terminology or value sets but these may be added when submitted to CaDSR and that broad application of the process still has a high likelihood of allowing conflicting definitions of clinical concepts to be created – and in a non-computable form

TB Domain Analysis Model (DAM) Project

Anita Walden presented a project scope statement to continue work on the TB DAM with further data modelling to be undertaken by May 2010. This proposal was supported by the CIC and would be taken forward to the Domain Experts Steering Division (DESD) for review and approval.

Australian perspective. Should HL7 Australia approach respiratory physicians in Australia to see if they have any interest or ability in contributing?

Immunization (POIZ) DAM project

Abdul-Malik Shakir provided an update on the Immunization Domain Analysis Model (DAM) project sponsored by the Public Health and Emergency Response (PHER) Work Group.

The objective of this project is to create a DAM describing the use cases, stakeholders, activities, interactions, and static information models needed to express the requirements of PHER sponsored immunisation projects. This includes support for V2 and V3 messages, structured documents, EHR and PHR profiles, service specifications, implementation guides, templates and terminologies needed for immunisation.

The UML model for immunisation is almost complete and is being harmonised with the IHE profile, which is influenced by existing HL7 POIZ artefacts. See:
http://www.ihe.net/Technical_Framework/upload/IHE-PHDSC_Public_Health_White_Paper_2008-07-29.pdf

HL7 usage of the acronym POIZ to refer to the Immunization Domain remains a mystery to Australian delegates.

Australian perspective. Should HL7 Australia approach Medicare Australia to see if they have any interest or ability in contributing?

Long Term Care (LTC) Functional Status Proposal

Dr Isobel Frean (a senior Australian nursing administrator and clinical informatician now based in the UK) provided an overview the Long Term Care (LTC) Functional Status Clinical Data Element project proposal.

The intent is that the Community Based Collaborative Care (CBCC) Work Group will work with the Clinical Interoperability Council (CIC) to collaborate with the interRAI clinical community, to develop a Domain Analysis Model (DAM) that defines content, flow and other requirements in LTC and CBCC needed to define clinical data standards for the “functional status domain” of the InterRAI assessment tool using TB/CV methodology summarized above.

A more detailed proposal is expected to come forward for communication to CIC, CBCC and other involved groups at the January WGM in Orlando.

Diabetes DAM Project Proposal

Rachel Richesson presented a proposed project to develop a diabetes domain analysis model (DAM). CIC members voiced support for seeing a project proposal.

Health Records and Clinical Content

Dr David Markwell (Clinical Information Consultancy, UK) gave a general presentation on "*meaningful records from meaningless boxes"* - sharing some of his insights on health records, clinical content and associated terminological and semantic issues. Highlights from his presentation include:

- The principal reason for clinical data capture is for re-use
- Most traditional analysis of information flow works in the direction:
  capture => storage => retrieval

  Clinical needs flow in opposite direction from retrieval back to source
- A meaningful health record makes it possible to answer relevant questions accurately and efficiently and is reusable in different contexts such as:
  - Clinicians involved in direct patient care
  - Epidemiologists and researchers
  - Service managers at local and national levels

  To meet these varied requirements the health record content must be represented in ways that encompass multiple perspectives and re-use.
- A common model of "model of meaning" for health care data is needed to allow effective questioning and retrieval of clinically relevant data.
- This requires specifications of clinical data content to be linked to a common model of meaning (terminology) - with informaticians working on each side of the problem understanding and truly communicating at detailed level with those working on the other side.
- Need semantic operability before it is possible to attempt semantic interoperability:
  - HL7 DSTU for "HL7 Guide to use of SNOMED in HL7 V3" (TERMINFO) is a good start.
  - Also DSTU for HL7 Clinical statements
  - Work is progressing on binding SNOMED to CEN13606 and *open*EHR.
- For more information, refer to the presentation slides and published paper (in accompanying documents): *"Representing clinical information using SNOMED Clinical Terms with different structural information models"* by David Markwell, Laura Sato (NHS Connecting For Health) and Edward Cheetham (IHTSDO).

Registry of clinical data actions –Update on pilot project engaging with professional societies

Gary Dickinson presented an update on a pilot project engaging with health-related professional societies to create a registry of clinical data actions and attributes. Discussion questioned the value of focussing on actions and their attributes, rather than information content. The work is continuing but is limited to clinical groups active within HL7 for the present.

Data Types, Metadata, and the Quest for Knowledge

Grahame Grieve gave a presentation "Datatypes, Metadata and the Quest for Knowledge" based on material he originally presented to the Metadata Open Forum on 22 May 2008 where he looked at how the ISO Healthcare Data Types interact with the requirements for metadata registries. Main points included the following.

The rationale for having a healthcare data types standard – given that clinical data includes many types of data found elsewhere. The underlying reason is the need for a standard framework that allows incompleteness and uncertainty to be part of a computable information collection, which is not directly addressed by the more fundamental data types (e.g. ISO 11404) – so health "rolls its own" but with as much re-use as possible.

Many people in health and elsewhere strongly support the ISO 11179 series of standards for metadata – which are used to support registration, search and classification of data elements based on a range of metadata, including: element name and its classification, relationships, data format ("data type"), representation, size, allowable values etc

However, registries of data elements based on ISO 11179 are not sufficient to provide interoperability between health information systems. Used in this way, they suffer a range of problems including:

1. In data registries based on 11179, data elements are defined in terms of representation not semantics – these representations are not sufficiently bound to technology to allow semantic interoperability and are also not sufficiently bound to technology to allow technical interoperability.

2. 11179 definitions interact confusingly with data types defined by models in other specifications - "Can use health care data types without loss of meaning since there isn't much in the first place"

3. Grammar matters – as a general rule, HL7 specifications have had to define re-usability at a much higher level than individual data elements. The assumed context for HL7 data types is much broader than the statistical and research information collections that underpin most registries based on ISO 11179.

To support true interoperability, a metadata framework needs to be wider than that proposed by 11179 and must include formal (computable) statements about: Identification, Classification, Operations, Life Cycle, Constraints, Conformance Requirements, and Relationships. The quest is therefore for a Metadata Framework that makes everything computable – we need metadata everywhere on everything – but how can this be achieved?

The approach being used within health is to concentrate on domains, simultaneously analysing and addressing the use and information needs for Services, Messages and Documents:

- Messages work by passing documents around to provide a business service
- Services work by specifying messages that exchange documents to provide a business service
- Documents are passed around in messages in the context of a business service.

In terms of convergence between HL7v3 and ISO 13606, he noted that:

- Both HL7v3 and 13606 have fully specified (but different) reference models that give them a solid ontological foundation
- Through archetypes (13606 Pt 2) and constraint models (HL7 - DMIM, DIM, RMIM, HMD, MT, CIM, LIM, TIM) both have a means of being adapted to a wide range of health/clinical contexts
- Through HL7 XML ITS wire formats and the exchange formats in 13606 Pt 5 both have a means of being implemented and made to work
- Both are moving to be underpinned by the same ISO 21090 health data types that connect the space from conceptual need to implementation
- Both sit on the same base of terminology foundations (following principles of ISO 704)
- We're all trying to solve the same problem - convergence happens spontaneously but we can only see it if we look for it – taking a different perspective.
- There is growing convergence in how HL7 and others view the business domain and represent it as a dynamic model – with increasing potential for interconversion and sharing of object models underpinned by identical data types.
- There is some flexibility as wire formats are formulated and re-evaluated in light of new services-based paradigms.
- The challenge remains relating the 13606 reference model to the fundamental HL7 RIM.

In summary: the Quest for Ubiquitous Healthcare Interoperability is our Holy Grail; Metadata is the path; but the journey will never end

CIC Master Data Element Project Discussion

Ed Hammond presented concepts to be pursued by CIC to address its proposed role in managing the master data element project. Highlights from the discussion include:

- General disagreement with getting data elements from clinicians in a yet to be defined format (?CaBIG at NDIS)
- Concerns that attempting to use HL7/CIC as a clearing house for data elements overlaps or duplicates many other efforts in this area (e.g. 400 data elements in DEEDS). Many expressed disagreement with the CIC pursuing this goal.

- Concerns about the level of granularity being sought and mismatches between the level of detail needed in different contexts. Hammond considers that an atomic data element is at a level of granularity that supports use, independent of the context – however, whether data elements can become generalised and have meaning separate from their context is not agreed.

- It was noted that the CIC's role in this activity is more focused on strategic engagement and gaining input from the clinical community, rather than the technical aspects.

Other matters – future directions for CIC

The following were among the matters covered in discussion of the CIC three-year strategic plan and the next meeting

- There are many different clinical societies in the US operating at different levels of granularity. Priority for engagement is those clinical specialty societies that bridge the therapeutic areas

- If its efforts are to be focused internationally, HL7 needs a better mechanism to go out and get international clinical input. Good engagement does not include simply asking the clinical societies to come to HL7 and has to be sustainable for the life of the standards.

- More clarity is required as to whether HL7 is seeking to control a process or only wishing to catalyse? In the apparent absence of any other, perhaps HL7 could consider seeking to be an overarching organization to facilitate input from clinical specialties on health data standards matters

- At this point, HL7 is taking what it can get in the way of clinical input but is trying to provide an environment for clinical content definition to occur. Hammond's view is that the CIC will eventually be a council governed by the clinical professional societies..

- While CIC will hand off clinical content to HL7 work groups, it needs to create something sufficiently useful that it can be used by the technical folk.

- The solo practitioner community simply needs help getting an ambulatory EMR to work for them; providing data for accreditation, addressing major work flow issues, etc. They want to learn more about where clinicians interface with IT.

- It is an issue that the Government wants to define quality, but non-medical practitioners are defining the standards by which clinicians will be judged. This topic should be addressed during the HL7 sponsored clinical specialty society meeting in April. One clinical society has been generating guidelines for years, but it never occurred to them that someone else would take these guidelines and create quality measures by which clinical performance would be judged. There certainly are also issues with the data, for instance, with the definitions of allergy, etc.

- Quality organizations are requesting more and more data and the IT systems can't provide it. The issue isn't going to go away. We need to be able to get the data out of the system to support reporting requirements.

- Communicating the value of CIC to leadership of clinical organizations and societies remains a challenge.

- The CIC needs to leverage the HL7 Ambassador Program more effectively and ensure that it meets the needs of clinical audiences.
- Kristi Eckerson, Audrey Dickerson, and Laura Heermann volunteered to assist with development of a CIC communications toolkit and it was also noted that:
  - Tony Shannon is doing a series of workshops that might be of interest (Dipak Kalra)
  - The National Governors Association (NGA) is developing an outreach program targeted at clinicians that may help with the communication toolkit efforts.
- To stay informed of CIC meetings, projects and discussions, visit http://www.hl7.org/listservice/index.cfm to subscribe to the CIC email list service.

Next Face-to-Face Meeting at Orlando WGM in January 2009.

- Consideration was given to having a separate non-technical forum for clinicians and a more technical forum for addressing the technical issues.
- While CIC should focus on engaging clinicians, practising clinicians with technical capabilities consider that they have a unique perspective and shouldn't be excluded.
- More time for discussion among clinicians about their needs for health IT was suggested with more time allotted to hearing from the specialty societies.
- There is a need to discuss what should be in a clinical definition. Help is needed in defining common terms used within the informatics community (e.g., modeling, architecture, etc.) – putting them in context with clinical examples.

17. Community Based Collaborative Care

Max Walker is a Co-chair of the HL7 Community-Based Collaborative Care (CBCC) WG. *The following comments draw on notes provided by Max that, among other things, focussed on issues arising in the CBCC WG.*

The CBCC WG and its agenda is still dominated by issues surrounding consumer consent (eConsent) – with work on the eConsent specification being promoted by representatives of the US-DHHS Substance Abuse & Mental Health Services Administration (SAMHSA). This has been included for information in the current HL7v3 ballot[4] and will be the main topic discussed by the WG at the January meeting and, although many have questioned whether CBCC is the correct place for this work, other potential hosts (including Security, PC, EHR, PA and SOA) seem to have accepted its being progressed by CBCC – which means that progressing interoperability standards for the non-acute sector has now dropped to a lower priority.

It was strongly suggested at this WGM that Australia might lead the establishment of a project and form a new group to meet the requirements of non-acute health services (to enable progress to meet needs emerging from the sector as evidenced by activity in British Columbia and here in Victoria). It was also suggested that the scope include non-health Community Services. This avenue is to be pursued within Australia.

[4] Available as a .pdf at: http://www.hl7.org/v3ballot/html/domains/uvmr/docs/RCMR_Consent%20Topic%20for%20Comment.pdf

Proposed action. Max Walker to take up potential formation of a separate WG to progress interests in non-acute care and welfare service settings with Australian interests including IT-014-06 before the January WGM.

Other matters of importance to CBCC WG dealt with at the Vancouver Meeting included:

- The HL7 V2.7 Ballot was completed for Chapters 11 and 12 (Referral & Patient Care) – including features sought by CBCC and potential Australian users
- Isobel Frean (UK – formerly from Australia) presented the proposed draft project proposal *"Functional status clinical data standards – long term care"* to both the CBCC and the CIC (see above) with deliverables to be completed by Jan 2010 including:
  - A static content model of the domain (DAM), and
  - A dynamic model of the domain in an activity model

  CBCC endorsed the draft project proposal in principle for discussion, finalisation and approval at the January WGM in Orlando.

18. Electronic Health Record (EHR)

In recent times, the work of the EHR WG has increasingly focussed on:

- Developing and balloting profiles based on the EHR System Functional Model (EHR-S FM).

  The EHR-S FM is a full ANSI/HL7 standard that identifies functions that Shall, Should or May be provided in an EHR system (supplied by a health IT vendor).

  EHR WG work in this area is driven by the need for specifications (in the form of profiles) that can be used by the Certification Commission for Health IT (CCHIT) in the US to certify various types of systems for use by providers.
- Development and balloting of the PHR System Functional Model. Whilst having many similarities to the EHR-S FM the context for consumer-controlled shared PHR systems and the associated features are sufficiently different to warrant a separate PHR-S FM standard. Part of the challenge has been getting reasonable agreement on what constitutes a "personal health record system" for this purpose – in the face of vendors seeking to exploit the "PHR factor".
- General oversight of activities relating to EHR/PHR technology as implemented in health IT systems (rather than the content of health records, which is addressed by domain WGs), this includes:
  - Sponsoring research and white papers – in recent times this has focussed on PHR issues
  - Progressing the promotion of the flagship EHR-S FM standard to a full international ISO standard through ISO/TC215.

    In TC215, this activity is managed by WG8 (EHR Requirements), which has Standards Australia as the Secretariat. The HL7 EHR WG welcomes international input but is inherently US-centric and regularly needs to be informed and reminded of ISO and international interests.

On-going maintenance and synchronisaaton of the international version and HL7 version of this standard is an issue currently before the JWG (see section 8 above)

- Tracking and supporting other HL7 EHR-TC standards and specifications that are being progressed and through the ISO processes – notably the EHR Interoperability Model (the value of which is still widely questioned)
- Liaison with Clinical Domain WGs with a view to ensuring that they participate in the development of EHR-S and PHR-S profiles affecting their interests and that their requirements and activities are addressed in the underlying EHR standards – to this end there has been a regular joint "clinical salon" in the EHR WG program at each Working Group Meeting.
- Liaison with the Structured Documents WG (on developments in CDA and CCD), Security (related to , SOA, Terminology and other technical groups within HL7 to ensure that their activities are compatible with the longer-term vision of maintaining clinical records based on the principle that information should be generated once and re-used many time – to this end there has been a regular joint "technical salon" in the EHR WG program at each Working Group Meeting.

The above is borne out by the following tabular summaries of EHR WG activities and progress (past and present) – reproduced with thanks to John Ritter of Verizon, one of the WG's Co-Chairs.

Product		
	Level/Stage	Date
EHR System Functional Model and Related Profiles		
EHR-S Functional Model Release 1	DSTU	Jul 04
	Normative	Feb 07
Child Health Functional Profile	Normative – Not TSC approved	May 08
Emergency Department Functional Profile	Registered	Jun 07
Long Term Care Functional Profile Release 1	Informative	Ballot closed 08 Sep 08
Behavioral Health Functional Profile Release 1	Normative – Not TSC approved	Ballot closed 03 Aug 08 in reconciliation
Records Management & Evidentiary Support Functional Profile Module	DSTU	Jul 08
	Normative – Not TSC approved	Ballot closed 08 Sep 08
Regulated Clinical Research Functional Profile	Informative	Jun 08
Vital Records Functional Profile	In development	
Quality Functional Profile	Discussed	
EHR-S Functional Model Release 2	Scheduled	

Product		
	Level/Stage	Date
PHR System Functional Model and Related Profiles		
PHR-S Functional Model	DSTU	Jul 08

Product	Level/Stage	Date
Health Record Banking Functional Profile	In development	
Health Authority Functional Profile	In development Draft for reference	
Payer-Based Functional Profile	In development Draft for reference	
Provider-Based Functional Profile	Scheduled	
Research Functional Profile	Discussed	
Platform-Based Functional Profile (or Model if required)	Discussed	
EHR-PHR Interoperability (if not picked up by Provider-Based) Functional Profile	Discussed	
Mobile Device –based Functional Profile	Discussed	

Product	Level/Stage	Date
Interoperability Model and Related Profiles		
EHR Lifecycle Model	DSTU	March 2008
ONC / AHIC / HITSP Use Case Alignment with EHR/PHR System Functional Models		Some done; some ongoing
EHR Interoperability Model	DSTU	Feb 2008
EHR/IM CDAr2 Reference Profile for EHR Interoperability	DSTU	July 2008
EHR/IM Legal Profile		Under review
"Coming to Terms" White Paper	done	March 2007
Intersection of EHR Lifecycle Events and HITSP Privacy Foundation	draft	

Some of the specific topics addressed in EHR WG sessions at the Vancouver Meeting included:

- (Mon Q5) Birds-of-a-Feather session on PHR-S Functional Model, including:
  - Overview of the PHR-S FM and profiles
  - International outreach and use of the PHR-S FM and functional profiles
  - Discussion of EHRs and PHRs in developing countries
- (Tue Q5) Birds-of-a-Feather session on application of the EHR-S FM, PHR-S FM, and EHR Interoperability Models, covering:
  - AHIC/HITSP use-cases as examples for other realms
  - Use of the models for gap analysis
  - The results: what are they? for whom? how can others leverage them?

  - Launching similar efforts in other countries – opportunities for collaboration?

- (Wed Q1) EHR and PHR deployment in Developing and Emerging (DnE) countries – serving them better with HL7's EHR/PHR standards.

- International engagement over maintenance of the EHR-S FM standard in terms of – HL7 updating to a new Release 2 while Release 1 is still proceeding through the ISO approval process; capture and incorporation of international requirements in Release 2.

  Among the matters resolved was agreement to keep the EHR and PHR System Functional models system architectural neutral and to include references in them to existing international standards on EHR architectures and content (much of which originally came from Australia in the first half of this decade).

  A key question for HL7 is whether the proposed EHR-S FM R2 needs to be published as a DSTU for two years before going to normative ballot. The matter was still under consideration at the end of the Vancouver Meeting and is likely to depend on the extent of the changes that end up being been made.

- Gap analyses are being performed reconciling the EHR-S FM and PHR-S FM against the *ISO 13606 EHR communication* standard, *ISO/TS 18308 Requirements for an EHR Architecture, ISO/TR 20514 EHR definition scope and context*, and *ISO DIS 21090 Harmonized data types for information interchange* with a view to enhancing its compatibility with international standards work. There appears to be a gap in relation to data types.

- Brazil, Ireland, The Netherlands all reported on their use of the EHR-S FM. Brazil agreed to work on an international public health profile – addressing some of the WHO's statistical reporting requirements. Ireland has produced their own EHR-S FM profile for GP systems and the Brazilian's have also used it to profile payor applications.

- A presentation by Mitra Rocca at the Vancouver Meeting on *ISO/HL7 Personal Health Record (PHR) Survey Results).*

- Joint meeting with Public Health Emergency Response (PHER) WG to consider:
  - whether there are gaps in the ability of the EHR-S FM and PHR-S FM to meet PHER WG needs.
  - a report on efforts to produce EHR-S Functional Profile for (US-centric) Vital Records; and
  - international issues regarding Birth and Death Records.

- EHR-S FM Conformance Criteria – including results of the eClinical Forum's review of Q-REC's EHR-S conformance criteria vis-à-vis the HL7 EHR-S Functional Model.

- CCHIT reports that it has now certified around 50% of EHR vendor systems and is moving rapidly to formulate criteria and test scripts for the certification of PHRs with a focus on security, privacy and interoperability. Work started in July and CCHIT anticipates final (third round) public comment on its criteria to close in April 2009 – allowin PHR certification to commence from July 2009

- Translation of the EHR-S FM into Japanese and Spanish is under consideration.

The following are among some of the sources of EHR WG materials available online:

- The EHR WG website: www.HL7.org/EHR
- EHR-S FM and PHR-S FM Profiles are freely available at: www.NIST.gov/profileregistry

Anyone seeking further information on EHR WG and its activities may contact Richard Dixon Hughes, Co-chair of IT-014-09, who participates in many EHR WG meetings and subscribe to its online email lists. His email address is richard@dh4.com.au.

19. Implementation/Compliance (IC)

At the co-chair ballot conducted for the Vancouver Meeting, Jane Gilbert, Director of the AHML, at the University of Ballarat, was elected a Co-chair of the HL7 Implementation/ Conformance WG – congratulations Jane!

The following comments are based on notes supplied by Jane that focussed on issues arising in the IC WG. A number of other members of the Australian delegation also participated in some of the IC WG activities at the Vancouver Meeting.

19.1 Cypress Healthcare Test Tools Collaboration

Brought together by the US Government National Institute for Standards & Technology (NIST), a group of organisations has agreed to work toward harmonising conformance and interoperability of healthcare test tool projects. The organisations currently involved include: Canada Health Infoway, The US Certification Commission for Health IT (CCHIT), IHE, MITRE and NIST, but the group is open to any other interested party.

Cypress's intent is to harmonize, organize and extend capability (where appropriate) with the following main goals:

- determining the collective requirements of testing and certification bodies,
- identifying the available tools, frameworks, and tooling gaps,
- reducing duplication of tool development through an effective collaborative effort,
- providing a single source site to obtain or reference test tools and materials,
- providing a medium for open dialog among stakeholders, and
- establishing a functional model (and to a limited extent develop code) that integrates tooling projects under a unified platform.

The harmonization effort includes a broad range of standards and certification bodies including but not limited to: HL7 standards, IHE Profiles, Pan-Canadian Health Information Standards and others identified by HITSP, NHIM, CCHIT, with a view to building on activities such as

- IHE Connectathons
- CCHIT: EHR certification and Network (HIE) certification.
- NHIN: HIE and NHIE

The architecture is still under discussion and development but potentially includes addressing the focus areas of: testing requirements, test data and common files for use with testing models that include: Healthcare enterprise testing; Connectathon testing; pre-Connectathon; virtual Connectathon; company internal, and certification testing.

Contributions toward the work to date have drawn on experience with:

- IHE Gazelle (based on MESA toolkit) – used to support IHE testing
- MITRE Laika (used for CCHIT certification)
- Canada Health Infoway tools (for Pan Canadian Standards compliance), and
- NIST approaches

More information is available from the program website at:
http://collaborate.nist.gov/twiki-cypress/bin/view/Cypress/WebHome

Significance and recommendations for Australia

Failure of relevant Australian bodies (primarily NEHTA, AHML and IHE Australia) to keep abreast of and, where appropriate, contribute to and/or exploit the results of the Cypress initiative would risk:

- Australia potentially having more costly and slower eHealth systems compliance regimes; and
- Internationally accepted harmonized approaches to eHealth systems and interoperability testing not being initially designed and readily adaptable to meet Australian requirements.

19.2 DSTU Testing Guidelines project

The HL7 development framework (HDF) provides guidance on how to develop an HL7 standard but it does not provide guidance on how best to evaluate the standard. Without guidance on how to evaluate a standard it is the burden of each technical committee (TC) to determine there own methods of proving a standard is fit for purpose. In addition, implementers have no clear way to claim that a system conforms to an HL7v3 standard.

The goal of this project is to provide guidance to implementers on when a HL7v3 standard is stable enough to implement and a mechanism to ensure a system conforms to an HL7v3 standard. During the course of this project IC WG may need to make a distinction on when a standard is ready for early adoption compared to full adoption.

This project does not directly address the testing of locally produced implementation guides, but it may inform such activity. This may become the subject of a future project. IC WG suggested that they should add a section to the register to specify which implementation guide the product/service uses.

19.3 Other IC WG matters

1. **CDA Conformance Profiles.** No update was available as Sarah Ryan was not in attendance.

2. **V2.7 Ballot – Truncation Character.** Truncation Character was changed from <= to # (as the previous uses two characters).

3. **V2.8 Proposals – Conformance Levels**. Documenting conformance levels, Frank Oemig has proposed that a section be added to v2.8 to specify conformance levels. Concerns were raised with the wording of the levels, Frank will revise and circulate.

20. Laboratory

The following comments are based on a report from Richard Harding that, among other things, addressed issues arising at the Laboratory and associated WGs – his full report has been provided as an accompanying document.

20.1 Pathology Reporting to become Normative

The HL7v3 Pathology Reporting Domain has passed its balloting requirements and will become a normative US standard and potentially an ISO standard in due course.

This is a significant milestone whose importance should not be under-estimated. The data structures now defined are to be used not only in v3 messages but also to define structured Pathology data when it is contained in CDA documents.

After the myriad of options allowed by v2 for Microbiology results, there is now a single normative structure for Microbiology results in v3. This structure has been thoroughly investigated by at least two intending implementers who are now quite convinced that the normative structure is suitable for their intended usage, and are advocating its wider uptake.

The Pathology group had no time allocated to V2 issues at this September meeting. This was a direct consequence of dedicating all available effort to finalizing the normative status of the v3 Pathology Results Domain.

20.2 Increasing use of v3 for Pathology

Several countries, after formally evaluating the options, are understood to have made an informed choice to implement v3 structures, rather than v2 messaging, for transmission of pathology information. A report on progress in Brazil, indicated that v3 had been chosen over v2 for Pathology messaging for a number of reasons including v3's richer information content. Some problems had been encountered (tools too complicated, language difficulties etc) but these had been overcome with better training.

20.3 Future Progression of Laboratory WG Activity

Both the Laboratory WG and the Orders and Observation Work Group (OO) have closely related work programs and have had very variable participation rates among volunteers in recent years, making progression of the work difficult. O&O is responsible for developing the general patterns to be used for orders and results, coordinating and striving for consistency among the Pathology, Diagnostic Imaging, Pharmacy, Patient Care, Clinical Genomics and other similar Work Groups. It plays a key role in collaboration with the Patient Care and Structured Documents WGs in maintaining the Clinical Statement pattern used in both v3 messages and CDA

documents – and designed to be compatible with data represented via openEHR/13606 archetypes.

To resolve tis situation, the Laboratory and OO groups have decided that the only possible way that this work can continue with the current levels of participation is that Lab and OO merge into a single group. This will be done very soon; however, it may mean that progress on lower priority activities will be much slower, but there are no other options.

Significance and recommendations for Australia

As a result of these developments in the wider context of HL7 developments, Richard Harding concluded that:

1. The standardized structure for Microbiology results should be translated to v2 for use in current Australian implementations, if appropriate, in preparation for a later move to the same structure being implemented in v3 or CDA.

2. Never having been an ardent advocate for the implementation of V3 in Australia, he considers that the publishing of a normative V3 structure for Pathology results and the growing adoption of v3 by other nations suggests that it may be an opportune time for the Australian health informatics standards community to revisit its decision to use V2 and CDA to see whether those options remain appropriate for Australia for Pathology results and, in the more complex domains such as discharge summaries.

3. Upgrading the REF message to encode *open*EHR-style archetypes in HL7v2 messages is, at best, an interim solution to the problem of v2 messages being too simplistic for the richness which is required by users and that it may be time for Australia to look to a mainstream v3 approach (potentially leveraging *open*EHR/13606 archetypes).

4. Recent proposals at IT-014 to reconsider the current committee structure used to handle messaging and communication work is consistent with the proposed merger of Lab and O&O in HL7.

21. Patient Care

The following comments on PC WG activity are based on notes provided by Max Walker and Dr David Rowed.

The Patient Care (PC) Work Group is mainly working on coordinating the application of HL7 Version 3 (HL7v3) across a range of different clinical domains. It also supports balloting of relevant Version 2 work, which is principally driven by the Community Based Collaborative Care Work Group - led by Australia and directed at requirements coming via Standards Australia's IT 14/6/6 Collaborative Care Communications Subcommittee.

At a generic, non-HL7 level, PC WG is one of the leading groups addressing the definition and modelling and definition of clinical concepts.

With the Care Provision message (which supports referral, discharge and general clinical information messaging in HL7v3) and related sections being currently in the V3 ballots, PC is seeking to maintain all its current work on care structures and messaging at the level of a Draft Standard for Trial Use (DSTU) and defer taking it to final

normative ballot. The aim of this strategy is to get benefit from community review and implementation, allowing it to further refine these artefacts, but avoid the pressures of normative ballot reconciliation which would tie-up committee resources at Working Group meetings. In line with this approach, it will seek extension of the time limit for which material can remain in DSTU status before being compelled to go to formal, definitive ballot. This is a sensible strategy given the breadth of its work and the limited resources of its team who are of mixed clinical and IT backgrounds. In line with this approach, work on the Common Observation topic has been moved to Orders and Observations which will manage it through formal ballot, and will continue to develop it in collaboration with PC WG.

The Patient Care structures, models and R-MIMs are closely linked to other work done in EHR, Clinical Statement, Clinical Interoperability Council, and on Guidelines; the PC WG will clarify this in future ballot documents with clearer linkages to sections relating to these other domains and bodies.

PC WG is currently working on Assessment Scales, Problems and Problem Lists, Concern (this is essentially the tracking through time of conditions which may change their nature, issue status, and particularly, diagnosis as they link to ongoing observations and assessments), as well as the Care Record and Care Plan R-MIM structures, the last two being looked at for clinical data and protocols in Clinical Trial use with the R-CRIM group.

In Assessment Scales, the current DSTU material gives a value and total assessment scale, which cannot be used for some measurements (e.g. Bartel). A proposal from Frank Oemig adds some more detail so all different scores & assessment systems can be accommodated. This seems to provide a very flexible, generic model that covers off the area nicely.

The ongoing work on Problems is being done in association with, and clarifying its relationship to, Order Sets and Guidelines by working with the Decision Support WG and others working in these areas within HL7.

Care Transfer is undergoing more detailed work - with some requirements emerging from dynamic modelling of related processes (principally from Canadian implementation efforts) – and identifying the need for new trigger events.

The PC WG is closely associated with the HL7 and ISO Detailed Clinical Model (DCM) projects with William Goossen of The Netherlands being a co-chair/chair of each of these three activities and there is now an agreed list of 10 top priority items (starting with blood pressure) for which UML models are being developed, independently of the existing HL7, CEN, and *open*EHR reference models.

Australia needs to ensure this new work on DCM is relevant to our requirements and well integrated with other international activities so that it does not divert too many resources into what some might consider a academic activity potentially developing isolated models without the methodology to scale consistently to large numbers of artefacts and support community validation of the outcomes.

The Patient Care Glossary needs to be enhanced for ballot to include, and accurately reflect, the concepts for which PC WG is developing models - such as Problems. Dr David Rowed has agreed to do this in co-operation with Heather Grain, co-chair of the Vocabulary Group – this should be facilitated by both being located in Australia.

22. Pharmacy

The following comments are based on a report from Dr Ken Harvey that focussed on several issues including Pharmacy – his full report has been provided as an accompanying document.

Given the demands of concurrent sessions, Ken Harvey was only able to be present for one session where this was by itself and a joint session with Clinical Decision Support and PHER (where the immunisation model was reviewed).

Co-Chairs: Tom de Jong (HL7 Netherlands) and Garry Cruickshank (HL7 Canada).

The aim of this group is to assure that the HL7 messages and models concerning medication related information (including prescribing, dispensing, and administering medication) address the requirements of the many stake holders and variations in different countries.

Relevant issues under discussion included work on a "Common Product Model" that was consistent across medication, structured product statement (US FDA-approved product information), immunisation, food and devices. **In the Australian context**, this work should be of relevance to the TGA which is also involved in harmonisation of regulatory procedures internationally.

In addition, there were discussions about harmonising individual patient safety reports and the identification of medicinal products between ISO / CEN / HL7. This will be further discussed at the Istanbul ISO TC 215 meeting in October. **This work is relevant to the TGA** plans for an increased effort in pharmacovigilance including facilitating adverse drug reaction reporting from prescribing software.[5]

23. Public Health Emergency Response

The following is based on notes provided by Max Walker in relation to PHER WG activity.

Given that there can be many different Public Health functions and accompanying IT systems – such as: registries, reporting, monitoring, surveillance - there seems to be considerable overlap between the activities of the PHER WG and those of Patient Care in other health domains. To a large extent, the potential for overlap is overcome by PHER working jointly with a large number of other groups – while providing a specialised PHER focus and attempting to ensure that work affecting the PHER domain is well coordinated, compatible and addresses PHER needs.

With respect to its own agenda, the Committee has been doing extensive work around Immunisation. This has included mapping many data sets back to their sources (this, of course, could apply to other areas of Public Health as well). This brings out the issue – data can be captured in other areas than where the actual ownership lies. So PHER would like to mount a project in Collaboration with CBCC and Patient Care to look at how data can be accessed at its source, particularly in the primary health care areas.

This would seem to be a very valuable activity to perform, and would have been an ideal activity for CBCC in its original form.

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[5] Therapeutic Goods Administration. Enhancements to post-marketing monitoring (Pharmacovigilance framework and establishment of the "Medicines Safety Committee"). Available at: http://www.tga.gov.au/regreform/common.htm#post

24. Services Oriented Architecture (SOA)

Various members of the Australian delegation, including Dr Vince McCauley and Richard Dixon Hughes attended several of the SOA WG sessions. Max Walker presented on Thursday Q3, with Klaus Veil also attending.

24.1 Overview of SOA WG activity

The following are among the matters noted:

- The final agenda and a copy of the consolidated minutes of the SOA WG proceedings at the Vancouver Meeting are available from the Healthcare Services Specification Project (HSSP) website at:
  http://hssp.wikispaces.com/event-2008-09-HL7-Vancouver

  Other related resources may be found at:
  http://hssp.wikispaces.com (including the Practical Guide to SOA in Healthcare)

- Topics addressed at various SOA WG sessions in Vancouver included:
  - Overall introduction, update on status of HL7 SOA projects and confirmation of agenda
  - Walkthrough of the Entity Identification Service (EIS) Specification – discussion of EIS normative ballot outcome
  - Walkthrough of the Retrieve Update Locate Service (RLUS) Specification – discussion of RLUS normative ballot outcome
  - Walkthrough of the Decision Support Service (DSS) Specification
  - Presentations and detailed discussions with HL7 CTO, John Quinn, on the SAEAF architecture, the ArB activities that had led up to it, its implications for joint HL7/OMG work on the HSSP, and the future role of SOA WG in delivering Services capabilities within HL7.

    SAEAF and its main features are discussed as a distinct outcome of the Vancouver Meeting in section and are not repeated here. The same slide decks used in discussion with SOA WG have been included in the material accompanying this report.
  - Discussion whether revised charter needed for SOA WG, taking into account SAEAF and new roles of TSC and ArB.

    It was basically resolved with John Quinn and representatives of TSC and ArB that SOA WG should continue its present activities and that the introduction of SAEAF did not involve any immediate change in the way HSSP and the relationship with OMG should operate.
  - Presentation of DHSV Human Services Directory by Max Walker (Australia) and its progression as the basis for a Directory Services standard (see below).
  - Joint meeting with key CDS WG members to review proposal for balloting a Virtual Medical Record payload standard – to be compatible with RLUS and DSS as supporting services components
  - Joint session with PHER WG on Immunization - use cases and SOA
  - Joint work with Security WG on the roadmap for PASS (Privacy Access Security Services) project - in relation to audit, access control, context management and security services architecture (see below)

- Participation in joint technical sessions with INM, MnM hosted by INM
- Education/Outreach: - Open Health Tools / HSSP Discussion; Planning for 2009 SOA in Healthcare Conference
- Reconciliation of CTS II (Common Terminology Services Revision 2) ballot – to be put through Vocab WG with SOA WG assisting. CTS II is based on a service-oriented implementation of LexGrid.
- Hosting joint session on HSSP and IHE collaboration
- Work on completing the "Practical Guide to SOA in Healthcare" - with a focus on advice to providers and practitioners.

24.2 Presentation of DHSV Human Services Directory

Max Walker gave a presentation on the DHSV Human Services Directory (HSD) to the SOA WG and HSSP members and demonstrated the Directory in use.[6] The intent is to SOA-enable the application.

This generated considerable interest and discussions with Canadian, Finnish and Japanese colleagues involving use cases for non-direct-care (e.g., finding a wheelchair, meals-on-wheels, etc) and how they complement and tie-in with Health Provider activities. Examples of how this may fit within Canada, Finland and the US State Medicaid market were put forward.

There was consensus that the work should be progressed rapidly with a stretch goal of going to ballot with HSD for the January 2009 cycle. To achieve this, conference calls will resume weekly at 7:00 am on Thursday 9 October 2008 Australian Eastern Time.

Other actions were allocated as follows:

- Max will investigate web session setup and distribute details.
- Les Marcum will reach out to other Canadian provinces to elicit interest
- Juha Mykannen will elicit review from a Finnish perspective
- Co-chairs have an action to pave the path for ballot.

Further information on this project can be obtained from http://hssp-provider-services-directory.wikispaces.com/ with the current version of the specification at http://hssp-provider-services-directory.wikispaces.com/Active+Work.

24.3 Other topics addressed

SOA support for VMR

VMR projects plan to use HL7 Care Record DSTU message for passing clinical data to a CDS system and returning recommendations with CareStatement carrying patient data and CarePlan carryings recommendations. The CareStatement message needs to have a broad range of capability, including the ability to transfer genomic/pedigree data as these models become available.

[6] See http://humanservicesdirectory.vic.gov.au

Four VMR projects have been identified as likely early adopters with several giving presentations at CDS and other sessions at the Vancouver meeting (notably one on a asymptomatic cerebral aneurysm application).

Based on discussions at the SOA WG it was noted that VMR applications would use RLUS and the proposed clinical Decision Support Service (DSS). Ken Rubin suggested that this would probably involve creating a VMR profile for DSS.

Progressing RLUS and EIS from DSTU to normative

SOA WG now needs to plan to incorporate feedback from the RLUS and EIS DSTU documents into specifications for normative ballot as full ANSI/HL7 standards.

Known implementations of the specifications were discussed with it being noted that:

- EIS is implemented by Webreach (Mirth) and Intel
- RLUS has only been implemented fully by Intel – but others have implemented Locate and Retrieve services without Update (only implemented by Intel)

The company that employs Alan Honey is considering broadening EIS to handle a broader set of data than the current EIS, including some of the data required for RLUS.

EIS is intended to resolve identity for client, provider, and point of service ("things"). Practical implementations would probably have different instances of the service on different ports to do client and provider.

Alan Honey agreed to take lead on conversion of EIS DSTU to a full Standard, with ambitious plan to ballot for May 2009 – with an immediate task of creating a web page to collect EIS lessons learned and solicit suggestions.

Consideration was given as to whether it would make sense to ballot RLUS narrowed to a Record Locator Service or split the Record Locator out from RLUS as a separate ballot. Ken Rubin is following this up with early adopters, Intel.

SOA WG still needs to find an owner for RLUS to progress it to a full standard. It was noted that:

- OMG submitters for EIS and RLUS should be complete next week – and may be available shortly thereafter.
- Canadian work in BC, Ontario, Infoway may be a good fit for RLUS and potentially ownership for EIS.
- Lee Coller will be approached about Oracle interest in leading RLUS SFM revision for normative ballot.

PASS Project

The PASS (Privacy, Access and Security Services) project is being conducted jointly by HL7's SOA WG and Security WG. Its goal is to define a suite of services that will provide a simple interface for all privacy, access control, consent, identity management and other security services that are needed in a service-oriented health information architecture

The activity seeks to provide privacy and security services in a simple, loosely-coupled and transparent way so that the experts involved in creating clinical applications don't

need to spend time worrying about how the privacy security is done. PASS Services will be expressed as a suite of Service Functional Models (SFMs) as well as other documentation as specified by HL7 SOA WG. Currently, there are two PASS subgroups:

- The PASS Audit subgroup, which kicked off in March 2008, and
- The PASS Access Control subgroup which planned to kick off in November 2008 - as agreed during the HL7 WGM discussion in Vancouver.

Original (aggressive) goal was to get approval of the PASS requirements as a DSTU in the ballot cycle for resolution at the Jan 09 WGM. While PASS Audit is close to being ready for ballot, there remains a policy issue in relation to potential for privacy disclosure through audit services. The Security Committee has agreed to take ownership of the balloting process within HL7.

Current [December 08 OMG] expectation is that PASS would be going to HL7 ballot for the May 2009 meeting cycle, which would position it for OMG RFP in either June 2009 or September 2009.

Full details of the PASS project and current progress may be located online at: http://hssp-security.wikispaces.com/ .

25. Structured Documents (SDWG) and CDA

The SDWG had a very full schedule with a lot of work related to detailed reconciliation of comments arising from the following ballots:

- QRDA (Quality Reporting Document Architecture)
- HAI - HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports Release 1 – DSTU
- PHM – HL7 Implementation Guide for CDA Release 2 – Level 3: Personal Healthcare Monitoring Reports, Release 1
- DIR – HL7 Implementation Guide for CDA Release 2.0 Levels 1, 2, and 3 Diagnostic Imaging Report – Universal Realm - DSTU
- Operative Note - Implementation Guide for CDA Release 2.0 Levels 1, 2 (and 3) Operative Note (US Realm) - DSTU
- SDA Structured document architecture (129 comment rows)
- HL7v2 Chapter 9 (Medical Records)

Final decisions on disposition of most items were to be taken by subsequent teleconference.

Because of the pressure of workload, SDTC held reconciliation sessions in parallel with some of its joint meeting commitments, including the joint meeting with OO, PC and Templates on the Clinical Statement pattern traditionally held on Thursday afternoons. It is understood that there is a move to establish Clinical Statement as a separate WG.

QRDA (Quality Reporting Document Architecture)

- There were 58 comment lines to reconcile arising from ballot of the QRDA specification. The co-chairs had prepared proposed responses to most of the

comments – which were mainly at a very detailed level and relating to the exact wording used, rather than matters of principle.

- The document specification is intended to provide patient and population quality summary measures by automatic extraction of relevant measures and entries from a clinical EMR system.
- Originally requested by Paediatrics to record data for quality measures, the QRDA project potentially has much wider application, especially given the recent focus on clinical care quality measures sweeping across the US health care system.
- It was agreed that the initial ballot would be US Realm specific with later possible extension to International if resources are made available. However the project scope is not US Realm specific.
- Dr Vince McCauley participated in deliberations about QRDA and noted that:
  - Comments had been received concerning a mismatch between the narrative and entries. Where entry is of type = <DERV> ("derived" - should be case for all observations) then narrative must exactly match in semantics and be derived from the entry.

    This was particularly noted where an observation had been given an additional meaning of "initial" (e.g. Entry = Sat = 85% at date/time)

    Narrative cannot be "Initial saturation = 85% at dd/mmm/yy"

    It must be "Saturation = 85% at dd/mmm/yy"

    Semantic of "initial" should be modelled by an act-relationship or conveyed by a SNOMED expression
  - There was also discussion of whether patient-dependent "stratification" variables needed to be addressed differently to "aggregation" variables but no proposal was made to change the specification.

HAI - HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports Release 1 - DSTU

- There were 101 comment lines to reconcile arising from ballot of the HAI Implementation Guide DSTU.
- This DSTU was produced and developed as part of a suite of interoperable data standards for the CDC's National Healthcare Safety Network (NHSN) in the United States although the need was perceived to be international.

  The US agencies most directly involved were the Division of Healthcare Quality Promotion, National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), and Centers for Disease Control and Prevention (CDC).
- Substantive comments leading to 7 negative-major votes mainly related to limitations arising from incorrect use of vocabularies and code sets and failure to allow more Realm-specific flexibility or more broadly applicable terminology such as SNOMED CT.

PHM – HL7 Implementation Guide for CDA Release 2 – Level 3: Personal Healthcare Monitoring Reports, Release 1

- There were 21 comment lines to reconcile arising from ballot of the PHM Implementation Guide (IG).
- The document is designed to build on the HL7/ASTM Clinical Care Document (CCD) format (but does not conform to all aspects of a CCD)
- The UK NHS CfH (Ian Townend) submitted notes about concerns relating to:
  - Device Definition and modelling of device characteristics as part of a Supply act
  - Version management in relation to the underlying CCD specification and updates to that specification
  - Misuse of SNOMED terminology in a key example
- Major negatives mainly relate to need for greater conformity with broader CDA modelling and constraint management principles. Vocabulary/term sets are also an issue for some.

DIR – HL7 Implementation Guide for CDA Release 2.0 Levels 1, 2, and 3 Diagnostic Imaging Report – Universal Realm - DSTU

- There were 80 comment lines to reconcile arising from ballot of the DIR Implementation Guide DSTU.
- This was a joint ballot of II TC and SD TC next cycle for acceptance of the Diagnostic Imaging report specification in CDA. Most of the comments related to compatibility with Imaging Integration (II) for resolution by II WG, rather than SDWG.
- At previous WGMs there had been detailed discussion about how to implement DICOM context changes (e.g. for previous film comparison) and overall management of context in both the CDA header and the body – noting that context must apply to the whole document.

Operative Note - Implementation Guide for CDA Release 2.0 Levels 1, 2 (and 3) Operative Note (US Realm) - DSTU

- There were 15 comment lines to reconcile arising from ballot of the Operative Note Implementation Guide.
- The comments were heavily debated – with suggestions of the following improvements being provided by a practising surgeon - James G. Mhyre:
  - **Implants.** While what is implanted into a patient is typically recorded separately in the facility procedure record, the operative note is more widely available and should provide for structured capture of prosthetics and biological materials (including potentially: Product name Manufacturer, Model number, Serial number)
  - **Photographs:** Increasingly photographs and even video clips are used to document surgical work and capture observations (e.g. tumours) and need to be recorded in the electronic record as part of the operative note.
  - **Carbon Copies:** There needs to be an ability to direct rep orts to referring physicians at the time of recording the operative note The CC

list at the bottom not only directs the staff where to send copies but it notifies future readers who received a copy previously.

- **The Operative Note is only one of four records of the procedure.** For operations done in a hospital operating room, there are typically four record: the facility operative report created by the circulating nurse, the anaesthetic record, the surgeon's brief operative note typically hand written in the progress notes, and finally the operative note which is the subject of this DSTU. There is considerable duplication of data elements, many on all four documents. Some data elements are primary to one and copies on the others. The needle, sponge, and instrument counts described in the DSTU operative note are copies of the primary data in the facility record. It is not clear if they serve a role in the operative note and for these it does not matter what is documented in the surgeon's operative note, it is the facility RN operative report that contains the primary medico-legal data.

- Problems with the conformance criteria were prominent issues among the negative ballots.

- Complications to become a required entry – with the surgeon noting "none" if none were observed.

- It was resolved to recommend publication as a DSTU, incorporating the changes arising from ballot reconciliation. The outcome will be "socialised" with the various surgical professional societies.

SDA Structured document architecture

- There were 129 comment lines to reconcile arising from the SDA ballot.

- Comments were largely very technical with the more important issues relating to compatibility of derived artefacts with tooling, the underlying CDA DMIM, clinical statement pattern etc. Others related to a lack of clarity and/or explanation for such a fundamental specification.

HL7v2 Chapter 9 (Medical Records)

- Reconciliation took place Wednesday Q3 but notes on outcomes were not available.

Clinical Statement pattern – Joint Session

Notes from those present indicate that the following issues were discussed in the joint session on Clinical Statement hosted by OO for OO, PC, Templates and SD.

- **New Work Group status for Clinical Statement.** It was resolved to seek separate Work Group status so that it can schedule face to face meetings and conference calls as required. It was also noted that the Clinical Statement mission and charter will need to be reviewed and there will need to be at least 4 active participants in addition to each session chair.

- The Clinical Statement DSTU runs out the end of December and must be either withdrawn, re-balloted as a DSTU with a new model or balloted as a full normative ANSI/HL7 standard. There are some change request that had not been applied but the model has been progressively updated with the change requests on the Wiki.

It was resolved to finalise the updates and go to Normative Ballot on Clinical Statement Model in the May 2009 ballot round.

- There were 4 change requests approved and not yet applied – there were also requests sent to submitters requesting they review their old requests, prior to dropping them if they do not respond back.
- Required changes include harmonising with Pharmacy WG on Medication / Prescription and ensuring (two-way changes) for consistency between the Pharmacy DMIM and Clinical Statement model.

  Work in Canada is aligning Pharmacy and Medication models with the HL7 Models and linking them together.
- It would be helpful for the ArB to have some questions that could be used to indicate if a domain should be including the Clinical Statement model, rather than developing incompatible content and trying to harmonise later.

  It was noted that the ArB has agreed look at what it means to get other groups to link into Clinical Statement and will work with TSC on pulling this together.
- A bug fix is needed for DMIM tooling of printing attributes.
- There are a number of publishing issues to resolve in relation to the Visio tools and others to be reviewed with the publishing team
- The attribute definitions on the Clinical Statement model need to be updated and completed prior to going to ballot – volunteers are being sought to assist.
- CMETs – there are two of them that have not been touched for over a year. Patrick Loyd and Charlie McCay agreed to review what is needed to get them synchronised with the most current Clinical Statement pattern.
- Further consideration required on how Clinical Genomics material should be reflected in Clinical Statement.

26. Vocabulary

The Vocabulary Work Group had a heavy schedule with preliminary work on the Sunday and a full program of activities in each available quarter throughout the week.

Heather Grain is a Co-chair of the HL7 Vocabulary WG and is also Convenor of ISO/TC 215 Working Group 3 (Semantic Content).

The following comments are based on a report from Heather that, among other things, focussed on issues arising in the Vocabulary WG and associated meetings – her full report has been provided as an accompanying document.

A number of other members of the Australian delegation also participated in various Vocabulary WG meetings and activities at the Vancouver Meeting.

For further information on any of the topics presented in this section, contact Heather Grain (heather@lginformatics.com).

26.1 CodeSystem version and binding

[See Heather Grain's report for examples and detail on the implications and actions]

Requirement

Both public health and direct patient care need to be able to identify unambiguously the data values that were available for selection at the point in time when a value was selected. It is asserted that this requires systems to know the applicable version and ValueSet extension – explicitly.

Use Case

In an outbreak investigation for a newly defined disease (e.g. SARS) the ValueSet for assessing symptoms of the disease initially included only respiratory symptoms. As knowledge of the disease evolved, gastrointestinal symptoms were added. To understand the disease and mine the data collected about the disease over time it is necessary to know what potential values were available for recording at the time that data was collected. A problem arises if the time at which the ValueSet changes cannot be identified.

The version also needs to relate to the level at which the CodeSystem is set – eg: national, state, local organisational, community or service based. Each of these levels may use a different version of the CodeSystem at a given point in time. At the local point of service the version might be Hospital SNOMED-CT while the national code set may be SNOMED-CT Canada. The ability to specifically identify the version used at all levels of our systems is required to support clear identification both of meaning and of the potential codes available for representation at any given point in time in any given system.

Where you have a specific list, as in the SARS model, and you want to build a statistical model, you need to know the code set from which people chose their codes – which is identified by the underlying code set version.

ValueSets are not just a list of codes, they are codes drawn from CodeSystems. There are tables of values that are persistent and the ValueSet is a view of the table showing the currently used elements of that table. The questions of versioning a ValueSet and what is persistent and what is not are still to be addressed.

The management and use of data being submitted to central data collections (such as the CDC) by a wide variety of agencies can also be an issue as it may not be possible to simply identify how the different ValueSets in different environments are versioned. Overt and explicit version control is required over the ValueSet expansion (the codes resolved at a particular point in time) as the identification of a point in time only is not sufficient to identify the correct version.

There is a need to control and be able to compute the version as well as the effective date. There is currently a time stamp for a ValueSet or ValueSet expansion. The MIF includes the ability to indicate an effective date for a ValueSet as well as a version.

If the ValueSet version and all the versions referenced by that ValueSet are captured then the ValueSet can be reconstituted as it was at the relevant time.

Metadata supporting this requirement needs to be identified clearly and consistently applied in all systems - based upon the overall semantic and not an individual one. The Vocabulary WG agreed that metadata, including the following items, should be returned along with the enumeration:

- ValueSetVersion

- All CodeSystemVersions used will be returned, even if it is explicit.
- Where content definitions are evaluated based on nesting of ValueSets the metadata for those values sets should also be included.
- Software version used to generate content.
- If you are querying by concept domain and binding realm, the binding statement that was used in resolving to ValueSet.

It follows that there is a need for a review of the assertions made in the current documentation and how this impacts implementation.

Actions recommended

- These concepts be included in the ISO work on governance issues.
- Go back to the position that the change of a definition is a new ValueSet.
- ValueSets be versioned, on extensional definition where a ValueSet is enumerated.

Terminology Services and Versioning

Implementation of terminology services has identified that in a federated collection of terminology services a ValueSet the content of which is implied by a particular date is not stable across the collection of terminology services because it is dependant upon the update status of those services. It gets back to the importance of ValueSet governance, source of truth. The terminology services is to define specifically the reproducible ValueSet (with the content specific to the Version/Date).

Actions required

- Provide input to ISO work on governance of terminological systems.
- NEHTA and State initiatives to be aware of the issue and provide feedback on standardization through IT14 WG2.

26.2 Core Principles Document

The Core Principles document aims to provide an introduction to the use of models and vocabulary in HL7 messages and as such must be comprehensible not only to those familiar with HL7 but also to those new to the development of these messages.

The initial document was confusing and inadequate though the objective is strongly supported. The meeting discussed many changes required and agreed on the direction of these changes.

A new version of the document is to be developed prior to the next meeting (January 2009) and it is to include the principles, the rationale behind those principles and examples that make the intent clear.

Implications for Australia

This document is likely to be of great value to those implementing systems in Australia and as such should be widely distributed for comment (outside the normal HL7 community) when it has reached a suitable state of completeness.

26.3 CTS SOAP interface

Russ Hamm presented a demonstration of the CTS SOAP interface. Working with Intel an architecture and tooling have been developed that will allow the use of CTS to support their SOA expressway for healthcare, but specifically to enable CTS APIs to be accessed via a service oriented approach and messages over the web.

Based upon Apelon's distributed terminology server (which includes a browser and plug ins) and installed DTS server instance was developed with the CTS server interfaces installed over the top as wrappers. This is implemented in Oracle or SQL server, which is where the codes and applications are held. The DTS server has APS that are able to extract the terminology content (for access and update) by the client APIs. The functionality of DTS is wrapped in a CTS terminology call. You can download a plug in to DTS, install it and you can access your terminology using a CTS call.

Implications for Australia

NEHTA terminology project and those working on terminology based issues in the States and the wider health information management sector need to be aware of these developments.

26.4 Multiple instances of original text with coded representation

The issue of how original text should be provided with a coded representation in order to represent clinical meaning consistently and accurately was discussed.

The current HL7 specification says *"what the user saw as a representation of the code on the data input screen, or in the situation where the user dictates or directly enters text, is the text entered or uttered by the user"*. The question raised was what happens if both occur? For example: where a concept is entered free-hand and then a code is selected from a drop-down, both of them might be 'seen' by the user. Which of the two takes precedence?

Discussion suggested the following principles should be applied:

- Where text is typed, and coded automatically or changed in some other automated way, the text typed is the "original' text,
- Where a description is chosen off a drop down list it is the description shown on that list that is the original text.
- If you enter a concatenated phrase it would be that phase that the user saw/chose as data entry.
- In cases where this is ambiguous concatenation of the text should be considered.

There is a need for a clear user interface design and local policy with the intent being to clearly retain the original meaning.

It was agreed that the text is the text as seen and/or selected by the user who entered the data and which represents the intended meaning of the user. Local implementations may influence what is required to represent that original text. Discussion on this and the development of additional use cases will be ongoing.

Implications for Australia

Local developers of clinical software systems and Clinical Information System implementation projects need to consider these issues and be aware of the implications.

26.5 Common Terminology Services (CTS)

Disposition of comments received on the ballot of the CTS document was undertaken at the Vancouver Meeting. A new version of this document will be produced for a further round of balloting.

Future action

NEHTA terminology project and those working on terminology based issues need to be made aware of the document when it nears completion (estimated mid next year).

26.6 ValueSet conformance and where it should be captured

When binding or defining a ValueSet there is a need to be able to differentiate the conformance expectations for the various codes in that ValueSet, and, also, its attributes. Is a code or attribute 'required', 'not supported' or 'undeclared(optional)'. It may be that some codes in the ValueSet might be 'required', while others remain 'undeclared'.

(There might be a requirement to distinguish further about what sort of 'support' is expected for required codes – i.e. required for display or for capture. Similar requirements might apply to attribute conformance too).

There might be a need to have different ValueSets for sending and receiving. (E.g. when receiving, all codes are required; when sending, some or all codes are optional.) Mechanisms are needed to make these distinctions are needed when doing a context binding - perhaps by distinguishing the concept domains for receiving vs. sending?

The possibility of defining multiple context bindings (Concept Domain, Binding Realm, ValueSet) with a property that differentiates 'for sending', 'for receiving' or 'both' is to be considered.

A proposal for 'code conformance' is to be discussed on a future Vocabulary WG call and to coordinate some MnM and Vocab joint calls to progress this work. Will do final refinements at the interim meeting and include the resulting content in the next release of the Core Principles document.

Future action

NEHTA Terminology project and those working on terminology based issues need to be advised of the document when it nears completion (estimated mid next year).

26.7 CodeSystems and Identifier systems

The Vocabulary WG has been investigating the difficult issue of when a CodeSystem (CS) should be declared and when an Identifier system (II) should be used?

Stan Huff and Ted Klein presented an introductory document to clarify this issue and present a solution. For more detailed exposition of the detailed arguments and examples – refer to Heather Grain's report in the documents accompanying this report.

It was noted that:

- The fundamental difference is whether the attribute in question is being used to identify the class to which an object instance belongs or whether it is being used to uniquely identify an object instance within a class. CD datatypes are applicable for the former and II for the latter.
- In some domains a system of codes/identifiers might be used use as the basis for an Identifier System (with II datatype) and in other domain models that same set of identifiers would be used as a CodeSystem (with CD datatype) – e.g. the same country codes can be used for citizenship (as an attribute with type CD) or to identify a country record (type II).
- An attribute used in a domain model to uniquely identify some object should be an II.
- Conversely, if it does not potentially identify an object in the domain model, then it's probably a CD. For example: a laboratory test – to identify the test done, you use a LOINC number, but the test itself is the order number.
- Identity resolution can only be done with II data types. Registration of entities is about identity and should use II – with numbers being assigned for the purpose of unique identification of an instance within a class. – with the value being only used for identification and for no other purpose.
- Some attributes such as drivers licence number does not clearly fall into either option. It is a choice, and the type must be declared when documenting the use case and developing the model.
- If terminology behaviours (such as synonyms, language specificity, relationships and reasoning logic) or CodeSystem machinery (such as Domains and ValueSets, synonymy, Print Names/Display Names, translations, etc) are to be supported, then a CD datatype should be preferred.
- Unlike CD, the II datatype does not provide inherent operational ability to recreate enumerated lists.

The Vocabulary WG considers there is value to be offered in giving guidance on each, through the definition of use cases. Such a guideline should also include identification of the implications of the choices made.

Actions required

Further discussion on this issue is required within HL7, and may represent a case for datatypes being managed functionally rather as a structural element. National and State initiatives need to be aware of these issues and discussions, which are expected to be ongoing for some time.

26.8 ISO international health informatics glossary

The purpose of the ISO standards glossary project is to provide a harmonized and consistent approach to the use of defined terms and glossaries in global/international health informatics standards.

A glossary tool (SKMT) is still in development based on a Canadian prototype, with a trial having been undertaken. The ability to handle different cultural and linguistic variations in terms is included in the tool, including spelling variations between US and UK English (colour and color).

Hugh Glover (UK) requested that the learning of the glossary process be forwarded back to the ISO TC responsible for ISO 11179 for their action to update metadata registry requirements and harmonize with the units of measurement work. Heather Grain will incorporate this into the objectives of the harmonized glossary process.

Action required

It would be appropriate for DOHA, NEHTA, the States, HL7 Australia and IT-014 to consider how they might use this work (and the associated tools) and make those involved in health informatics aware of this work when it is openly available (anticipated to be mid next year).

26.9 Terminology and standards harmonisation

Progress in relation to the Joint Initiative Council (JIC), the JWG, the initial work on the cataloguing of standards and the identification of gaps is reported in section 8 above.

From a terminology viewpoint, the UK work on an inventory for the EC Mandate M/403 classifying the core content of each standard according to its relationship to areas of application, process and/or technology was noted. It is considered that this work might have longer-term potential for managing the global health informatics standards portfolio. There is also a possibility that the EU might fund an ongoing work program from this process. There essential element has been work on identification of key words associated with each of the standards documents to assist in referencing and retrieval of documents. The ISO international health informatics glossary work may also support development of standard keywords.

In more practical terms, the principles of harmonisation are being followed in the Vocabulary space with each of HL7, ISO, CEN (and potentially others such as CDISC) becoming clearer about their own and the others' roles. This is supported by a growing level of cross-participation of key individuals

As an example, in relation to the issue of CodeSystem and ValueSet versioning (as described in section 26.1 above), the HL7 community are documenting and standardising the method for representation and communication of versioning, while ISO will develop procedural standards for the management of versioning that considers

the international, national, state and local requirements and variations. Active decisions to divide work activities between the organisations has not occurred before and is a great move towards a more coordinated and cohesive approach to standards development. This has been achieved largely through cross-membership of committees.

Proposed action

Ongoing Australian support of cross-representation between HL7, ISO and IHTSDO offer significant opportunities to simplify and speed the process of standards development and the avoidance of inefficient overlaps.

27. Security and Privacy Vocabulary Project

This project will provide additional vocabularies needed for the HL7 Role Based Access Control – Healthcare Permission Catalogue. The current vocabulary does not contain security-oriented constraints required by the role engineering process. In particular, there is no mechanism to express time, location, cardinality and other separation of duty policy constraints typical of a health care environment such as.: time of day, location, separation of role/functions.

Privacy and consent catalogue. The vocabulary does not contain a patient privacy and consent oriented constraint vocabulary capable of enforcing patient consent directives or personal preferences.

There is a new topic proposed on composite privacy consent directives that will require such a vocabulary (see section 17 above) and January 2009 ballot materials at:
http://www.hl7.org/v3ballot/html/domains/uvmr/docs/RCMR_Consent%20Topic%20for%20Comment.pdf

The main difference is the need to query shared secrets and how this will function for a service oriented architecture. A set of use cases is being developed for presentation at the January Meeting in Orlando.

Implications for Australia

Though it is heartening that greater cohesion is emerging on these issues, there are still difficulties in having the US address its requirements in collaboration with those of the rest of the international community. This issue requires ongoing attention and oversight.

27.1 Terminological systems - conformance, maintenance and governance

ISO work items on maintenance, governance and conformance of terminological systems are evolving and will be made available to the HL7 Vocabulary WG for review and input.

Action required

As Convenor of ISO/TC215/WG3, Heather Grain will ensure that HL7 discussion on version management from the Vancouver Meeting is considered by WG2 for inclusion in the evolving documents on terminological systems within ISO.

27.2 Pharmacovigilance terminology

HL7 pharmacovigilance terminology work focuses on identifying the syntax of names to be used in describing pharmaceuticals and the description of their properties. The code for laboratory results will be impacted by the structure defined in this work. This includes maintenance of terminological systems for pharmacovigilance – and this requires harmonization with the WG3 activities in ISO where consideration of generic maintenance and governance activities are being defined.

Reference ranges are also being considered but this requires further work before it will progress due to the issues related to HL7 messages. These work items are designed to be generic as the actual content differs over item.

Action required

NEHTA, TGA, NPS and State initiatives should be advised of this activity (along with other pharmacovigilance standards work) and be invited to contribute.

27.3 Harmonization of terminology models for V3 and V2

It would be desirable to have the power and strength of the terminology model from V3 incorporated into V2 terminology representation. This will guide appropriate terminology use for V2 implementations and allow a single set of terminology tooling to handle a single HL7 terminology set that is based on a single HL7 terminology model. There may be less divergence in the actual models than first thought, much of the difficulty relates to the terms used to describe different concepts.

Version 2 joins many of the concepts of versions, ValueSets, CodeSystems together and this work will assist in disentangling these and support the linkage to static models (including fields) using the same V3 processes for binding. It is intended that this work will be developed incrementally.

ValueSets in V2 do not include formal codes for flavours of null. This (and other issues related to backward compatibility) will need to be addressed as a part of this work. The coded data types must support the terminology model.

This issue will be included into the Vocabulary Workgroup work plan and will be progressed in close collaboration with the InM WG

Further discussion of this will occur at the January WGM in Orlando.

Action required

NEHTA should be kept advised of progress of this work as this will make the mapping/representational components between V2 and V3 less painful.

27.4 Vocabulary and Meaning in Standards

The need for health informatics standards developers and health information systems implementers to understand of the importance of vocabulary as it relates to implementation of meaning in health information systems in general (and not just clinical systems) was discussed. The fact that this issue is not well understood outside the Vocabulary Work Group was seen as a problem which HL7 needs to address. A strategy for addressing this issue was not identified.

27.5 Perceptions of IHTSDO

Dick Harding noted in his report on the Vancouver Meeting (see separate report in the documents accompanying this report) concerns expressed by several delegates about their perceptions of the effectiveness and responsiveness of the newly-formed International Health Terminology Standards Development Organisation (IHTSDO).

He noted two quite distinct conversations in which different people (who he believed to have reasonable expertise of practical SNOMED usage) expressed their disappointment at the way IHTSDO was heading. They perceived it to be a huge bureaucracy of bewildering complexity, they noted that the well-known instances of inconsistency and sheer bad terminological practice had not started to be addressed and expressed some scepticism that SNOMED could ever be developed in a timely and quality fashion.

Attachments

Attachment A – HL7 Plenary & Working Group Meeting Vancouver 2008 – Meeting Schedule

The full program for the Vancouver Meeting was extensive and encompassed the following Work Group meetings and other scheduled activities set out in the following schedule. Areas of Australian interest and involvement have been highlighted, with those of greatest Australian interest and/or actual participation being shaded more heavily.

The tutorial, information and examination sessions have also been included as it is important for most new delegates to attend some of these during their first few working group meetings to ensure that they have relevant background for engaging in more detailed standards development activities.

Some 30 sessions are joint sessions shared between two or more WGs (out of a total of around 350 distinct sessions excluding tutorials); however, several of the larger WGs break into several smaller groups, which is not reflected in the

[Session codes: 0=pre-breakfast (0700); B=General Breakfast Session (0800-0900);
1, 2, 3, 4 = the four HL7 “quarters” during the day; L=Lunch session (1230-1330);
5=Quarter 5 (1700-1800); 6=early evening (1800-1930); D=Dinner session
E=Evening (1900 until late)]

	Sat	Sun	Mon	Tue	Wed	Thu	Fri
General & technical governance meetings							
Australian Delegation Pre-meeting	----5	-----	-----	-----	-----	-----	-----
Affiliates’ Council (AC) Meeting	--	123--	-----	-----	-----	-----	-----
JWG ISO/CEN/HL7 SDO Harmonisation	--	---45	-----	-----	-----	-----	-----
HL7 Plenary – 2008 (CEO report from 0800)	--	-----	B12--	----	-----	-----	-----
Technical Steering Committee (TSC)	1234	------6	----	--L--	-----	-----	-----
Architecture Board (ArB)		12---	----	---4	---4	--34-	----
Co-Chair Information Meeting	--	-----	---5D	-----	-----	-----	-----
Steering Div Mtg – Domain Experts	--	-----	------E	-----	-----	-----	-----
Steering Div Mtg – Foundation & Technology	--	-----	------E	-----	-----	-----	-----
Steering Div Mtg – Structure & Semantic Design	--	-----	------E	-----	-----	-----	-----
Steering Div Mtg – Technical & Support Services	--	-----	------E	-----	-----	-----	-----
Report s of TSC/ArB, AC, Marketing to WGM	--	-----	-----	B-----	-----	-----	-----
Board of Directors Meeting	--	-----	-----	--4>E	-----	-----	-----
Report of Board to WGM	--	-----	-----	-----	B-----	-----	-----
Management report & official presentations	--	-----	-----	-----	-----	B-----	-----
Clinical Interoperability Council (CIC)	--	-----	-----	-----	-----	1234-	-----
Marketing Council	--	-----	---4--	-----	-----	123--	-----
Education Committee	--	-----	--34-	-----	-----	---34-	-----

	Sat	Sun	Mon	Tue	Wed	Thu	Fri
Electronic Services Committee	--	-----	-----	-----	--34-	-----	-----
Governance & Operations Committee (GOC)	--	-----	-----	-----	12--	-----	-----
International Mentoring Committee	--	-----	-----	-----	-----	--34-	-----
Outreach Committee For Clinical Research	--	-----	-----	-----	----5-	-----	-----
Process Improvement Committee	--	-----	-----	-2L3-	-----	-----	-----
Project Services Committee	--	-----	-----	-----	---4-	-----	-----
- Project Facilitators Roundtable	--	-----	-----	-----	--L--	-----	-----
- PMO Project Insight tool presentations (alt's)	--	---4-	-----	-----	-----	--3--	-----
Publishing Committee	--	-----	-----	-----	--34-	--34-	-----
Tooling Committee	--	-----	-----	12---	-----	12---	-----
Technical work group (WG) meetings							
Anatomical Pathology (AP)	--	-----	--34-	12---	-----	-----	-----
Anaesthesiology (Gas)	--	-----	-----	1234-	-----	-----	-----
Arden Syntax (AS)	--	-----	-----	1234-	-----	-----	-----
Attachments WG	--	-----	--34-	123--	123--	12---	-----
Clinical Context Object Workgroup (CCOW)	--	-----	-----	-----	1234-	-----	-----
Clinical Decision Support (CDS)	--	-----	---4-	1234-	1234-	-----	-----
Clinical Genomics (Clin Gen)	--	-----	-----	-----	1234-	1234-	1----
Community-Based Collaborative Care (CBCC)	--	-----	--34-	--34-	12-4-	-----	-----
Electronic Health Records (EHR)	--	-----	--34-	1234-	1234-	12---	-----
- EHR BoF Sessions – Implementation feedback	--	-----	----5	----5	-----	-----	-----
Emergency Care (EC)	--	-----	-----	1234-	1234-	-----	-----
Financial Management (FM)	--	-----	-----	1234-	1234-	1234-	-----
Government Projects (GP)	--	-----	-----	--34-	-----	-----	-----
Health Care Devices (Dev)	--	-----	--34-	1234-	1234-	1234-	1234-
Imaging Integration (II)	--	-----	-----	1234-	1234-	-----	-----
Implementation/Conformance (IC)	--	-----	--34-	1234-	12L34	12---	-----
Implementation Technology Specifications (ITS)	--	-----	-----	-----	--34-	1234-	-----
Infrastructure and Messaging (InM)	--	-----	--34-	123--	1234-	12---	12---
Laboratory (Lab)	--	-----	--34-	1234-	1234-	1234-	-----
Modelling & Methodology (MnM)	--	--34-	--34-	1234-	1234-	12---	12---
- MnM Facilitators Roundtable	--	-----	-----	-----	-----	--5>E	-----
Orders & Observations (O&O)	--	-----	--34-	1234-	1234-	1234-	12---
Patient Admin (PA) & Scheduling Logistics (SL)	--	-----	--34-	1234-	1234-	1234-	-----
Patient Care (PC)	--	-----	--34-	1234-	1234-	1234-	12---
Patient Safety (PS)	--	-----	--34-	1234-	1234-	1234-	-----
Pharmacy (Pharm)	--	-----	--34-	1234-	1234-	1234-	12---

	Sat	Sun	Mon	Tue	Wed	Thu	Fri
Public Health Emergency Response (PHER)	--	-----	--34-	1234-	1234-	1234-	-----
Regulated Clinical Resrch Info Mgt (RCRIM)	--	-----	--34-	1234-	1234-	1234-	-----
RIM-Based Application Architecture (RIMBAA)	--	-----	--34-	----56	-----	-----	-----
Security (Sec)	--	-----	--34-	1234-	123--	1234-	-----
Services Oriented Architecture (SOA)	--	-----	--34-	1234-	1234-	1234-	-----
Structured Documents (SD) [i.e. CDA, CCD &c]	--	-----	--34-	1234-	1234-	1234-	-----
Templates	--	-----	-----	--34-	-----	-----	123--
Vocabulary (Voc)	--	-----	--34-	1234-	1234-	1234-	12---
- Vocabulary Facilitators Roundtable	--	--3--	-----	-----	-----	-----	-----
Information, tutorial & training meetings							
HL7 Ambassador Briefings	--	-----	-----	0----	0----	-----	-----
Official Networking Reception	--	-----	-----	-----	------E	-----	-----
First-Time Attendee & HL7/Process Orientation	--	----56	-----	-----	-----	-----	-----
(alternative times)	--	-----	0------	-1---	-----	-----	-----
New Co-Chair Induction Training	--	-----	-----	-----	-----	0----	-----
Tut – v3 Implementation for Project Managers	--	-----	--34-	-----	-----	-----	-----
Tut s- Intro to v3 (2-part series)	--	-----	-----	1234-	-----	-----	-----
Tut – v3 XML ITS and Data Types	--	-----	-----	-----	12---	-----	-----
Tut – v3 Message Wrappers & Transport	--	-----	-----	-----	--34-	-----	-----
Tut s – v3 Messaging Implementation(2-part series)	--	-----	-----	-----	-----	1234-	-----
Tut – HL7v3 and Public Health	--	-----	-----	-----	12---	-----	-----
Tut – RIM-derived Relational Database Design	--	-----	-----	-----	--34-	-----	-----
Tut – HL7v3 RIM Certification Test Prep	--	-----	12---	-----	-----	-----	-----
Exam - HL7v3 RIM Certification	--	-----	-----	-----	-----	---56	-----
Tut – TermInfo & SNOMED CT	--	-----	--34-	-----	-----	-----	-----
Tut – Introduction to Vocabulary	--	-----	-----	12---	-----	-----	-----
Tut – Advanced application of Vocabulary in HL7	--	-----	-----	--34-	-----	-----	-----
Tuts –CDA (2-part series: Intro & Advanced)	--	-----	-----	-----	1234-	-----	-----
Tut – CDA Specialist Certification Review	--	-----	-----	-----	-----	12---	-----
Exam – HL7 CDA Certification Exam	--	-----	-----	-----	-----	---56	-----
Tut – Electronic Health Record	--	-----	--34-	-----	-----	-----	-----
Tut – Personal Health Record	--	-----	-----	-----	12---	-----	-----
Tut s- Intro to v2 (2-part series)	--	-----	-----	1234-	-----	-----	-----
Tut – v2.5 Control Specialist Certification Review	--	-----	-----	--34-	-----	-----	-----
Exam – v2.5 Control Specialist Certification	--	-----	-----	-----	-----	---56	-----
Tut – SOA in Health Care IM/IT	--	-----	--34-	-----	-----	-----	-----
Tut–Imaging Interoperability: DICOM, HL7 & IHE	--	-----	-----	-----	--34-	-----	-----

	Sat	Sun	Mon	Tue	Wed	Thu	Fri
Tut – HL7 Development Framework	--	-----	-----	-----	-----	12---	-----
Tut – V3 Specification Development Tools	--	-----	-----	-----	-----	--34-	-----
Did not meet in Vancouver							
Paediatric Data Standards WG (PDS)	--	-----	-----	-----	-----	-----	-----
MITA Project	--	-----	-----	-----	-----	-----	-----

Attachment B – HL7 Technical Organisation and Work Group Structure

As covered in previous reports on HL7 Working Group meetings, the Technical Steering Committee has been restructured from a large gathering of all co-chairs into a smaller, formally constituted organisational unit with overall responsibility for working with the CTO in managing HL7's technical work program. It has the following structure and membership:

Position/Role	Person
Chair, TSC (& International Representative) (to Dec 09)	Charlie McCay, Ramsey Systems Ltd (UK)
Chief Technology Officer (CTO)	John Quinn, HL7
International Representative (to Dec 08)	Frank Oemig CTO, Agfa Healthcare
International Representative (Jan 09 to Dec 10)	Navi Natarajan NHS, CfH, UK
Domain Experts – Representative (to Dec 08)	James Case. American Association of Veterinary Laboratory Diagnosticians
Domain Experts – Alternate (to Dec 08)	Austin Kreisler SAIC - Science Applications International Corp
Foundation & Technology – Representative (to Dec 09)	Ioana Singureanu Eversolve LLC, supporting US Dept of Veterans Affairs
Foundation & Technology – Alternate (to Dec 09)	George (Woody) Beeler Jr PhD Beeler Consulting LLC
Structure & Semantic Design – Representative (to Dec 08)	Calvin Beebe Mayo Clinic/Foundation
Structure & Semantic Design – Alternate (to Dec 08)	Gregg Seppala US Dept of Veterans Affairs
Technical & Support Services – Representative (to Dec 09)	Kenneth McCaslin. Quest Diagnostics, Inc.
Technical & Support Services – Alternate (to Dec 09)	Helen Stevens Love Canada Health InfoWay

Karen van Hentenryck, Deputy Executive Director, provides staff support to the TSC on behalf of HL7 Headquarters.

Architecture Board (ArB)

The HL7 Strategic Roadmap identifies that "Architecture" is an essential characteristic of HL7 standards, to be managed by the ArB within the following guiding principles:

> *"HL7's Standards and Technologies are founded and managed by a set of Architecture principles that help to assure that they are internally congruent, consistent with appropriate measures of quality and have been prepared according to the appropriate approved associated HL7 methodology.*
>
> *HL7's Architecture Board (ArB) keeps and manages the HL7 architecture(s). The ArB defines and documents both the "goal architecture" for the suite of current HL7 products and the gaps that exist between this "goal architecture" and the current or "de-facto" architecture as it currently exists. The HL7 "goal architecture" is consistent with both the HL7 Mission and the current HL7*

Strategic Plan as defined by the HL7 Board.

The ArB provides recommendations to the TSC and CTO that move the HL7 organization and their products towards the current "goal architecture".

The ArB works to improve the consistency and effectiveness of committee operations relating to overlap of committee scope or gaps where no committee is working."

The ArB was reconstituted with Charlie Mead as chair in January 2008 in order to address these principles effectively and realise the following specific goals of the original HL7 Roadmap:

1. Create a defined set of Architecture principles associated with each HL7 product by June 2008.

2. Position the ARB to work with all relevant committees of HL7 to proactively lead HL7's adoption of HL7's approved Architecture and establish a process for its continuous review and update by December 2008.

   and, to address principles for adoption of Emerging Technologies:

3. Include coherent and complementary static and dynamic modelling concepts in HL7s "goal" Architecture by December 2008.

The ArB members are appointed by invitation on account of their specific expertise and ability to cover HL7 organisational, v2, v3 vocabulary, domain and international (realm) interests. Current membership of the Architecture Board is:

Person	Affiliations	Country
Chair: Charles Mead MD MSc	Booz Allen Hamilton	United States
John Quinn	HL7, Chief Technology Officer (CTO)	United States
Yongjian Bao	GE Healthcare Integrated IT Solutions	United States
Jane Curry	Health Information Strategies Inc	Canada
Grahame Grieve	Kestral Computing Pty Ltd	Australia
Anthony Julian	Mayo Clinic/Foundation	United States
John Koisch	Booz Allen Hamilton	United States
Cecil Lynch	OntoReason, LLC	United States
Nancy Orvis	U.S. Department of Defense, Military Health System	United States
Abdul-Malik Shakir	Shakir Consulting	United States
Rene Spronk	Ringholm Institute	The Netherlands
D. Mead Walker	Mead Walker Consulting	United States

The most important activity of the ArB in the six months leading up to the Vancouver Meeting was the production of the SAEAF.

Steering Groups

As can be implied from the titles of some of the representatives on the TSC, there are four Steering Groups, with the distribution of Work Groups between the four Steering Groups being as set out in the following table:

Domain Experts Steering Group		
Anatomic Pathology	Anesthesiology	Attachments
Cardiology	Clinical Guidelines	Community Based Collaborative Care
Emergency Care	Government Projects	Health Care Devices
Imaging Integration	Laboratory	Patient Care
Patient Safety	Pediatric Data Standards	Public Health Emergency Response
Pharmacy	Regulated Clinical Research Information Management (RCRIM)	
Foundation & Technology Steering Group		
Implementable Technology Specifications		Implementation/Conformance
Infrastructure & Messaging	Java	Modeling & Methodology
Security	Service Oriented Architecture	Templates Vocabulary
Structure & Semantic Design Steering Group		
Arden Syntax	Clinical Context Object Workgroup	Clinical Decision Support
Clinical Genomics	Electronic Health Record	Financial Management
Orders & Observations	Patient Administration	Scheduling & Logistics
Structured Documents		
Technical & Support Services Steering Group		
Education	Electronic Services	Process Improvement Committee
Project Services Committee	Publishing	Tooling

It has been noted that the TSC and ArB now demand extensive time from the participants, or as Richard Harding observed

Attachment C – HL7 Roadmap - Strategies (v2.1.1)

HL7 Roadmap Version 2.1.1
August 10, 2008

Strategic Overview

The Health Level Seven, Inc. (HL7) Roadmap has evolved from the contributions of the taskforce and stakeholders within HL7 at large. The scope is far-reaching and detailed. It provides guidelines for technical and process development spanning a window of the next 18 months to three years. The Roadmap embraces the vision but is burdened in places with specific tactical requirements and deliverables.

A broader overview of management and business objectives for the same time period is required. This outline of the strategic initiatives and their ultimate outcomes is summarized in this Strategic Overview. It encompasses five major strategic imperatives:

- Expand, reinvigorate and streamline HL7's production, processes and technologies
- Evaluate HL7's competitive environment and define HL7's roles, positions and actions
- Enhance communication and outreach: make HL7 more useable, useful and understandable and share the ideas worldwide
- Embrace the Electronic Health Record (EHR)/Electronic Health Record System (EHR-S)/Personal Health Record (PHR) as the focal point of technical development of health informatics standards
- Connect to the clinicians, an essential HL7 community

This document is meant to be focused but highly flexible. It represents the larger goals embodied within the Technical Plan. Moreover, it assists in bringing focus to future technical development strategies, not steady state operations. At the same time, the Roadmap is informed by the requirements of the stakeholder community and supports the initiatives and timelines upon which it is built. Some elements of the Technical Plan detail near-term and operational activities (for example, continued development of Version 2). While these elements are essential to the success of HL7, they are neither strategic nor reflective of our priorities for the three-year horizon. Consequently, not all of the elements of the Technical Plan map to the five strategic priorities.

STRATEGY 1 – Expand, reinvigorate, and streamline HL7's production, processes and technologies

1. Design and produce new and better tools for standards developers, users and implementers globally. Increase commitment to tooling for standards developers and users, including but not limited to:
    - Static and dynamic constraint modeling
    - Vocabulary bindings
    - Version 3 (V3) -based standards implementation guides
2. Enhance ballot management. Evaluate alternative processes to improve the development and balloting of HL7 standards.
3. Better enable V3 products and technologies:
    - Migrate modeling and publishing processes to commercially available platforms
    - Develop HL7 V3 methodology training that is tool enabled and produces implementable specifications
    - Build a catalogue of model messages with constraint mechanisms for modification
    - Establish a mechanism for collecting existing best practices
4. Embrace emerging healthcare information technologies. To do this we must extend the methods of electronic communications beyond messages and documents. For example, today this should include Service Oriented Architecture (SOA).

STRATEGY 2 – Evaluate HL7's competitive environment and define HL7's roles, positions and actions

1. Evaluate and prioritize the relationships between HL7 and other agencies and organizations.
2. Define our involvement in US agencies and organizations. Develop a course of action for each of these groups
    - American Health Information Community (AHIC)
    - Certification Commission for Health Information Technology (CCHIT)
    - Centers for Disease Control and Prevention (CDC)
    - Electronic Health Record Vendors Association (EHRVA)
    - Healthcare Information Technology Standards Panel (HITSP)
    - National Committee for Quality Assurance (NCQA),
    - National Quality Forum (NQF) (quality and outcomes)
    - Office of the National Coordinator (ONC)
    - Standards Developing Organization (SDO) Summit members
    - The Joint Commission (JCAHO)
    - Object Management Group (OMG)

3. Define our interests, partnerships and interactions with each of these international groups. Monitor related activities.
    - European Committee for Standardization (CEN)
    - EU Mandate 420 (CEN 13606)
    - International Conference on Harmonization (ICH)
    - Integrating the Healthcare Enterprise (IHE)
    - International Health Terminology Standards Development Organization (IHTSDO) (i.e., Systematized Nomenclature of Medicine – Clinical Terms (SNOMED))
    - International Organization for Standardization (ISO)
    - Joint Initiative Council (JIC)
    - National Ministries of Health and Standards bodies
4. Define relationship with US SDOs. Strengthen ties and collaborate on projects.
    - American Dental Association (ADA)
    - ASTM
    - Clinical Data Interchange Standards Consortium (CDISC)
    - Digital Imaging and Communications in Medicine (DICOM)
    - Institute of Electrical and Electronics Engineers, Inc. (IEEE)
    - Medbiquitous
    - National Council for Prescription Drug Programs, Inc. (NCPDP)
    - The Accredited Standards Committee X12 (X12)

STRATEGY 3 – Enhance communication and outreach: make HL7 more useable, useful and understandable and share the ideas worldwide

1. Produce easy to understand manuals, implementation guides and product overviews for our suite of standards.
2. Launch an integrated marketing, education and communication (outreach) campaign to educate all stakeholders on the value and ease of use of HL7 standards.
3. Promote activities that foster the discovery and support of regional Security and Privacy standards into HL7.
4. Focus on opportunities for making standards more usable including, for example, HITSP use cases, the (Biomedical Research Integrated Domain Group (BRIDG) model, and ISO/JIC projects.
5. Capture, categorize and effectively communicate improvements resulting from successful implementation(s) of HL7 standards and translate those benefits into tangible, quantifiable values.

STRATEGY 4 – Embrace the EHR/Electronic Health Record System (ERH-S)/Personal Health Record (PHR) as the focal point of technical development of health informatics standards

1. Leverage our ongoing investments in EHR and PHR standards
2. Invest in the EHR and PHR activities that engage the clinician and consumer communities
3. Embrace EHR architecture through collaborative efforts
4. Promote content development of the EHR including the integration of genomic data
5. Evaluate opportunities and/or develop functional models for health information exchange and other data uses
6. Establish HL7 as the leader in global health initiatives on EHR and PHR

STRATEGY 5 – Connect to the clinicians, an essential HL7 community.

1. Invigorate the Clinical Interoperability Council initiative in order to effectively engage the key clinical organizations to learn what they need, and then HL7 builds the standards that they need.
2. Develop a global vision and strategy for effective use and deployment of data elements, terminology/ontologies and clinical decision support.
3. Focus Chief Executive Officer (CEO) activities on outreach to this community.
4. Develop clinical decision support/clinical guidelines that adhere to current and best technology practices, including:
    - Rules driven communication to clinicians
    - Health surveillance and pharmacovigilance
    - Disease management

Attachment D – HL7 Roadmap – Plan Tasks

Roadmap Plan Completed Tasks
October 09, 2008

ID	Due Date	Milestone	Strategy	Leader
-	2008 Q1	Reorganize and establish a new ArB based on its new mission	1.4	CTO
-	2008 Q2	The HL7 Project Tracking tools will be brought current with actual work in progress	1.1	CTO
-	2008 Q1	Commit to development of v2.n standards at least through v2.7		CTO
39	2009 Q1	Develop and implement a process by which members of HL7 can suggest additions to the Roadmap. Include a plan and process for vetting and approving the entries.		CEO

Roadmap Plan, Scheduled Task List
September 11, 2008

ID	Due Date	Milestone	Strategy	Leader
1	2009 Q1	Define new balloting procedures based on better interpretation of ANSI requirements. The procedure should include a plan for managing change to the normative ballot.	1.2	CTO
2	2009 Q2	Evaluate the potential for certification, including but not limited to certification types, partnerships, models, obstacles, expenses and revenues,	2.1	CEO
3	2009 Q2	The HL7 website will maintain a list of the individuals that are certified by country and by specification.	3.2	CEO
4	2010 Q2	Develop a tight relationship with CCHIT to enhance and optimize the movement of HL7-developed EHR functional module standards into the certification process. Inform CCHIT of HL7 activities that will impact and influence future work of the CCHIT. That activity should include functional modules being developed in the following areas: • PHR functional profile • Provider-based PHR system functional profile • Payer-based PHR functional profile • Health records banking PHR system functional profile • Health authority-based PHR functional profile • Clinical Research functional profile • Long Term Care functional profile • Behavioral Health functional profile • Child Health functional profile • Vital Statistics functional profile • Quality functional profiles • Records management and evidentiary support functional profile • Other functional profiles as they become defined	4.1	CEO

ID	Due Date	Milestone	Strategy	Leader
5	2009 Q3	Actively educate clinicians and consumers on the benefits of EHR and PHR standards	4.2	CEO
6	2009 Q1	Engage clinicians in developing data content and data definition requirements for the EHR through the HL7-AHIMA-AHRQ-AMA collaboration	4.2	CEO
7	2009 Q3	Engage consumers (via consumer groups or advocates) in the development of PHR system standards	4.2	CEO
8	2008 Q4	Incorporate the interoperability model, life cycle model, and use case and alignment efforts into the mission of the EHR WG	4.3	CTO
10	2009 Q1	Begin defining data content for the EHR through the Clinical Interoperability Council	4.4	CEO
11	2009 Q4	Provide the standards to collect genomic data and integrate into the EHR	4.4	CTO
12	2009 Q3	Define clinical content model for the PHR	4.4.	CTO
13	2008 Q4	Submit EHR-S FM to ISO as part of Standards Partner agreement to become ISO IS	4.6	Chair
14	2008 Q4	Cultivate a relationship with Q-REC (EuroRec) and encourage references to the EHR-S FM for certification purposes	4.6	CEO
15	2008 Q3	Create a task force composed of Board members and stakeholders to investigate reasons and opportunities for working together and obstacles for partnering with an external organization to partnering with an external organization.	1.1	Chair
16	2008 Q3	Finalize Memorandum of Understanding with the newly incorporated IHE organization.	2.3	CEO
17	2008 Q4	A task force will be assigned to explore, document, and analyze all organizations that do or have the potential to influence, overlap, compete, or harmonize with HL7'scope, mission and activities. • This material should be documented in a matrix in which the columns will include a column for each of the above topics plus current status (MOU/Associate charter agreements), mutual activities, potential activities, any other topics as identified by the task force. • This documentation will be made available on the HL7 web, and a plan will be made to keep this material up to date. • Organizations will be invited to comment on the matrix to make sure that there is mutual agreement about relationships and cooperative work. • As new organizations are identified, a process will be defined to establish appropriate working relationships.	2.1 2.2 5	Chair
18	2008 Q3	Hire TSC Assistant solely to support TSC	1.2	CTO
19	2011 Q1	Increase revenue targets: • 10% revenue growth and 5% net annualized growth through 2009 • 15% revenue growth and 7.5% net annualized growth through 2010 • 20% revenue growth and 10% net annualized growth through 2011		CEO

ID	Due Date	Milestone	Strategy	Leader
20	2009 Q2	Create a Revenue Development Task Force, • Comprised of members of the Finance Committee, other HL7 Board members, and non-Board members, • Charged with assessing the existing revenue streams and with proposing new opportunities to the Board		CEO
21	2009 Q2	Create a task force to develop an HL7 management position on creation of a US affiliate		Chair
22	2009 Q3	Develop a set of expectations of affiliates' responsibilities to the HL7 organization.		Chair, International affiliate
23	2009 Q2 Assign 2009 Q3 Report	The TSC will establish criteria for prioritizing new projects.	1.1 5.1	CTO
24	2010 Q1 Assign 2010 Q2 Report	The Board will appoint a task force to survey the need for future standards and implementation guides.	1.1 5.1	Chair
27	2009 Q2	Create a task force to evaluate Operations Management schema in other standards development organizations and recommend to the Board its findings and various management options. An organizational model that aligns the relationship of Operations personnel and their respective roles with the operational needs of HL7 (to provide a foundation to achieve the mission and roadmap) should be developed; the management options should be evaluated based upon the HL7 needs/requirements in this regard. This evaluation should include a comparison of contract management vs. hired staff or a mixture thereof as well as the findings, risks, benefits and overall consequences to work products, volunteer perception, and organization of using paid project managers to lead current or future HL7 products Task force members will include Board members, members of the management team, and external experts.		CEO
28	2009 Q1	Create a task force to evaluate the compensation model for the existing management structure and report to the Board. The compensation model for HL7's Operations management group (AMG) and the tasks/roles being provided to HL7 by AMG shall be evaluated in the context of the requirements for Operations personnel developed by the above task force.		Chair
29	2009 Q1	Deliver an HL7 management position on one-member-one vote issue		Chair
30	2009 Q2	The Marketing Council will provide recommendations for funding and governance of an enhanced role for Marketing. The Council members will be supplemented by Board members and outside expertise as the need and resources permit.	3	CEO

ID	Due Date	Milestone	Strategy	Leader
31	2009 Q2	The Marketing Council will have created 15 Ambassador Program presentations (of dedicated HL7 domain experts for speaker venues and publications) for targeted global industry conferences. The goal is to have 5 Ambassador modules created by May 2008 at least 15 Ambassadors by June 2008. HL7 Board members are encouraged to help identify conferences for Ambassadors to present.	3.2	CEO
32	2008 Q4	The Marketing Council will make a recommendation regarding establishment of an HL7 User Group to provide input on current and needed marketing programs.	3.2 3.5	CEO
33	2009 Q2	Produce or commission documentation providing an overview of the organizational structure, process, and history of HL7	3	CEO
34	2009 Q4	Produce or commission documentation providing an overview of the various HL7 standards and their application to interoperability	3.1	CEO
35	2008 Q4	Create a Communications Office • Led by a Communications Director, employed by HL7, and reporting to the CEO • Responsible for coordinating marketing, communications, education and outreach, and the respective volunteer committees • Charged with the enhancement of revenue streams associated with — Training, — Publications — Membership development — Outreach and Ambassador programs — Non-Foundation funding	3	CEO
36	2009 Q4	The HL7 ambassador program provides international affiliates with educational material on the value of HL7's leadership in the EHR and PHR	4.6	CEO
37	2009 Q1	The HL7 website lists all existing HL7 implementation guides, describing their scope, the language of the guide, the Affiliate that created the Guide, a link to the guide, etc	1,1, 3.1 3.5	CTO
38	2008 Q4	Develop and implement a process to track progress and manage Roadmap Task list		CEO
39	2009 Q1	Develop and implement a process by which members of HL7 can suggest additions to the roadmap. Include a plan and process for vetting and approving the entries.		CEO
40	2009 Q3	Appoint a task force to develop next version of roadmap for HL7		Chair
41	2008 Q4	TSC review and comment on the HL7 Roadmap. TSC should specifically evaluate due dates and work group.	1.2	CTO
42	2009 Q1	The TSC shall provide a Project Registry of all the Work Groups' planned deliveries, spanning the next three years, highlighting any areas of potential conflict or inconsistencies.	1.2	CTO
43	2008 Q4	Create a defined set of architecture principles associated with each HL7 product.	1.4	CTO
44	2008 Q4	Position the ArB to work with all relevant committees of HL7 to proactively champion the adoption of an approved HL7 Reference Architecture and establish a process for its continuous review and update.	1.4	CTO

ID	Due Date	Milestone	Strategy	Leader
45	2010 Q1	The Modeling and Methodology (MnM) Work Group will produce a plan and time-line for major methodological and modeling work. Specific activities with deliverables are: • Review, update and complete the initial version of the HDF • Review, correct and update RIM documentation. • Review need for Model Interchange Format (MIF), delivering, if necessary	1.2 1.4	CTO
46	2009 Q2	The TSC will task the Implementation/Conformance Work Group to create an HL7 Standards and Implementation Guide Inventory Report that lists HL7 standards and corresponding implementation guides, either currently available or under development (including those developed by outside organization) This will provide users with easy access to available implementation resources and provide insight to HL7 as to where implementation guides for existing standards needs to be developed	1.1 5.1	CTO
47	2009 Q2	Deliver a first balloted reference architecture document to include a services delivery approach as a means of using HL7 Standards in SOA.	1.4	CTO
48	2009 Q1	The Marketing Director will develop an updated HL7 Product Strategy.	1.3	CEO
49	2009 Q1	Complete the complete landscape of standards necessary for effective and interoperable HIT. Identify where HL7 standards fit; identify where other appropriate standards fit. From this landscape map, identify gaps in required standards; then determine which standards HL7 should pursue. This landscape map can also be used to identify existing tools and where they fit, and to identify additional tools that might be required.	4.1	CEO
50	2010 Q2	Develop appropriate work products in areas where gaps have been identified, and continue the process as an on-going operational effort	4.1	CEO
52	2010 Q2	Work with and within clinical organizations to develop a process for the creation of a master set of data elements, both atomic terms and compound structures, with attributes, that is accepted and used by the clinical community.	5.2	CEO
53	2011 Q2	Develop implementation guide for users implementing HL7 v3 data interchange standard		CTO
54	2008 Q4	The CTO will develop a plan for ballot publishing of each HL7 product from ballot through final product. The plan will include a description of publishing approach and methodology, documentation for the individuals involved and a catalogue of computer-based tools that are used to accomplish each step of the methodology if applicable.)	1.1	CTO
55	2010 Q2	All balloting work should be using a new tooling platform. The new tooling should be available for beta testing to support the ballot publication process	1.1 1.2	CTO
56	2009 Q4	Understand the tooling requirements for certification. Either find commercially available tools or develop a plan for their design and development.	1.1 2.0	CTO
57	2008 Q4	The CTO establishes an initial tooling requirements catalogue and defines a process for maintaining this catalogue.	1.1	CTO
58	2008 Q4	The CTO / Tooling Committee recommend a tooling planning investment plan	1.1	CTO
59	2009 Q1	The Board to approve funding of at least $250,000 to deliver the first phase of the investment plan	1.1	Chair

ID	Due Date	Milestone	Strategy	Leader
61	2009 Q4	Produce or commission documentation providing comprehensive guidance on the use of the tooling supporting: • the development of HL7 standards • (the integration of HL7 standards) • the implementation of HL7 standards.	1.1, 1.2 3.1	CTO
62	2009 Q2	Establish criteria for relationship building with targeted controlled vocabulary organizations	2.3 5.2	CTO
63	2009 Q2	Determine the set of internal HL7 vocabularies that are subsumed by an existing external standard vocabulary (e.g., ISO)	2.3 5.2	CTO
64	2009 Q2	Develop comprehensive proposal with specific controlled vocabulary groups to incorporate those terminologies appropriately into the HL7 RIM and appropriate standards.	2.3 5.2	CTO
65	2009 Q2	Establish a working relationship with groups creating ontologies for health care. Define how these ontologies will be integrated into HL7 standards.	2.3 5.2	CEO

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
CDISC	Clinical Data Standards Interchange Consortium
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CMET	Common Message Element Type
CfH	Connecting for Health [within UK NHS]
DCM	Detailed Clinical Model
DHHS	US Department of Health & Human Services
DICOM	Digital Imaging and Communications in Medicine
DIS	[ISO] Draft International Standard
DMIM	Domain Message Information Model
DoHA	(Australian Government) Department of Health and Ageing
DMP	Dossier Médical Personnel (Personal Medical Record) [France]
DSTU	Draft Standard for Trial Use
EC	European Commission [the administrative arm of the EU]
EHR	Electronic Health Record
EHRS	Electronic Health Record System
EHRVA	Electronic Health Record Vendors Association
EMEA	European Medicines Agency
EN	European Standard (Européen Norm)
EU	European Union
FDIS	[ISO] Final Draft International Standard (for publication vote)
GLIF	GuideLine Interchange Format
HDF	HL7 Development Framework
HIMSS	Healthcare Information and Management Systems Society
HISO	(New Zealand) Health Information Standards Organisation
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
HSSP	Healthcare Services Specification Project [joint HL7/OMG]
HTTP	HyperText Transfer Protocol
ICH	International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
ICSR	Individual Case Safety Report [related to Medicines/Devices]
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standards Development Organisation
IS	International Standard
ISO	International Organization for Standardization
IT-014	Standards Australia Committee IT-014 (Health Informatics)
ITS	(HL7) Implementation Technical specification
JI	Joint Initiative [of ISO, CEN and HL7]
JTC 1	ISO/IEC Joint Technical Committee 1 Information Technology
JWG	Joint Working Group [under the JI, unless otherwise specified]
LOINC	Logical Observation Identifiers Names and Codes
NCI	(US) National Cancer Institute

List of Acronyms (continued)

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
TCP/IP	Transmission Control Protocol/Internet Protocol
UML	Unified Modelling Language
VHA	(US) Veterans' Health Administration
W3C	World Wide Web Consortium
WG	Working Group
XDS	(IHE's) cross enterprise Data Sharing protocol
XML	eXtensible Markup Language