IT-014 Health Informatics Committee

Australian Delegation Report – HL7 International Working Group Meeting – May 2009

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1 Introduction

The benefits that the Australian Healthcare Community derives from Australian representation at international standards meetings such as this HL7 International Working Group Meeting are significant and ongoing. It is recognised that it is vitally important to ensure that an Australian national position is represented at such meetings. The most effective way of achieving this is to ensure that a delegation is comprised of the appropriate mix of skills and expertise in order that priority areas are comprehensively addressed.

Standards Australia coordinated the Australian delegation's attendance at the HL7 meeting in May 09. The delegation at this meeting also included representatives from NEHTA, whose contribution along with other employer funded representatives in the Australian team was invaluable. This collaborative approach represents a very positive step in the national and public interest.

This report identifies priority areas for strategic engagement from all relevant parties who have an interest in the national e-health agenda and quality/safe health information management in Australia.

This report provides an outline of the activities of HL7 internationally and the important recommended actions and messages for the Australian Healthcare Community. It also considers the capacity of the Australian Delegation to engage in HL7 activities thereby highlighting the issues relevant to achieving the defined objectives for international standards participation and influence at HL7.

This report is produced as a result of the input of the Australian Delegation and in particular those delegates co-funded by the Department of Health and Ageing without which support Australia's contribution and ability to respond to the issues discussed here would be severely impeded.

Information is presented by topic and areas of specific concern to Australian stakeholders are highlighted and appropriate action should be considered by those stakeholders. Information is provided for contact to Australian expertise in each area for those who would like further information or to participate. Many of the issues will be discussed in detail at upcoming IT-014 subcommittee and working group meetings which are open to all interested parties.

For details of IT-014 subcommittees and working groups contact Standards Australia (healthinformatics@standards.org.au)

2 The Working Group Meeting International Attendance

Analysis of pre-registration documentation showed that this meeting had 221 participants from 26 countries. Additional attendees who did not pre-register brought the attendance to 241 people from 27 countries with 20 HL7 Affiliates formally represented.

There were 15 Australians at this HL7 meeting all of whom have contributed to this report. The funding source for these delegates is indicated in Table 1 below.

Funding Source	Number
Full funding by employer: Private	2
Full funding by employer: States/Territories or National Initiatives	4
Part funding – DOHA through Standards Australia contract.	9
Total:	15

Table 1 Delegation by funding source

DOHA-funded delegates were selected through an independent panel process jointly with NEHTA, DOHA and Standards Australia. There were no first time attendees in the Australian delegation but new attendees from the last meeting returned to the delegation on this occasion. The delegation's capacity to deliver the intended outcomes of participation, information distribution back in Australia and to influence developments to support Australian requirements is enhanced by a balanced delegation of experienced people along with

"new blood" who can both challenge the processes and increase the pool of understanding of these complex issues in Australia.

Figure 1 indicates the investment being made by the international community to participate in, learn from and influence the development of standards at this HL7 working group meeting. The figures shown represent attendance by country at the two meetings for 2009, with meeting 2009-2 representing this meeting. This shows Australia in a strong attending position, with increasing attendances from the Asia pacific area and less from the UK, France and Canada while attendance from the Netherlands was 60% greater than at the last meeting. The figures for attendees from the USA are not included as they represent a strong majority of attendees. At meeting 1 there were 234 registered attendees from the USA representing 68% of attendees, while this meeting has 78 attendees from the USA representing 35% of attendees.

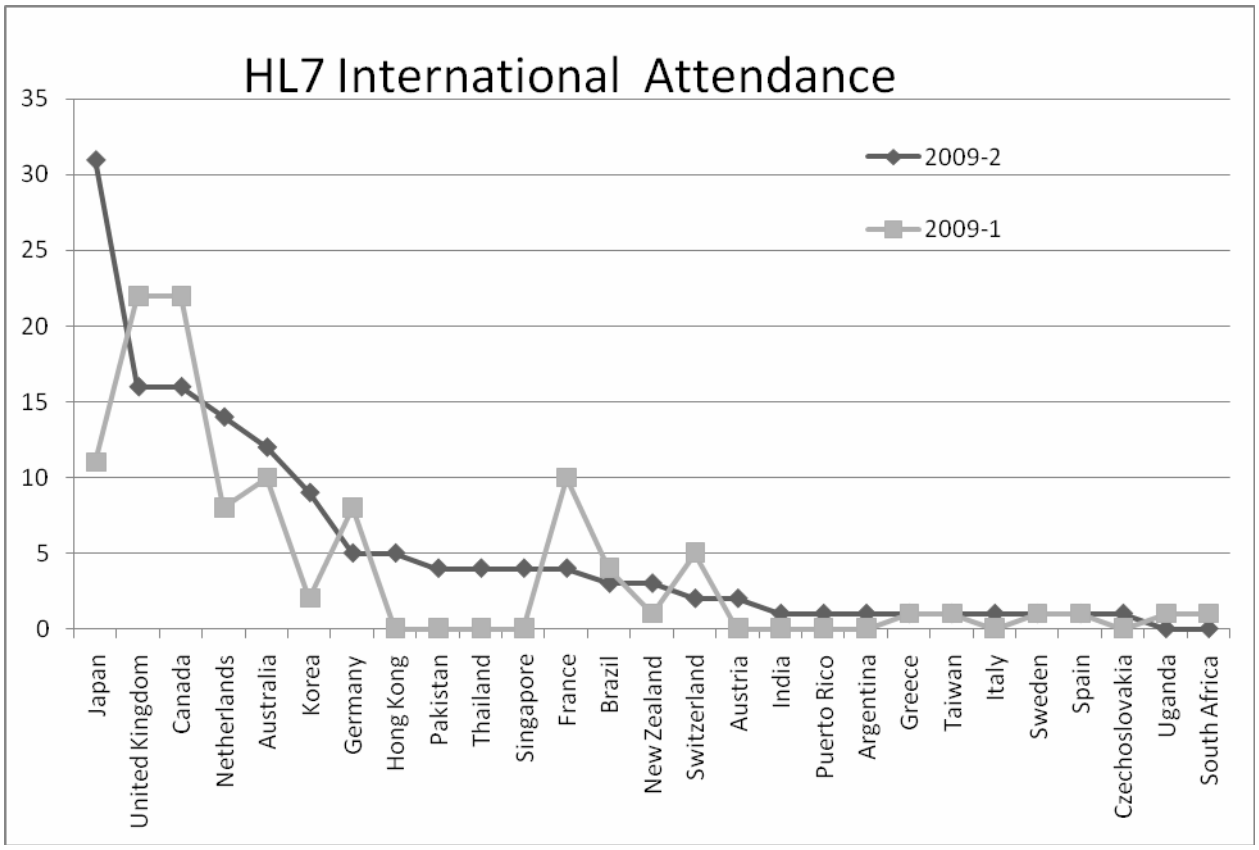

Figure 1 International Attendees

These international attendees are largely fully funded to attend by their employer, or they are funded as employees or consultants to national programs to influence HL7 developments, and return expertise to their own country. This financial support does not negate the voluntary nature of much of the work which is done on weekends and evenings, out of work time, but does indicate the value attached to the activities by employers and national programs.

The attendance, particularly from the USA was disappointing due to a number of factors including:

- The economic downturn
- Attitude of many USA companies that do not see the relevance of international activities and have difficulty funding travel for such activities
- The Obama e-Health US $34 Billion program – initial submissions for funding have to be submitted by early June (discussed later in this document)
- The 'Swine Flu' epidemic.

In fact, one of the HL7 employees was quarantined for the entire meeting as she flew into Tokyo on a flight with a confirmed case. Some Japanese companies had also placed an embargo on their employees having contact with overseas visitors until 10 days had elapsed from their arrival in Japan.

Action required: The Australian contribution to, and learning from, the HL7 development processes needs to continue if existing gains are to be reinforced and future requirements influenced. The size and constitution of the delegation needs to be pro-actively planned well in advance, including consideration of skill extension and support.

3 Meeting Logistics

In recent years the HL7 Working Group Meeting has grown from 4.5 days to ~8 days

	Sun	Mon	Tue	Wed	Thur	Fri
Affiliates Council	X				X	
Architectural Review Board (ArB)	X		X	X	X	
Board of Directors		X				
Clinical Interoperability Council					X	
Clinical Statement				X		
Community Based Collaborative Care		X	X	X		
Electronic Health Records	X	X	X	X	X	
Electronic Services				X		
HL7/CEN/ISO	X					
HL7 meeting for nurses				X		
Implementation conformance		X	X	X	X	
Implementation Technology Specification				X	X	
Infrastructure and Messaging				X	X	
Marketing Council		X			X	
Modeling and Methodology	X	X	X	X	X	
Orders and Observations		X	X	X	X	
Patient Administration		X	X	X	X	
Patient Care		X	X	X	X	
Patient Safety		X	X	X	X	
Pharmacy		X	X	X	X	
Process Improvement		X				
Public Health Emergency Response		X	X	X	X	X
Regulated Clinical Research Information Management		X	X	X	X	
Security			X	X	X	
Services Oriented Architecture		X	X	X	X	
Structured Documents		X	X	X	X	X
Templates		X				
Tooling	X		X		X	
Vocabulary	X	X	X	X	X	

Figure 3: Meeting Schedule highlighting areas of major Australian interest

HL7 meetings have a heavy schedule of activities, though the venue, being away from accommodation limited the number of breakfast meetings sessions still began at 8am daily and went to late night sessions (it is not uncommon for these to finish after 10pm). The HL7 meeting is just that, a working meeting, rather than a conference and all attendees are active throughout the meeting time.

Figure 3 shows some of the larger groups meetings from among some 63 separate work groups, committees, councils and the HL7 Board. Tutorials are also offered and these are of great value to both

newcomers and older hands, to bring them up to date on generic changes made that may not be discussed in their individual committee areas (eg vocabulary submission requirements). Shaded areas indicate groups where items of major Australian interest are being discussed. The number of concurrent sessions makes it impossible for a small delegation to effectively follow the issues and to influence change. It is noted that delegates funded by their employer, or individually to international meetings have no obligation to work with or relate information back to the Australian delegation, though some have done so in the past. It is clearly desirable that there be a cohesive Australian position. The size of the delegation and the reduction in the number of sessions held assisted in our capacity to cover the most important requirements of Australia.

4 International HL7 Interoperability Conference 2009

T. Connell-Clark, V. McCauley, K. Veil, M. Walker, C. Lynton-Moll, R. Dixon Hughes and H. Grain

Prior to the HL7 meeting the 10th International HL7 Interoperability Conference was held (IHIC 2009 – www.HL7.jp/ihic2009) .

Papers centred on implementation and research as well as standards development. Attendees from the Australian Delegation were not covered by DOHA sponsorship for this event; however, there were two presentations by Australians on the program and attendance from personally funded, and State and National program funded representatives present. This conference was relatively well subscribed. It attracted approximately 120 delegates, mostly from Japan.

The conference featured four main themes:

- Reports on HL7 adoption at national levels by a number of national representatives from countries such as Japan (Prof Michio Kimura), the Netherlands (Michael Tan), South Korea (Il Koon Kim), Taiwan (Prof Chien Tsai Liu), Australia (Klaus Veil)
- Research and/or experimental HL7 V3/CDA projects by research students from mainly Pakistan and Taiwan
- “Show me your CDA” presentations from countries such as USA (on CCD implementations), UK (the use of CDA templates to support telemedicine documentation), and New Zealand (pilot implementation of regional CDA-based dispensing notification repository), and others
- Presentation on vocabulary, terminology and standards harmonization work including HL7/CEN/ISO Harmonization (by Prof Yun Sek Kwak of South Korea), SNOMED-CT interoperability (by Colleen Brooks), and approaches to practical harmonization (by Heather Grain - Australia). This stream of presentations ran concurrently with the “Show me your CDA” session.

At the Affiliates Council meeting it was suggested that the scope of the IHIC conference series be formally expanded to recognise its role in sharing HL7 scientific and academic research, as well as experience and techniques for application and implementation of CDA and other HL7-based solutions. A change of title might also be appropriate (e.g. International Research and Interoperability Conference on HL7 - IRICH).

This was the first time that IHIC had been co-located with an HL7 Working Group Meeting. The location and date for IHIC in 2010 and 2011 have yet to be set. Over 50% of those present at the Affiliates' Council felt that the co-location had worked well, but this is only one of the factors that HL7 needs to consider for future conferences. Others include the available locations, the potential proximity of other meetings (such as ISO/TC215, IMIA, WoHIT, Euromed, HIMSS, IHTSDO etc).

4.1 International Adoption of HL7

Japan reported on Ministry of Health mandated projects based on HL7. These included:

- A 500 million yen “Shizuoka Style” EMR project that provided a wide variety of functions including progress notes, nursing records, referrals, medical images, and CPOE (computerized physician order entry). The EMR supports inter-hospital/clinic information exchange using HL7 V2.5 for prescriptions, lab results and DICOM image exchange. All other information exchanges including discharge and referrals are in CDA.

- An 88 million yen nationwide referral project: Referral documents are transferred together with a web browser, DICOM image reader onto a CD. Patient presents at a doctor's clinic and the referral contents together with any diagnostic images are then available.
- Post Market Drug Adverse Event Reporting: This project also uses the CDA standards developed for referral and other document exchange projects. The report contains patient demographics, prescription history, lab results and adverse events data input by doctors.

The Netherlands reported on its national eHealth program, NICTIZ, comprising national ICT infrastructure such as unique identifiers (patient and provider), national switch point (infrastructure to share patient information) which include identification, authentication, authorization, pointer and indexing services, and a national EHR based on HL7 V3 messaging and CDA specifications. Messaging is used for lab, diagnostic imaging results, prescribing, and dispensing notification. Documents are used for discharge summary and referral. It supports a wide range of terminologies including ICPC, ICD9, DSM-4 and SNOMED-CT. The Netherlands opts to implement a de-centralised EHR repository architecture as it failed to reach national agreement on a centralized architecture.

Taiwan reported on a national clinical forms project. In 2003/2004 Taiwan established a national clinical forms program in which over 100 clinical reports were identified from 130 participating hospitals and standardized into EMR templates. Since 2008 the Department of Health sponsored a project to simplify the EMR templates (reducing the numbers) and to transform the templates in CDA R2. The Department of Health has established a set of goals and milestones for EMR implementation national wide:

- By end of 2010 – at lease half of hospital accredited at Grade A level (excellent), 20% of Grade B level (pass grade) and 10% primary care clinics will use EMR to support daily clinical functions
- By end of 2011 – 100% of hospital accredited at Grade A level (excellent), at least 50% of Grade B level (pass grade) and 30% primary care clinics will use EMR to support daily clinical functions.

USA reported continuous support in CCD (continuity of care document which is a CDA R1 implementation of the continuity of care record) implementation. It was interesting to hear that the continuity of care record (CCR) had effectively lost its "standard" status in USA. The presenter was unable to provide reason(s). However, it was reported in a joint Structured Document and Patient Care Technical Committee meeting that the Massachusetts Medical Society (sponsor of the CCR project) has begun the processes of developing CCR version 2, but no information was available. HL7 had undertaken to develop a CDA R2 implementation of the current CCR specification while waiting for the CCR version 2 development details to emerge.

The **South Korea** government sponsored a project to consolidate various types of biomedical information and their associated clinical information. The delegate reported a prototype system that included HL7 gateway systems and CDA to facilitate the information exchange between biomedical systems and hospital information systems. The HL7 message gateways sit on the hospital side and mediate communication between hospital information systems and biomedical information (administration and patient demographics) systems (which are actually clinical information systems). CDA is used as the transport technology for all clinical information exchanged.

Australia: a brief report on HL7 V2 development work, the new national e-health strategy, and featuring NEHTA's "year of implementation" commitments.

The **National Library of Medicine** delegate (Dr Clem McDonald) reported a trial implementation of Personal Medical Record. This trial project was established to test a PHR portal for its usability and acceptance. The web portal provides various dynamically customizable tables for users to enter medical history and physical exam data. It can also accept data in "OBX" segments from HL7 messages giving it the potential ability to import clinical data such as lab results.

4.2 Research and Experimental Projects on HL7 V3

The presentations were dominated mainly by two groups of research students from Pakistan and Taiwan.

- Pakistan's presentations focused on the implementation of experimental V3 messages over SOA / web services infrastructure.

- Taiwan's research projects featured the use of CDA/V3 to allow information from monitoring devices and from ambulances to flow to hospitals to support integrated care. Another project reported the mapping of Taiwan's national health insurance clinical codes into LOINC.

4.3 "Show me your CDA" Presentations

Each presentation was given 20 minutes including discussion; hence not a lot of detail was available on each of the projects. The conference organizer is yet to provide access to the presentation slides to allow the presenters to be contacted for follow-up discussions.

Argentina: reported a project on a "structured report editor for HIBA (Hospital Italiano de Buenos Ares) Multimedia EHR". The system is built on SUN GlassFish 9.0 and visual tool for editing CDA R2 documents. It imports a plain CDA R2 document and incorporates multimedia content into it before publishing the contents as a multimedia-enabled CDA R2 document. It supports both English and Spanish.

Austria: presented its national EHR project (ELGA, which is the Austrian acronym for EHR). It uses the CDA R2 specification with a local extension for its EHR documents. LOINC codes were used to provide semantic interoperability at the data level. Austria is not yet a member of IHTSDO and is currently not able to use SNOMED-CT. Suggestions were provided by a few delegates on how Austria could move towards using SNOMED in its national EHR program.

Germany: presented a project using a CCD-based template for nursing summary. The contents of the summary are based on the CCR. It uses a nursing reference terminology to provide the semantic interoperability required. A PDF version of each nursing summary is also provided.

Japan: established a national project to provide a regular health check-up and monitoring of citizens with metabolic syndromes. The results of the checkups are reported and communicated using CDA. A government sponsored website has been established to provide validation and viewing of the checkup information.

New Zealand: reported a pilot project that was displayed as a poster in HIC2008. This project uses CDA R2 to transport electronic dispensing notification information from community pharmacies to a regional repository hosted by one of the district health boards. The dispensing information can then be queried by authorized users from primary care (e.g. GP) and also by doctors in acute care hospitals. The goal is to allow a more complete picture of a patient's medication management to be gradually built over time. The project is expected to go live in Q3 of 2009 and may be extended to cover the electronic transmission of prescription information should the evaluation results prove to be favourable.

UK: delegates presented a project using CDA to communicate telemedicine information. The project was initially conceptualized to use V3 messages but later decided to switch to a "templating" approach. A library of reusable clinical content templates was developed for implementation in CDA R2. All the templates were essentially "hand-crafted" due to the complexity of the clinical content. These templates are currently being trailed.

USA: two projects were reported by the same group of people from a consulting firm specializing in CDA implementations.

- The first is a "CDA development" project using templates. Multi-level reusable templates are developed: entry level, section level and aggregating into document level templates. The templates were developed for CCD and could be reused by others. It is intended that a website to host the templates may be developed providing easy access by interested parties to the templates and template definitions.
- The second reported on tools for "multi-level" CDA validation. The tool is intended to support first the generic CDA specification validation, and then if the CDA document validates with no error, it can move onto template specific (e.g. CCD) validation. It uses Schematron for validation.

In Summary this conference delivered a number of philosophical statements that are relevant for the e-health community. They include:

- Mapping lasts forever – Ed Hammond HL7 Chair

- Good Enough is the enemy of Great – Charles Jaffe, HL7 CEO
- Nothing will ever be attempted, if all possible objections must first be overcome – Samuel Johnson
- If you put the Federal government in charge of the Sahara Desert, in 5 yrs there would be a shortage of sand - Milton Friedman

Action: Part of the strategy of international standards involvement is to bring skills back into Australia. Standards Australia, DOHA and NEHTA should consider the methods most appropriate to raising knowledge and awareness of national and international standards activities and products at greater depth within the Australian health community.

5 HL7 International

This section provides details of HL7 organisational activities including:

- Two new task forces have been established – a CEO Evaluation task force (Chair Bob Dolin ,HL7 Board Chair elect))and a Chief Technical Officer (CTO) Evaluation task force (Chair Charles Jaffe, HL7 CEO)
- A new Grants and Contracts Committee has been created which will oversee a pool of paid professionals and a repository of potential candidates, to address contracts and grants whilst preserving the autonomy and control by volunteers as well as respecting the interests of the international committee. The Committee has Richard Dixon-Hughes (Australia) as an inaugural member and will provide expertise, staff support and grant proposal monitoring.
- The balance between people being paid to work on HL7 standards by HL7 International and the volunteer workforce will be a delicate balancing act in the months ahead.
- Klaus Veil (Chair HL7 Australia) was also appointed to the Due Diligence committee tasked with approving new International Affiliates and monitoring the performance of existing affiliates.
- HL7 will spend approximately US$3 million dollars in the coming year to improve tooling for producing standards and making use of HL7 standards easier for implementers.

5.1 HL7 Strategic Issues and Direction

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At various points during the week (including at meetings of the Board, the Affiliates' Council, the TSC and the general membership), the Chair of HL7 (Prof. Ed Hammond), the CEO (Dr Charles Jaffe), CTO (John Quinn), the TSC Chair (Charlie McKay) and others gave reports on some of the strategic issues and directions being addressed by the HL7 Board, TSC and executive management team. These included:

- Considerations that HL7 might move more of the focus of its stakeholder involvement from vendors and health care providers toward influencers and regulators (eg national programs and certification organisations)
- Efforts to position HL7.org to effectively participate in the recent US Stimulus packages - with a total of US$34 billion to be spent on stimulating the uptake of health IT under the American Recovery and Reinvestment Act (ARRA) signed into law by President Obama on 17 February 2009.
- The potential impacts of a 100-fold increase in funding and urgency with which the Administration's eHealth agenda is being pursued should not be underestimated. These measures have created an environment in which all organisations involved in healthcare policy and standards have had to respond rapidly to the needs of the Administration in to order to remain relevant as part of the future solution.
- The continuing efforts being undertaken to provide the HL7 community with sustainable and affordable tooling
- The continuing issue of the relationships and relevance of HL7's four major standards: V2.x V3, CDA and web services

- SAEAF - the services-aware Enterprise Architecture Framework, for which a new title is under consideration.
- The continued transitioning of HL7 into a global SDO with the associated questions about the possible formation of an HL7 Affiliate in the USA.

Where, relevant, these points are further elaborated in the following sections of this report.

5.2 Developments in US eHealth Reform

R. Dixon Hughes

The combined impact of the election of the Obama Administration with its healthcare reform agenda and the urgent need to deal with the Global Financial Crisis (and its flow-on effects on accessibility to healthcare) has created an unprecedented focus on the need for urgent action in the USA to invest in, implement and use eHealth solutions to effect significant reforms. Because of the GFC, there is a strong sense of urgency with limited time for discussion, debate and planning. The overall sense is one of urgency, with limited time for detailed planning.

Initial measures aimed at stimulating the uptake and planning of e-Health were signed into law when President Obama gave assent to the American Recovery and Reinvestment Act (ARRA) on 17 February 2009.

The Act aims to stimulate the economy through investments in infrastructure, unemployment benefits, transportation, education, and healthcare. It includes over US$20 billion to aid in the development of a robust IT infrastructure for healthcare and to assist providers and other entities in adopting and using health IT. Out of a total budget of some US$734 billion, funding included for health IT (and related activities) is as follows:

Office of the National Coordinator (ONC)	US$2 billion
Incentives through the Medicare and Medicaid reimbursement systems to assist providers in adopting EHRs	US$20.819 billion
National Telecommunications and Information Administration's Broadband Technology Opportunities Program	US$4.7 billion
US. Department of Agriculture's Distance Learning, Telemedicine, and Broadband Program	US$2.5 billion
Construction, renovation, and equipment for health centers through the Health Resources and Services Administration	US$1.5 billion
Comparative effectiveness research within the Agency for Healthcare Research and Quality (AHRQ), National Institutes of Health (NIH), and the Department of Health and Human Services (HHS)	US$1.1 billion
Health IT, including telehealth services, within the Indian Health Service	US$0.085 billion
Social Security Administration	US$0.5 billion
IT within the Veterans Benefits Administration	US$0.05 billion
Total:	US $33.254 billion

There are also incentive funds for eHealth adoption and provision of PQRI quality measures under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), discussed further in section 17.4 below.

As briefly touched on by the CEO and Chairman in their addresses, some political structures, processes and decision-makers will continue under the new regime and others are being changed, replaced or removed - with the picture only now beginning to emerge.

HL7 is clearly attempting to respond positively and rapidly to this situation and to continue being able to make representations and contributions on behalf of its membership, as it did under the previous arrangements involving ONCHIT, AHIC, HITSP and the CCHIT

In this regard, the position of National Coordinator for Health IT is retained under the Obama Administration, with Dr David Blumenthal assuming the role from Dr Robert Kolodner. Importantly, the ONC has now been recognised under Congressional Law as an agency within the US Department of Health and Human Services which means that its work can continue between Presidential Administrations without interruption.

The budget of the Office of the National Coordinator (ONC) has been increased from $80 million under the previous Administration to over $2 billion.

For the next six months Dr Blumenthal will be assisted by Dr John Glaser a health informaticist and CIO of Partners Healthcare in Boston. Other organisational and advisory structures include:

- The **Health IT Policy Committee** is a Federal Advisory Committee that makes recommendations to the National Coordinator on the policy framework for the development and adoption of a nationwide health information infrastructure, including standards for the exchange of patient medical information.

- **HITSC - the new Health IT Standards Committee**, which was formally announced the week of the Kyoto meeting, is chaired by Dr Jonathan Perlin, CMO of Healthcare Corporation of America and former Under Secretary for Health for US-DVA.

  The role of HITSC is to make recommendations to the National Coordinator in relation to standards, implementation specifications, and certification criteria for the electronic exchange and use of health information.

  Initially, the HIT Standards Committee will focus on the policies developed by the Health IT Policy Committee with an early priority being to establish the standards and compliance framework needed to identify what constitutes “meaningful use” of health IT in order for a health service provider to qualify for federal funding under the stimulus law.

  The Health IT Standards Committee has 25 members of whom the following have had a strong involvement with HL7 in leadership or senior advisory positions: Chris Chute, (Mayo Clinic), Janet Corrigan (National Quality Forum), C Martin Harris (Cleveland Clinic), Stan Huff (Intermountain Healthcare, HL7 Board) and Wes Rishel (Gartner).

- HITSP - the Health IT Standards Panel, chaired by Dr John Halamka (Harvard Medical School and Practice Partners) was formed under the previous Administration but is in the process of revamping its work to fit the new goals of ONC - with a focus on accessibility of standards for data elements, vocabulary and transmission to support routine information exchange. HITSP continues to exist, for the present, but is no longer pursuing its previous focus on development of detailed use case documentation to address the needs of specific health care settings.

- CCHIT - the Certification Commission for Health IT is also understood to be continuing its activities but with greater involvement of Government through an increased role for the National Institute for Standards and Technology (NIST) in its activities.

The former **AHIC (American Health Information Community)** completed its work as a Federal Advisory Council under the previous administration in November 2008 and was transitioned to a private-public organization, the National eHealth Collaborative (NeHC). The NeHC is recognised by ONC as facilitating collaboration to create a secure, interoperable, nationwide health information network that will advance the American public’s interest in health and improve the quality, safety, efficiency and accessibility of healthcare.

A major health reform bill addressing access to and cost of clinical services, the structure and administration of health services and changes in health insurance arrangements is expected to be released for discussion in June/July 2009.

In this environment, many parties are putting in plans for investment that deliver economic and e-health stimulus in the short term. In the midst of these investment proposals, the administration’s nominee, Tom Daschle, did not see through his nomination so significant upheaval and confusion has resulted in the direction of this planning process. HL7, along with many other e-health bodies, have put forward funding proposals and these are not expected to see responses until the fall (09Q3) of 2009. Many are expecting a re-organisation of existing national investments in e-health including support for standards, conformance, and solutions. Many are looking to existing national approaches including Medicaid/Medicare, Indian Health Service, US Defense, and Veterans Affairs to be included in these new e-health investments.

Action: The billions of dollars being invested in USA e-health outcomes will significantly alter the standards and vendors environment. Australia needs to ride with this change in approach as it manifests over the next 6 months. In particular, the standards bodies (including HL7 and IHE) will likely forge stronger implementation models to support the implementation requirements of solution providers.

Groups to whom this may be of interest: NEHTA, Standards Australia and HL7 Australia

5.3 HL7 Global Board Meeting

T. Connell-Clark. M. Walker, V. McCauley, K. Veil and R. Dixon Hughes

The HL7 Board convened on Tuesday with apologies from Ken Lunn (UK NHS CfH). Affiliates are also allowed to observe the meeting, which finished in record time of 3.5 hours (previously it has run for up to 9 hours). No board papers are provided for Affiliates for the board meeting. There was less emphasis than usual on some of the administrative and governance issues at the HL7 Board meeting and also in the general sessions. This may have been partly due to it being an international meeting not attended by some key HL7 personnel from North America or because key administrative support personnel were quarantined on arrival and unable to support the executive team - or a combination of factors. Nevertheless, there was robust consideration of strategic issues,

Ed Hammond welcomed the board and invited guests, followed by the Chairs Report (Hammond), Treasurers Report (Hans Buitendijk), CEO Report (Jaffe), CTO Report (Quinn)

- Financials were reported for education and working group meetings
  - Kyoto provided a US$182,000 anticipated loss
  - Kyoto had the highest number of new attendees and international affiliates
- Web site has been updated and is under budget
- 2008 Financials and Treasurers report presented and accepted

HL7 Australia has a proposal in play to hold the 2011 international meeting in Sydney. A US$182000 projected loss for the Kyoto meeting along with additional potential lost revenue of at least US$40,000 has caused concern to the US-centric board. There is considerable concern from the international affiliates that HL7 has for some time been looking for reasons to hold the HL7 WGM only in the US and statements made by Charles Jaffe, CEO, further support this.

A meeting was held with Charles Jaffe to discuss opportunities to mitigate any potential deficit and HL7 has agreed to pay a local Australia event organizer to calculate break-even figures for a WGM in Sydney. This is being coordinated by HL7 Australia with contributions in the creative ideas department from NEHTA. A meeting with the HL7 Australia board is scheduled to discuss the opportunity further and to identify where, if at all, NEHTA could assist with the promotion of the opportunity for the benefit of the Australian health informatics community.

HL7 remains USA-centric and it would be very strategic to have Australia co-opted onto the board of HL7. This was discussed at a meeting with the HL7 Australia members present and received very strong support not only from Australia but from the other International Affiliates who share the same concerns. The discussion is ongoing.

Actions required:

1. Continue to monitor the direction of the HL7 Global Board
2. HL7 Australia to review local implications of the HL7 Financial Plan for the US (Simborg Plan) [See further discussion under CEO Report].

5.4 CEO Report

R. Dixon Hughes and K. Veil

The CEO of HL7, Dr Charles Jaffe MD PhD, presented reports to the Affiliates Council (on Sunday), to the General Business Meeting on Monday and to the HL7 Board Meeting on the Tuesday evening, during which he highlighted the following aspects and issues of current importance to HL7.

5.4.1 The HL7 Roadmap

The initial HL7 Roadmap identified a 3-year horizon and totalled some 45 pages. It has been decomposed into a short strategic overview focussing on key initiatives needed to achieve substantial progress against five strategic imperatives and a schedule of strategic projects targeted at realising the desired outcomes.

The short-term goals and outcomes for HL7 are now reasonably clear - the challenge is achieving them - with funding of the project wish-list being the major obstacle. In recent times, some major HL7 development activities have been well supported by external stakeholders but these supporters now need to focus more on their other local priorities. In particular, significant further investments are needed to complete HL7 tooling despite substantial contributions from UK NHS and Canada Health Infoway.

The Roadmap Taskforce's current efforts are focussed on scheduling the work and mapping of resources into projected milestones, rather than considering changes to the schedule.

As an organisation, HL7 has had to balance the progression of its roadmap activities against the need to respond appropriately to a rapidly changing external environment driven by shorter-term needs of key stakeholders (particularly in the US, but also in Europe and emerging regions).

5.4.2 Marketing Plan 2009-2010

The first revision of the Marketing Plan document is available under "documents" for download from the HL7 Marketing Council page on the HL7 website.

Dr Jaffe noted that the initial draft of the *PR, Marketing and Communication Plan 2009-2010* has a strong North American perspective but was developed with some Affiliate input;. Sourcing of non-US expertise to respond effectively to international opportunities remains a major concern for HL7 - particularly for the anticipated expansion of HL7 marketing to Europe and Latin America in 2010.

Even though Dr Jaffe acknowledged that more work is needed on making the Marketing Plan more international, its lack of sensitivity and focus in relation to international interests remains a concern to most international Affiliates.

Dr Jill Kaufman and the members of the HL7 Marketing Council were thanked for their efforts in producing Revision 1 of the Marketing Plan - with Affiliates being encouraged to become more involved. HL7 intends that the document be extended to better address international perspectives and related marketing initiatives (initially for Canada, Europe and Latin America) and is seeking increased involvement in this process.

It was somewhat surprising to the representatives of international Affiliates present in the meeting that the HL7 Marketing Plan had been developed with so little apparent input from the Affiliates. The reason given when this was questioned was that the plan needed to be completed quickly to position HL7 to exploit "near-term opportunities from the US ARRA funding". It was pointed out by the Affiliate representatives present that other national programs (NHS, Canada Infoway, NEHTA, etc.) also had substantial stimulus funds.

5.4.3 HL7 Financial Plan for the US

This is shorthand for a six-page outline proposal entitled: "A Proposal to Streamline the Standards Development Process to Serve the Needs of the US Health Information Technology Initiative by Health Level Seven, Inc.". In discussion of this document, Dr Jaffe indicated that:

1. It aligns with HL7's strategy of working directly with **Profiler/Enforcer Organisations (PEOs)** and, in this regard, builds on *"significant input from UK, Canada and Australia"* and represents *"significant leveraging of experience with Affiliate development initiatives"*

2. Release 1 has been sent to US PEOs [specifically US Government health care policy and delivery agencies] for comment and feedback

3. The current document is strongly oriented toward current needs in the US but HL7 intends shortly intends to re-purpose the document for deployment in non-US settings.

It has been a time of reassessment and change in the US as the new Obama Administration determines which organisations, political structures, processes and decision-makers will continue and which will be changed, replaced or removed. For the past 5 months, HL7 has been engaging with the political process to identify where and how it can best integrate into the various plans of the US Government, existing and emerging PEOs and other key stakeholders.

5.4.4 Collaboration and Outreach

HL7 continues to support both collaboration and outreach activities, including engaging closely with:

1. The ISO/ CEN/ HL7/ CDISC/ IHTSDO **Joint Initiative Council (JIC)** for SDO Harmonisation and its subsidiary Joint Working Group (JWG).

   HL7 is now convinced that the decision to start the JIC with just three organisations was correct. While achieving harmonisation is still widely accepted as a worthwhile goal, the practical experience of aligning ballot standardization processes and principles established over a 20-50 year period in HL7, CEN and ISO has highlighted many difficulties, which have been progressively resolved with goodwill. It would have been much harder to achieve the same results involving more organisations.

2. **IHE International and CDISC** in relation to required standards and common approaches -and sponsoring CDISC as a JIC member.

   [Note: IHE's ability to enter into agreements with other bodies is limited by not having its own independent corporate identity - an apparently simple matter which appears to be taking a long time to resolve!!]

3. Other US-based standards development organisations through the **"Standards Charter Organisation" (SCO)** - more details of which are given at the end of this outline of the CEO's report.

4. The HL7 **Clinical Information Interchange Collaborative (CIIC)**. This was formed as an outcome of HL7's recent *"Bridging the Chasm"* event, held on 20 April 2009, which brought together representatives of over 100 different clinical speciality organisations to have an open exchange to inform the international informatics community of their needs. While mainly attended by US professional societies, some also came from Europe, UK, Canada, Asia and Latin America. .

   Strong common areas of interest relate to vocabulary, clinical workflow and the need to facilitate the sharing of clinical information among various all clinical practitioners providing health services to a consumer. HL7 was encouraged to take a more active role in bringing these things about. A written charter is being prepared as the next step in formalising the arrangements.

5. **UN/WHO (World Health Organization)** - particularly following HL7's participation in the Rockefeller Foundation workshops on information support for healthcare in the developing world, held at lake Como, Italy in mid-2008.

5.4.5 Interoperability

Introducing the central theme *"Collaboration breeds Interoperability"* Dr Jaffe stressed the widely acknowledged observations that:

- Interoperability adds the dimension of re-use of information leading to further efficiencies and benefits; and

- Standards development can no longer operate in a vacuum.

Specific initiatives in which HL7 is seeking to promote the ideal of interoperability through collaboration include:

1. **Decision Support**
   Where the critical element is driving EHR value and adoption with collaborators: CDSC and Morningside Consortium and the objective: a unifying architecture and multiple specifications

2. **Quality**
   Moving beyond metrics to change the care paradigm, with collaborators: National Quality Forum, PQRI, and the Quality Collaborative and the objective: translating best practices, clinical guidelines into evidence-based medicine into actionable information

3. **Clinical Research**
   Patient care and clinical research are not stand-alone entities. They must be linked effectively so that research informs patient care and patient care informs research, with collaborators: CDISC, National Cancer Institute, FDA and the objective: seamless interchange of clinical and research data via implementation of the BRIDG Model

4. **Biosurveillance**
   Major new approaches to Biosurveillance are driven by the need for data exchange in real time and success of CDA , with collaborator CDC and the objective: bringing local data to a central warehouse and informing the local and regional Departments of Public Health

5. **Internationalism**
   Healthcare operates and needs standardization on a global stage, with collaborators: Joint Initiative Council (JIC) - ISO, CEN, CDISC, IHTSDO - supported by JWG - and the objectives: enabling harmonization AND identifying and closing the gaps in standards coverage

6. **Healthcare Capacity Building**
   With collaborators: WHO, AMIA, Rockefeller Foundation and the objective: bringing standards development to the emerging nations.

7. **Pharmacovigilance**
   To ensure post-approval drug safety, with collaborators: CDISC, FDA, EMEA, CEN and the objective: ensuring that patient protection does not end at drug and device approval

8. **Clinical Workflow** - **Clinical Information Interchange Collaborative (CIIC)**
   With representatives of physicians, nurses, pharmacists, physical therapists, scientific researchers & the continuum of healthcare delivery.

   The ultimate challenge for HL7 and the CIIC members is how to convert clinical information into clinical knowledge that can be readily and seamlessly applied for clinical decision support by both clinicians and clinical information systems

9. **Clinical Workflow - Inclusion of caregivers**
   Inclusion of caregivers in the processes for which solutions are developed, with supporters: AHRQ, medical and other specialty Societies, and the HL7 Clinical Interoperability Council and the objective: defining of the needs of the clinician relating to workflow, terminology, and business needs.

10. **Fostering SDO collaboration**
    Formation of the SCO (the SDO Charter Organization - see next subsection).

5.4.6 The Standards Charter Organization (SCO)

The Standards Development Organisation (SDO) Charter Organization arose from a series of meetings convened by the USA National Council for Prescription Drug Programs (NCPDP), an ANSI-Accredited Standards Development Organization (SDO).

NCPDP provides the current chair and secretariat support for the SCO which operates as an executive-level forum with a view to *"facilitate the creation of industry wide, interoperable standards that will support a sustainable healthcare information technology (HIT) in the US."* John Quinn, HL7 CTO is the chair-elect and will become chair in 2011.

The formal mission of the SCO is to *"coordinate among its charter members to achieve true collaboration and harmonization of standards and interoperability that will support meaningful improvements in healthcare outcomes.*"

The SDOs that are members of the SCO are: HL7, NCPDP, ASC X12, CDISC, ASTM, and WEDI. Formal observer status is accorded to: ANSI, FHA, HITSP, ONC, SSA, IHE and the ISO US TAG - these include the most significant Profiler/Enforcer Organizations in US healthcare.

More information on the formation of the SCO is available in a press release, which can be downloaded via the HL7.org website at:
http://www.hl7.org/documentcenter/public/pressreleases/HL7_PRESS_20090319.pdf

5.5 CTO Report

R. Dixon Hughes and K. Veil

The CTO, John Quinn, also reported several times - to the Affiliates Council, General Business Meeting on Monday and the HL7 Board Meeting, focussing on the following three themes:

- HL7 Architecture - SAEAF
- HL7 Tooling (reported in section 37 below)
- HL7 and other SDOs

5.5.1 Progress in implementing SAEAF

An introductory overview of SAEAF and its development was provided in the Australian delegation report to the September 2008 HL7 Plenary and WG meeting in Vancouver.[1] SAEAF aims to provide a rational needs-driven framework to drive development of HL7 specifications for standard messages, documents and services; it will also 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.

As presented to the Kyoto meeting, SAEAF has evolved under the leadership of Dr Charlie Mead and the Architecture Board (ArB) from an overview into a more detailed ("alpha-version") specification that:

- Currently consists of five-parts, with three core components:
  - Snapshot (High-level Overview)
  - Introduction
  - Behavioural Framework (encompassing "dynamic model")
  - Governance Framework
  - Enterprise Compliance and Conformance Framework (ECCF)
- Is now stable/mature enough to begin "pilot" implementations that:
  - Will produce SAEAF-compliant message, document, and service specifications
  - Utilize and provide feedback for SAEAF-centric education
  - Execute under SAEAF-triggered change management processes
  - Report to the TSC or its designate

[1] Available at: http://www.e-health.standards.org.au/downloads/HL7_Vancouver.pdf pp.16-19.

The initial SAEAF concepts involved a combination of practical and theoretical considerations and were further refined by ArB through a process that involved a 3-day face to face meeting in April and practical input from Canada Health Infoway, US-NCI and others. The latest SAEAF documentation is available online by following the links from the ArB/SAEAF page on the HL7 Wiki to its GForge location.[2]

In his presentation, John Quinn stressed that SAEAF is a framework that focuses HL7 activities on their relationship to the wider healthcare environment. It is an architectural framework and not an architecture of itself. SAEAF therefore needs to be implemented by exposing, defining and refining the relationships between each piece of HL7 work and other pieces of HL7 work and the external healthcare environment. It seeks to provide the means of positioning work such as various v2, v3 artefacts, CCOW etc. The main goal is to change HL7 activities to align with the SAEAF approach to address the wider interoperability needs of the external environment of health care, life sciences and clinical research.

Implementation of SAEAF will be a key focus of TSC activities going forward and will involve education, change management throughout HL7 and the establishment of "Alpha Projects" across each of HL7's interoperability paradigms. These projects a will address application of the SAEAF framework through examination and documentation of the following aspects:

1. Introduction
2. Behavioural Framework
3. Information Framework
4. Enterprise Conformance and Certification Framework
5. Governance Framework
6. Implementation Guide
7. Examples

Any group within HL7 is welcome to propose an Alpha Project. It was noted that these projects are likely to cut across WG scopes and that the focus is on the dynamic aspects, with the static framework largely being addressed by the RIM and associated models such as CDA etc.

ArB activity on SAEAF in Kyoto focussed on mapping the SAEAF requirements to the key building block components and activities within the HL7 enterprise architecture: the RIM, Vocabulary, Data Types, ITS, CDA, CMETS and other Domain-specific composite artefacts

The lessons learnt from these exercises are expected to lead to further revision of the SAEAF to deliver a "beta-version" followed by formal release of tested specifications for the framework - in accordance with best practices in ICT standardization.

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

5.5.2 Relationships with other SDOs

HL7s relationship with other SDOs is focussed on two main streams of activity:

- relationships with ISO/TC215 and the international standards community through the JIC/JWG and
- relationships with US-based SDOs, PCOs and Government through the newly-formed SDO Charter Organisation (SCO)

With respect to ISO/TC215, the JIC and JWG which all met in Edinburgh end of April:

- New processes for joint balloting now appear to be working - despite having to overcome many teething problems. The key appears to be aligning the completion date of the final ballots, after most of the major issues have been ironed out with good communication at the earlier stages.
- ISO/TCC215/WG6 (Pharmacy) is progressing 7 projects in the areas of : Identification of Medicinal Products (IDMP); Medical Product and Device Listing and Individual Case Safety Report (ICSR). These are all expected to be confirmed as JIC Projects with formal HL7 involvement.

[2] Currently, http://hl7projects.hl7.nscee.edu/frs/?group_id=64

- The joint balloting of the EHR-S Functional Model is progressing to the next (and final) stage for full acceptance as a joint ISO and HL7 standard

As reported in the CEO report above, HL7 is a charter member of the SCO and John Quinn is the chair-elect. Initial discussions are now well underway on the applicability of HL7 standards (e.g., RIM) to other US standards groups who have a need to support the interchange of clinical information in new business settings. A particular driver has been the need for retail pharmacies to exchange a much wider range of clinical data apart from prescriptions as other clinical functions (e.g. primary medical and/or nursing care) are now being provided as part of retail pharmacy operations - they need standards for information interchange and do not wish to reinvent any wheels.

5.6 HL7 Chair's Report to Membership

R. Dixon Hughes

In presenting his report to the general membership, the Chair of HL7, Dr Ed Hammond PhD indicated that he endorsed but would not repeat the material presented by the CEO and CTO earlier in the week and went on to discuss the following topics.

5.6.1 Charter agreement with ADA (American Dental Association)

Following a period of negotiation, HL7 has entered into an Associate Charter Agreement with American Dental Association. Under this agreement:

- There will be mutual liaisons between HL7 and the ADA, with each liaison to be person who is a member of both organisations
- Pat Van Dyke of Oregon Dental Care and Delta Healthcare, co-chair of the HL7 EHR WG will be HL7 liaison with ADA
- The priority activity is harmonization between the HL7 RIM and ADA Specification No.1000 (which provides a complete information model for a dental record system)
- Further projects in dental health informatics standards will be carried out as joint standards, and
- ADA members may attend HL7 meetings as HL7 members

5.6.2 Due Diligence Committee

The Due Diligence Committee assesses applications from organisations seeking to become the HL7 Affiliate for their country, monitors the compliance of Affiliate organisations with their obligations under the HL7 Affiliate Agreement and resolves any issues that arise. The exercise of these responsibilities requires persons of integrity and experience in the conduct and management of Affiliates.

The committee was reconstituted by the HL7 Board with **Klaus Veil (Chair of HL7 Australia)** and Dr Michio Kimura (Chair of HL7 Japan) as new members. An early question to be addressed by the Due Diligence Committee is an expected application to form an Affiliate in the Russian Federation.

5.6.3 Evaluation Task Forces

In line with the principles of good corporate governance, the HL7 Board resolved to establish two evaluation task forces to evaluate the performance of HL7's key executives:

- The CEO Evaluation Task Force has Chair-elect Dr Bob Dolin as its chair, with the HL7 Executive Committee as its members; and
- The CTO Evaluation Task Force has the CEO, Dr Charles Jaffe as its chair.

5.6.4 Speakers for the 2009 Plenary in Atlanta

This year's Plenary Session being held at the 2008 Plenary and Working Group Meetings in Atlanta, Georgia comes at an important time in the development of the US and some overseas health care systems. It represents a key opportunity to showcase HL7's capabilities and learn first-hand from those responsible for driving and responding to the new agendas. Speakers that have been invited include:

- Dr David Blumenthal, US National Coordinator for Health IT, ONCHIT
- Janet Corrigan, President and CEO of the National Quality Forum (NQF)
- DrJohn Tooker, CEO of the American College of Physicians (ACP)
- Dr Jeremy Thorp, UK NHS, Mandate M/403 and other European initiatives

5.6.5 Other Matters

- The "Financial Planning" Proposal and the formation of the Grants and Contracts Infrastructure (G&CI) Committee - as reported further in section 5.7 immediately below.
- Overview of matters discussed in the HL7 Board meeting (as reported separately in section 5.3 above).
- Outcomes of the "Bridge the Chasm Meeting", which was held in Washington DC on 20 April, 2009 - resulting in the formation of the CIIC as noted in the CEO report. Effective follow-up is now seen as being critical.
- The HL7 Board now considers that the so-called question of "One Member One Vote" has now been effectively resolved for the present by allowing members of Affiliate organisations equal right to vote in standards ballots and for technical leadership positions - and granting Affiliate organisations a block of votes in proportion to their actual membership numbers.
- Consideration is being given to the formation of a US Affiliate. It is recognised that this is a contentious question for both US and non-US members and, while it continues to be actively explored, no firm decisions have been taken.

5.7 Grants and Contracts Infrastructure Committee (G&CI)

R. Dixon Hughes

As discussed previously under the CEO's report, HL7 has prepared a "Financial Plan" outlining initiatives to be undertaken in the US with a view to HL7 participating strongly and gaining funding to progress activities required to implement significant reforms in clinical practice and healthcare administration through the application of EHR systems and technology .

To undertake work at the scale of operations required, the HL7 Board is considering the creation of a unit within HL7 consisting of paid professionals that will enable HL7 to meet priorities for standards development through contracts and grants - initially from the US Government and PEOs, but also from other national programs seeking to progress similar initiatives.

In forming such a professional services unit, HL7 wishes to preserve autonomy of volunteers and their control of HL7 activities as well as respect the interests of the international community.

More detailed plans and policy need to be developed to progress these matters for consideration and decision by the HL7 Board and in time to realise the opportunities likely to emerge in the next 6 months. The HL7 Board commissioned the Chair of HL7, Dr Ed Hammond, to select and convene a high-level Grants & Contracts Infrastructure (G&CI) Committee to investigate and advise the HL7 Board on how to proceed in developing a plan to address these needs.

At the Kyoto meeting, **Richard Dixon Hughes** was approached by Dr Hammond and invited to serve on the G&CI Committee on the basis of his senior executive and SDO board-level experience, international focus and his knowledge of HL7 and its strategic environment from his work on the Advisory Council to the HL7 Board. Having ascertained the extent of the expected commitment, timeframe and scope of the work and discussed the proposal with senior members of the delegation, he accepted the invitation, noting that most of the meetings would be by teleconference.

The final membership of the G&CI Committee is:

- Dr Charles Jaffe, HL7 CEO as Chair (USA)
- Richard Dixon Hughes, Managing Director, DH4 Pty Ltd (Australia)
- Dennis Giokas, CTO Canada Health Infoway, Member HL7 Board (Canada)
- Dr Ed Hammond, Current HL7 Chair (USA)
- Dr Stan Huff, IMHC, Member HL7 Board (USA)
- Dr Becky Kush, President & CEO, CDISC Inc (USA)
- Dr Don Mon, Vice President, AHIMA (USA)
- Wes Rishel, Gartner Group, long-term former Member of HL7 Board (USA)

Plus HL7 Staff: John Quinn (HL7 CTO), Mark McDougall (Executive Director HL7) and Karen van Hentenryck (Deputy Executive Director HL7)

Points to be considered as part of the initial scope include:

- Selection of paid professionals and selection process
- Applicable rates
- Repository of candidates with expertise, CVS
- Staff support and resources required
- Management structure and reporting lines
- Progress monitoring
- Grant proposal writing
- External Contacts - engagement with other groups for input and feedback including the HL7 Treasurer and finance committee, Marketing Council, International interests (including TSC National Initiatives Project), others.

6 Affiliates Council

T. Connell-Clark, V. McCauley, K. Veil, M. Walker, C. Lynton-Moll, R. Dixon Hughes and H. Grain

The Affiliates Council (which is a forum for discussion of international interests within HL7) met with representatives being present from the Affiliate bodies in Australia, Austria, Argentina, Brazil, Canada, Czech Republic, France, Germany, Greece, India, Japan, Korea, New Zealand, Spain, Switzerland, Taiwan, The Netherlands and the UK. Delegations from the USA and Pakistan also attended, as well as senior HL7 office-bearers.

The Affiliates Council received reports from the Chair, CEO and CTO and on the activities of the HL7 Board, TSC, Marketing Council and Education Committee and in relation to HQ Liaison. Many of the more important topics have already been reported in the above sections on HL7 strategic issues and direction. Other matters of particular relevance to the Affiliates included the following.

6.1 Future Working Group Meetings

The next non-US Working Meeting is scheduled for May 16-21, 2010 in Rio de Janeiro, Brazil

The proposal to hold the 2011 non-US Working Meeting in Australia has been approved by the International Affiliates Council and was well-received by the HL7 leadership, which now requires assurance that the attendance and the costs are satisfactory.

Action: This proposal will need consideration and input from the Australian HL7 community, the Standards Community through Standards Australia and the broader e-health initiatives, if maximum advantage is to be taken of this opportunity to both influence and learn.

Groups to whom this may be of interest: HL7 Australia, Standards Australia, DOHA, NEHTA, Jurisdictions and Healthcare Organisations.

6.2 Affiliate Directors on HL7 Board

There are two directors elected to the HL7 Board by the Affiliates. The term of one of the two current directors (Michael Van Campen (Canada)) expires in December 2009 and he indicated that he would be seeking nomination to stand for a second 2-year term.

It was also noted that Grant Gillis (Canada) was stepping back from standards work to take on a new role in charge of Standards and Conformance in Canada Health Infoway. This would leave a position to be filled on the "Due Diligence Committee", the Committee that oversees applications from organisations seeking to become Affiliates for their countries and deals with problems arising from the allegations of non-compliance under the Affiliate agreement. Klaus Veil advised the Affiliates Council of his interest in taking on the role when the HL7 Board considered the issue at its meeting on 12 May (he was subsequently appointed, along with Dr Michio Kimura of HL7 Japan).

The Affiliates Council expressed its appreciation of Grant Gillis' work in HL7, ISO, CHI and HL7 Canada with a round of applause.

Action: This result is a strong one for Australia and should be supported. However it also raises the issue of our ability to be strategic in these circumstances and to take leadership positions in HL7 such as co-chair positions. Clarity on the most advantageous strategic opportunities and our capacity to support the delegates appropriately need to be further considered in Australia. A specific process for identification and support of appropriate nominees and areas where we would / should seek leadership should be identified by the Australian community.

Groups to whom this may be of interest: HL7 Australia, Standards Australia, DOHA, and NEHTA.

6.3 Health Informatics Standards Glossary

Heather Grain, Chair of IT-014 and convener of ISO/TC215/WG3 Health Concepts gave a presentation and demonstration of the health informatics standards glossary which is being compiled under leadership of WG3 and support from Canadian Institute for Health Information using the SKMT (Standards Knowledge Management Tool) of which she is the principle designer. Those Affiliates that were present supported the inclusion of HL7 definitions in the Glossary and documents and products into the Document Register element of the SKMT, noting that this would be a major undertaking.

The role of the tool in classifying the content of health informatics standards to assist in harmonisation activities and the identification of gaps was also presented and discussed.

Significant work will be needed to advance the HL7 inclusion into the tool. Meetings occurred between Heather Grain and Charlie McCay to identify requirements and potential progress mechanisms.

Action: The national update of this work is significant and Australia should consider whether to include our national glossaries and documents into the tool. It has been built and tested to ensure compatibility with existing NEHTA documents and glossary.

Groups to whom this may be of interest: HL7 Australia, Standards Australia, DOHA, and NEHTA

6.4 Other Matters from Affiliates Council

MIE 2009

The MIE 2009 Conference will be help in Sarajevo, Bosnia and Herzegovina, 30 Aug. - 2 Sept. 2009 (www.MIE2009.org). The draft program and submitted papers are substantial and have the depth of an international conference. Affiliates were encouraged to support the event. Heather Grain of Australia has accepted an invitation to speak at the conference on the topic of standards harmonisation.

ISO 215 Update

A number of HL7 standards are moving through various phases of the ISO standards process, in particular:

- ISO/HL7 27931 Health informatics - HL7 Version 2.5 messaging standard (in press)
- ISO/HL7 27932 Health informatics - Clinical Document Architecture - Release 2 (in press)
- ISO/HL7 FDIS 10781 Health informatics - HL7 Electronic Health Record System Functional Model - Release 1
- ISO/DIS 21090 Health informatics - Harmonized Data Types for Information Interchange (about to go for FDIS ballot)

One-Member-One-Vote (OMOV) Task Force

The OMOV Task Force has made steady progress, with a consensus resolution to increase the number of Affiliate votes being agreed in Kyoto with the Task Force disbanded and being replaced by a new TF with a broader brief. However, the "HL7 USA Affiliate" is still an unresolved issue.

Affiliate Status Update

There are now 33 Affiliates with interest shown from Hong Kong, Russia, Pakistan and Puerto Rico to become new Affiliates. The issue with some Affiliates nearing "lapsed" status needs to be addressed by the Affiliates Due Diligence Committee (see above).

2009 University Program, Ambassador Program, Marketing and Educational Outreach

The University and Ambassador Programs are developing steadily, with more intensive approaches to universities required. Teaching units are being developed that can be taught separately or in combination.

6.5 HL7 Affiliate Update Presentations and Minutes of the Meeting

Individual Affiliates' reports and minutes of the Affiliates Council Meeting are expected to be posted in due course in the records of the Affiliates Council on the HL7 global web site at: http://www.hl7.org (follow links → Work Groups → Affiliates Council → [Tab] Minutes or Documents/Presentations. At the time of writing the documents had not been posted to the site but a copy of all available presentations to the Affiliates Council may be obtained by emailing Richard Dixon Hughes: richard@dh4.com.au.

7 Joint Initiative Council and Joint Working Group (JIC/JWG)

R. Dixon Hughes and H. Grain

The Chair of HL7, Dr Ed Hammond, is also Chair of the Joint Initiative Council (JIC), which was formed by ISO/TC215, CEN/TC251 and HL7 under the 2006/07 Charter for Health Informatics Standards Development Organisation Harmonisation - with the objective of harmonising work programs and reducing duplication in international health informatics standards development. CDISC recently became a full charter member of the JIC and the International Health Terminology Standards Development Organization (IHTSDO) is expected to become a full member on completion of its probation period. LOINC, IEEE and DICOM have been identified as further potential members.

Dr Hammond provided an update on the activities of the JIC, which is a decision-making body focusing on harmonisation comprising the senior executives and chairs of the Charter members.

An associated Joint Working Group (JWG) is formally constituted as ISO/TC215/ WG9 with Standards Australia providing the Secretariat. The JWG is open to participation from all members of the Charter organisations and is convened through ISO with co-chairs drawn from each of the Charter members. It role is to assist the JIC by identifying processes and opportunities for harmonisation, and considering, prioritising, monitoring and making recommendations on processes and on potential joint work items to the JIC. It is an advisory rather than a decision-making body (decisions that are binding on the Charter Members can only be taken by the JIC) and it does not develop standards, as such. Joint standards are developed in accordance with processes developed by the JWG, approved by the JIC, and adhering to the following broad principles, as outlined by Dr Hammond:

- The working environment is one in which joint standards are developed jointly among the participating SDOs (but not all SDOs need participate in each standard)

- Goal is one standard for one business case
- One SDO acts as host with project lead; participating SDOs provide co-chair(s)
- Work may be done in multiple settings
- Resulting work is balloted across each group simultaneously, with comments being dealt with collectively
- Publication of standards will identify all participating SDOs and will be available from each SDO.
- SDO representation at the JIC is restricted to chairs of each SDO plus two alternate representatives

The meeting was advised of the process for proposing JIC projects via the standard template, available from any of the participating SDOs, to include:

- Definition of scope (very important) - to cover what is not covered as well as what is to be covered, the deliverables and the time line
- Justification and global interest
- Participating SDOs, how the project is to identified and involvement governed within each participant and the level of commitment being offered
- The SDO that is proposed to lead the work, the nominated lead personnel from each of the and , each SDO leads

HL7 members seeking to propose or work on joint projects need to work through the CTO, John Quinn, who is the designated contact point with the JIC and other SDOs involved. His involvement is also to ensure that JIC work is coordinated with ongoing HL7 work, that its scope and requirements meet HL7 needs and that the HL7 involvement (including balloting commitments) are managed.

HL7 members attending ISO (or CEN) meetings were reminded that they do not represent HL7 at such meetings (unless specifically sent by HL7 for that purpose) - under normal circumstances they would be representing their ISO national member body (NMB) e.g. ANSI TAG, BSI, DIN, NEN or Standards Australia.

The Kyoto HL7 meeting noted that both the JIC and JWG had both met some two weeks earlier in conjunction with the ISO/TC215 meeting in Edinburgh, Scotland and that it had therefore been decided that it would not be appropriate to hold a further JWG or JIC meeting in conjunction with the HL7 meeting in Kyoto; however, a session to update HL7 members on progress was held at the normal time for considering JWG business, immediately after closure of the Affiliates Council meeting. There were some who argued that strongly that the meeting should proceed as a fully constituted meeting of the JWG, despite the other Co-chairs and the Secretariat not being present but this view did not prevail.

It was noted that the JIC meets by teleconference approximately monthly with Audrey Dickerson of HIMSS providing the Secretariat. A brief report was given on progress of joint projects, noting that Data Types R2 was approaching its final ISO/FDIS 21090 and ANSI/HL7 normative ballot. Other projects on the current and proposed JIC work program of interest to HL7 include:

- Individual Case Safety Report (ICSR) - for pharmacovigilance
- 13606-1/HL7 v3 Implementation Guide
- Document and Glossary and Document Registry (being led by Heather Grain - Australia)
- The HL7/CDISC BRIDG model
- CTRR (Clinical Trials Registry and Results), with CDISC as lead, confirmed participation from HL7 and ISO and pending participation by CEN and IHTSDO. JIC has emphasized the importance of communication with WHO and NLM on this work.

IDMP (Identification of Medicinal Products) - for pharmacovigilance (proposed)EHR-S FM (ISO 10761) R1.1 was also about to go to final FDIS ballot in ISO. After considerable discussion of issues in Edinburgh the UK had withdrawn a negative vote on the understanding that its concerns about conformance issues are addressed in R2. It was noted that there is definitely a need for genuine international collaboration to resolve differences and achieve a higher standard of excellence in R2 of the EHR-S FM and also in moving forward with the PHR-S FM work. The HL7 EHR WG is now attuned to these issues - with considerable input from Canada Health Infoway.

It was also noted that the following HL7 standards are also in various stages of becoming full International Standards through ISO:

- Methodology Development Framework

- HL7v3 Reference Information Model (RIM) R1 - ISO/HL7 21731:2006
- Clinical Terminology Services, R1 - ISO/HL7 DIS 27951
- V2.5 Messaging Standard - ISO/HL7 27931 (in publication)
- Clinical Document Architecture R2 - ISO/HL7 DIS 27932

Clinical Genomics - PedigreeOther HL7 work being considered for submission to become future ISO standards include: Arden Syntax, GELLO, InfoButton, HL7v2.6 and an updated version of the HL7v3 RIM.

A considerable amount of time was spent on the question of whether the arrangements for JWG meetings were satisfactory to the needs of HL7 members with some (particularly those with heavy HL7 commitments and from HL7 European Affiliates) considering that there should be a JWG meeting at every HL7 Working Group meeting. Their view was supported by their perception that by far the largest amount of health informatics standards development in terms of specification preparation, ballots and participation occurred in HL7.

The alternative of having a JWG meeting whenever one of the member bodies met was also discussed but Richard Dixon Hughes pointed out that this would lead to a large number of meetings and reduce joint discussion (now that there are 5 member bodies holding over 10 separate meetings a year and potentially more members). If such an approach were adopted, proposed joint decisions would effectively be discussed in silos focussed on the needs of individual SDOs with virtually no cross-fertilisation and continuity. Under these circumstances there would be little ability to serve the group cost-effectively with a permanent secretariat. These points were taken; however, there is a strong feeling that more JWG meetings should be held in conjunction with HL7 working group meetings, the holding of meetings at HIMSS events (a non-member) is not appropriate and that update sessions

8 Architecture Review Board (ArB)

A. Bond and G.Grieve

The ArB continues to engage the Service-Aware Enterprise Architecture Framework (SAEAF) through HL7. The Enterprise Compliance and Conformance Framework (ECCF) sets the basis for SAEAF governance through the matrix of RM-ODP viewpoints and MDA layers. The week was split between considering the implementation issues arising out of work on implementation of SAEAF and ECCF and, also the future plans of for the ArB, with ArB members being invited to submit artefacts that support the ECCF matrix of governance.

SAEAF implementation is proceeding satisfactorily. As more committees engage with the architecture framework, more parts of it are being scrutinized and concerns and issues are being raised and responded to. The TSC is leading work to reorganize the SAEAF and related documents, into a single greater document, and a proposal to rename the SAEAF was considered, as many have issues with many aspects of the name; however, no decision has yet been made. At a joint meeting involving many HL7 work groups, there was still some concern applying SAEAF to the existing projects within HL7.

ECCF development continued through the meeting. This specification shows considerable promise for bringing consistency to the language HL7 and its community use to describe conformance and compliance, which is an area of considerable ambiguity. A number of other SDOs, consortiums, and national programs are interested in adopting ECCF as well.

CTS2 (Common Terminology Service) and PASS are two internal HL7 projects applying SAEAF. In addition, II4SM, NCI, and Infoway have projects applying SAEAF. CTS2 are having issues with identifying the independence of conceptual, platform independent specifications, and platform specific implementations.

The HL7 Development Framework (HDF) is to be re-purposed to provide a SAEAF implementation guide. This is representative of core HL7 projects coming into alignment with SAEAF approaches.

The Behavioural Model work has progressed, and is starting to look promising. ArB will work with Orders/Observations to start developing practical examples. See notes under InM.

The ArB may take an active role in considering the future of the templates DSTU. No one has implemented the DSTU directly, though there are number of implementations that reference or use parts of the

specification. So it would not be appropriate to make it normative at the end of its trial period, but there is some considerable dissension over what to do next.

Action: Alignment of NEHTA architecture governance to the SAEAF framework will enable greater reuse of HL7 products at conceptual and platform modelling layers.

Groups to whom this may be of interest: NEHTA

9 Clinical Decision Support (CDS)

D. Rowed

Clinical Decision Support, Arden Syntax, and Clinical Guidelines did not meet at Kyoto. A joint meeting with Patient Care and CDS had been scheduled to continue the combined work on order sets but only Patient Care were present and progress was therefore minimal with most matters held over to the next meeting.

10 Clinical Interoperability Council (CIC)

V. McCauley, D. Rowed, and R. Dixon Hughes

This group was formed several years ago to address the needs of clinical groups such as cardiology and paediatrics, which were coming to HL7 and proliferating as Special Interest Groups (SIGs) under sponsorship of the Patient Care (PC) Work Group. It was recognized that those with a clinical focus would not want to be involved in detailed technical development but that a process was required to engage them within HL7 and ensure that their technical requirements would be identified and met.

The Clinical Interoperability Council (CIC) is gaining momentum as more clinical groups are coming into HL7. In general, groups are coming and presenting data requirements and specific application areas that need collaborative management. There is no strong co-coordinated methodology for taking this forward and work tends to be fairly ad–hoc. There is little emphasis on formal requirements management although this should be a key aspect across the implied work areas. This will hopefully correct itself as specific projects get underway in CIC working with relevant supporting technical groups within HL7.

A major HL7 clinical initiative “Bridging the Chasm” was held in April and saw approximately 200 medical practitioners from a wide range of professional organisations attend a high level meeting in the USA. Participants were self-funded and included European and South American participants (but none from SE Asia or Australasia). It was held with significant support from Dr Ed Hammond, current Chair of HL7 and initial chair of the CIC. There had been initial resistance within HL7 to supporting and engaging in this. It was a non-technical and specifically non-HL7 focussed event.

Ed reported that there were widely different attitudes of attendees as to the value of standards-based health IT development. It is recognized that this meeting had inadequate international attendance.

From the Bridging the Chasm meeting leads have been established and the resultant group called Clinical Information Interchange Collaborative (CIIC). It may in future meet in association with HL7 but will not be part of HL7. At this stage it appears that it will maintain its strong clinical focus rather than be concerned with specific technologies or standards. CIIC is a potentially important development as these are the very groups which, through business process and value acceptance, can enforce the workflow changes and standards utilization which constitute the missing factor in collaborative care communications such as e-referral and EHR exchange.

Initiatives similar to the CIIC should be re-started in Australia and the head of the new Clinical Leads group at NEHTA has been advised of the developments.

The CIC continues with pursuing a number of USA centric “data set” defining exercises in Diabetes, Tuberculosis and Cardiovascular Disease with a 100 data point minimum data set in conjunction with the American Specialty colleges. These data sets are making their way to HL7 standards and are informing work such as CDA and Clinical Statement. Specification of these data sets remains an issue with various meta-data repositories being trialled. Most recently it is hoped that the Detailed Clinical Models initiative will provide some clarity in this area though the HL7 Templates registry (which is likely to include *open*EHR archetypes) and the *open*EHR Clinical Knowledge Manager are also under active consideration. However it

was felt that Model representation is not too big a deal as getting the model content is much harder than transforming clinical models (even by hand).

Dr Steve Bentley gave a presentation to the CIC on the role of the Logical Record Architecture (LRA) for Health and Social Care Project in establishing the basis for clinical information sharing under UK NHS Connecting for Health. Dr Bentley is Acting Head of the LRA Project until Laura Sato returns from maternity leave in January 2010.

The overall aim of the LRA project within the broader context of the NHS CfH Informatics Data Standards Programme is to improve:

- Communications between clinicians (via their care record systems) to support the care process
- The re-use and standardised meanings of care records data for both care management and secondary (population) analysis - across the full spectrum of health and social care.
- National processes for data standards development, quality assurance, validation and re-use - providing a focus for translating clinical content requirements to data-level interoperability specifications, using methods that recognise the relationships between business requirements, data queries and models and allow them to be traced.
- The processes also seek to promote the re-use of business artefacts and technical artefacts in standards, products and implementation projects and, also, working collaboratively with suppliers and using demonstration testing as a key part of standards development
- The availability of detailed SNOMED CT implementation guidance (such as through limiting choices within the context of small care record components for specific data retrieval requirements)

At the level of business requirements and specifications, the LRA project seeks to establish: what information needs to be shared / integrated / re-used? for what purpose? by whom? how? when? and where? The types and uses of information considered span a wide variety of contexts, including: shared care records, care outcome indicators, adherence to professional guidelines / standards, etc.

The LRA identifies such requirements in terms of data retrieval requirements explicitly linked to data definitions, structures and codes, with technical outputs as computable logical data models. The technical specifications:

- Are represented by information models (identifying record structure) and SNOMED CT (for clinical meaning)
- Will ideally be capable of being mapped and supporting integration between various information modelling standards (e.g. NHS Data Dictionary, HL7v3 and *open*EHR/13606)

Downstream from the LRA project, these artefacts will provide requirements-driven input used to produce implementable data standards for information systems that can communicate at a consistent level of meaning with one another. These standards will, in turn, be applied across multiple different implementation projects - in some cases based on different families of data standards.

In summary, the LRA is intended to provide one 'model of meaning' for care records data, supporting many 'models of use. Further information is available online at:
http://www.connectingforhealth.nhs.uk/systemsandservices/data/lra

Progressive revisions of the LRA are planned to take place each March, July and November - with the first preliminary draft having been published in April 2009.

Dr Bentley indicted that the LRA Project was hoping that their work would closely align and enable mutual benefit to be derived from definitions coming out of the HL7/ISO work on Detailed Clinical Models (DCM).

With respect to the modelling approach, the resulting data models aim to be compliant with the ISO 13606 EHR Communication standard and SNOMED CT, while still reflecting the needs identified in their use cases and being understandable to clinicians (i.e. the modelling shold only be as complicated as it needs to be - and no more).

Many of the requirements are initially captured using simple spreadsheets, providing information that can be loaded into industry-standard enterprise architecture tools for further refinement. Some clinical user groups require much more support than others - it is difficult to generalise about the .

In response to a question on the relationship between CfH data modelling and standards activities and the strict requirements for data standards review set by the UK Information Standards Board for Health and Social Care (ISB HaSC), it was noted that CfH is working with ISB HaSC to develop its own subsidiary processed for technical regulatory approval of data and information standards produced within the CfH program (including SNOMED CT and clinical terminologies and data standards arising from the LRA project).

It was noted that the HL7 CIC and the NHS LRA Project could gain considerable mutual benefit from sharing information on each others processes an outcomes.

11 Clinical Document Architecture (CDA)

CDA is managed by and is reported under the Structured Documents (SD) Work Group (at section 35 below). Significant CDA issues are also reported under Clinical Statement (CS) (section 12 below), Medications Management/Pharmacy (particularly at 27.1) and Templates (at section 36).

12 Clinical Statement (CS)

NEHTA , Richard Dixon Hughes, Vince McCauley

The clinical statement is a HL7v3 common pattern (as a D-MIM) which is used by Patient Care, Structured Documents and Orders and Observations to express rich clinical content. It has been developed over more than 3 years and allows nearly any clinical statement to be encoded in its rich, recursive structure. The CS specifications passed ballot as a DSTU some two years ago and now needs to be reviewed for upgrade to a full ANSI/HL7 normative standard; however, there was no specific “home” or owner within HL to manage this work between WGMs. This led to the formation of a separate Clinical Statement Work Group at the January 2009 HL7 WGM in Orlando with representation from both technical and clinical content committees. Its workspace can be found at
http://wiki.hl7.org/index.php?title=Clinical_Statement_Harmonization_Project

Kyoto was the second face-to-face meeting of CS WG as a separate work group. Isobel Frean (who still regards herself as an Australian despite her move to the UK) is the publishing facilitator for this group but was not able to be present in Kyoto.

During the early development of the CS pattern, Australian delegates were instrumental in ensuring that it was capable of being used directly to represent clinical information modelled by *open*EHR/13606 archetypes but continual efforts are needed to ensure that this capability is not lost as HL7 adapts it to more closely meet its other needs.

At the Kyoto meeting, detailed consideration was given to topics related to achieving greater compatibility between the CS pattern and detailed models from domains in which it might be applied (notably Structured Documents in relation to the emerging requirements of CDA R3).

Given that the CS pattern is deliberately broad, comments were put forward in the recent CS ballot seeking to address the likelihood that the same clinical statement could be represented in more than one way when using the CS pattern. Alternatively, many clinical statements might also be represented using data elements from some domain models. The WG is looking to HL7 to resolve these problems through its tooling initiative and, also, through better harmonisation and classification of use cases to identify and reduce duplicated work and inconsistencies.

The CS WG also started to consider the outcomes of a comparison between the desired use of Patient Administration (PA) CMETs within CS. It was found that the CMETs have not been applied consistently across the potential change requests to PA to enable those CMETs to be applied consistently.

At the last WGM in Orlando, the CS WG agreed to enhance the Clinical Statement to support:

- Capture of laboratory test kit IDs

- The ability for the data enterer to be a device as well as a person - to allow CS to explicitly support transcription devices and laboratory automation
- For public health, the ability for an investigated person to be the subject of a clinical statement

The enhanced Clinical statement was balloted in the most recent ballot cycle and two sessions at this working group meeting were spent resolving some of the more contentious ballot comments.

Nearly an entire quarter was spent dealing with a comment from Bob Dolin (Co-chair of the Structured Documents Committee and HL7 Inc Chair elect). His comment was that the current clinical statement pattern was not sufficient to allow adoption by the Structured Documents Committee as had been proposed for Clinical Document Architecture release 3 (CDA R3). He pointed out in his negative ballot comment that the balloted Clinical Statement did not permit a number of use cases already implemented in CDA R2 or planned to be implemented in CDA R3. Without those enhancements it would make it difficult to adopt the Clinical Statement as the primary basis for clinical content in CDA R3 which is the current proposal by Structured Documents.

One proposal was to allow the clinical statement to support nearly all RIM moods and data elements. However this could not be supported by the current tool set though there is work in progress to enable this. After significant debate the comment was dismissed as non-persuasive and it was agreed that a formal change proposal submission needed to come from the Structured Documents Committee so that the requested specific changes to support current and near-future use cases can be considered for the next ballot cycle.

As CDA R3 is not due to go to ballot until early next year this would still provide sufficient time for an enhanced clinical statement to be included.

Proposed work items now being pursued by the CS WG include the following, to which Australian contributions would be welcome:

- Introducing an Act CMET into Clinical Statement. Dr William Goossen is to submit a change request for consideration at the Atlanta meeting in September
- Structured Documents have proposed a Z-SEG extension to CDA, with a proposal to be presented at the Atlanta meeting.
- Harmonization with work on the ICSR (Individual Case Safety Report) from the Pharmacy domain
- Family History/Pedigree – being progressed through current conference calls
- Harmonization with Clinical Genomics on incorporation of other genomic material into the CS pattern.

Action: Determine the priority for input and action on the new work items proposed.

Groups to whom this may be of interest: IT14, NEHTA and DOHA.

13 Community Based Collaborative Care (CBCC)

M. Walker

A very productive meeting was held around knowledge sharing on National initiatives that impacted, or were impacted on by Privacy & Consent. Countries participating were Austria, Australia, Germany, Japan and USA.

It is not surprising that concerns about these issues are shared across these realms; however, it was important to emphasise this again. The more exciting elements included the USA embarking on an almost identical direction on e-Referral as Australia with similar timeframe requirements. The Office of the National Coordinator (ONC) has been directed by Congress to fix the core components needed for e-Referral , such as Patient and Provider Id's, Standards adoption, Privacy and Security.

The one big difference between USA and Australia is that the ONC in the USA has also been instructed to establish how EHR systems should be used within clinical practices and facilities. The result is that 20 luminaries have been interviewed and the results are being documented. It is expected these will be shared

with Australia. The US are also considering the idea of randomly generating a number that represents a concept that can then be displayed in any language you wish, including clinical or patient or Greek etc.

It was also noted from Europe that privacy concerns coupled with the re-naming of Patients to Clients or Consumers has destroyed the traditional Physician Patient relationship. Work is being done there to try and re-establish these bonds. It was reported that Germany is using Ontology to handle message transformations so that compromising of privacy does not become an issue.

The Community Based Collaborative Care Committee is still dominated by consent issues, which leaves little window for other CBCC activities (e.g. Community Health information requirements) to be addressed.

Action: Form another Committee to pursue interests outside of the traditional Domains and cater for Australian developments and requirements. Australia's capacity to engage with and learn from these international activities needs to be considered.

Groups to whom this may be of interest: All Australian E-Health groups and organisations

14 Detailed Clinical Models (DCM)

M. Walker, D. Rowed and R. Dixon Hughes

The reasons for this joint ISO/HL7 DCM project were presented as addressing:

- Specification of common frameworks for defining clinical data elements for use in EHR and electronic messages. The need to progress this is undisputed (as evidenced by work with ISO/TC215 and increased clinical interest and involvement through the HL7 CIC and CIIC);
- Numerous more specific attempts at capturing clinical information models, which are going on in splendid isolation, in particular within working groups of standards organisations themselves;
- Claims that scientific approach has been lacking in reviewing and referring to existing materials;
- Debates as to which is the best approach versus few testing results;
- Explosive growth of such developments, each with its own purpose and methods applied, with different levels of quality and usefulness.

DCM work at HL7 is now done mainly by Patient Care (PC) WG but continues to involve the Templates WG. It works alongside the DCM project at ISO with both the ISO and HL7 projects being led by Dr William Goossen of The Netherlands (also a PC co-chair). DCM activities have also been reported from a PC perspective in section 31.3 below.

The project aims to provide common static models using technology-neutral UML for key clinical concepts modelled in specific technologies, principally HL7 RIM, CEN, and *open*EHR.

So far there are about 10 such models (blood pressure, temperature, respiratory rate, pulse rate, assessment scales etc) considered by the relevant WGs to be complete. New DCMs are proposed for pain measurement and to address concepts coming from the Diabetes project in The Netherlands.

These DCMs are equivalent to archetypes and can be easily developed as *open*EHR representations using existing archetype tools.

The overall aims and individual components of the DCM project were presented, noting that the project is seeking to provide an organised framework and quality standards for:

- Capture, verification, maintenance and governance of clinical content
- Quality of representation of information in DCMs and for their storage/retrieval including: vocabulary bindings, Metadata etc
- DCM modelling
- DCM repositories - including search and retrieval.

For more details, see the DCM workshop report distributed through ISO/TC215 following the August 2007 TC 215 working group meeting in Brisbane.

It has been agreed that standardisation of the above quality measures is to be the focus of ISO/TC215 work on DCM, with the first draft of the standard on DCM quality measures having now been circulated for ballot as a New Work Item Proposal (NWIP). It has also been agreed that HL7 will focus on the specification of clinical content and the establishment of a repository - focussed on a standardised process for capture of domain analysis models (DAMs) in UML and the description of associated data elements. For more in this aspect, refer to comments on the Templates WG in section 36 below.

There is an emerging approach within both the Detailed Clinical Model (DCM) and Templates projects to register the various DCM's and Templates from HL7 stakeholders so as to better determine overlaps and share approaches. Stan Huff from Intermountain Healthcare demonstrated their DCM repository used for a number of years to house their various detailed models. Cecil Lynch then presented an OWL approach that in theory provides built in reasoning capabilities over the model set. Mark Shafarman is actively seeking participation in a templates/DCM registry.

Australian interests have had some concern at the particular modelling approach which is being promoted through the DCM project by Dr Goossen and the technical leadership within HL7 who believe that progress in the use of archetyping is incompatible with HL7's strategic goals of specifying clinical content in terms of standard data elements. Contrasting with his approach, there are many in Australia who see that DCM standards need to be equally applicable to archetypes and the Clinical Knowledge Manager (CKM) tool as to the approaches being promoted by HL7.

Although DCMs represent clinical requirements, the project has no practical way to gather these requirements in a clinician-understood format and to provide for professional review (the ISO standards work is aimed at defining quality criteria for collection, storage, interoperability and content of DCMs). Current DCMs are hand-crafted using UML tools.

Many hundreds of DCMs will be needed, as evidenced by developments in the archetype space, but at the current rate this will not be achievable in a useful time frame.

The registry being developed by the Templates WG is intended to be used as a repository for DCMs. A UML modification of the *open*EHR CKM tool had been proposed for this at the previous meeting.

Action: NEHTA has been invited to participate in the Templates registry project and has been encouraged to contribute DCM's/Templates that we have created. If others likewise contribute, this will provide a valuable resource for further template/DCM building as well as create an enabler for alignment.

Groups to whom this may be of interest: All Australian E-Health groups and organisations

15 Diabetes Data Strategy Project

M. Walker, R. Dixon Hughes, NEHTA

This is a joint project between Patient Care (PC), Electronic Health Record (EHR), ArcRIM, Public Health & Emergency Response (PHER) & the Clinical Interoperability Council (CIC).

A joint meeting of the PC and EHR WGs discussed how to progress this joint project on development of a diabetes data set/template to support acute care (primary use), research and public health reporting (secondary use) purposes. Given the intensity of the project, the two groups agreed on the following scope:

- Focus on paediatric Type 1 Diabetes Mellitus
- Investigate how the secondary use requirements will impact on data collection during primary use processes (i.e. in an acute care environment). The main aim is to ensure that secondary use requirement will not cause extra data collection burden on acute care, and if it does, how this should be satisfactorily resolved. Also identify how the data requirements are tied to/aligned with the EHR functional requirements and the functional profiles for each domain (i.e. paediatric Type 1 and secondary use requirements)
- Identify the data categories in the harmonized data, where the data for each category are collected, how are they collected and what type of transform that might be necessary if one category of data is to be used for another, also to identify missing data that may need to be collected to satisfy all

requirements if they are not already in the EHR, and an assessment of how all the HL7 artefacts work together.

- Demonstrate a set of processes and standard methodology to harmonize data for primary and secondary uses
- Investigate how the domain analysis model (DAM) and detail clinical models (DCM) could be aligned with each other

The principle of collect once and use many times underpins this initiative, combined with: How do we get data into the EHR? The project has started with Diabetes assessment as a simple example, but has already raised two significant questions:

- Can we get the DAM & DCM to work together? and
- Can their functions be tied together in the EHR?

Action: This is an example of early consideration of the data continuum from clinical point of care to secondary data use. Australia should consider how to engage in these discussions both to influence the discussion and to bring learning back to Australia. Input from both those in direct clinical practice, medical, nursing and allied health as well as data users is required.

Groups to whom this may be of interest: AIHW, Jurisdictions implementing clinical information systems and data managers, as well as clinical professional colleges.

16 Education WG and eLearning Course

C. Lynton-Moll and K. Veil

An intensive one-day workshop was held in Kyoto concentrating on administration of the eLearning course that has been developed by HL7 Argentina and has been taken by over 750 students so far (in English and Spanish).

Diego Kaminker and Fernando Campos lead the group through all aspects of setting up and running the course for their HL7 Affiliate. There were representatives from Austria, Czech Republic, Australia, India, Japan and Pakistan. The first session was lead by Gora Datta, HL7 Ambassador and Mark Shafarman, past Chair of HL7.

Moodle is a software package for producing Internet-based courses and web sites. It is a global development project designed to support a social constructionist framework of education. The word Moodle was originally an acronym for Modular Object-Oriented Dynamic Learning Environment, which is mostly useful to programmers and education theorists. All group members installed Moodle onto their notebooks and were then taken through the process of setting up the course; the course administration; setting up teaching staff; setting up and changing course content; setting up all students and handling of course notes, exercises, quizzes and assignments.

All participants have installed on their notebooks all of the software and materials to run a course in their Affiliate country. It is essential that an Affiliate wishing to run an eLearning course sign the addendum to the Affiliate Agreement. Australia has signed the Addendum to the Affiliate Agreement.

Action: consideration should be given to the strategic use of, or modification of this program to support Australia's skill development needs.

Groups to whom this may be of interest: HL7 Australia, DOHA and NEHTA

Overview of the eLearning Course

General Purpose of the Course. The eLearning course is a 14 week, self paced distance learning course. At the end of the course, participants should:

- Understand how to confront a project involving interoperability amongst disjointed healthcare information systems

- Understand how to read the most widely used HL7 standards
- Understand the need for controlled vocabularies, master files, and entity registries
- Read and write V2.X messages
- Read and write V3 messages
- Read and write CDA R2 documents
- Understand when to use each HL7 artifact (messages, documents).

Structure and objectives of the program course Module 1: Introduction:

- Week 01: Intro to Healthcare Interoperability
- Week 02: Intro to Vocabulary
- Week 03: Intro to UML / Intro to XML

Module 2: Intro to HL7 V2.x:

- Week 04: Intro to HL7 V2.x Data Types, ACK
- Week 05: HL7 V2.x patient admin, orders and results
- Week 06: Z-Segments, Implementation, V2.x Profiles
- Week 07: HL7 V2.x XML

Module 3: Intro to HL7 V3:

- Week 08: Intro to HL7 V3
- Week 09: RIM and Derived models
- Week 10: V3 data types and their XML representation
- Week 11: HL7 V3: from the model to the message

Module 4: Intro to CDA R2:

- Week 12: Intro to CDA R2
- Week 13: CDA R2 Basic Architecture: Header, Body, Entries
- Week 14: CDA R2 Implementation Guides / Clinical Statement

Having completed the workshop, HL7 Australia is now in a position to hold and run their own eLearning courses. HL7 New Zealand has expressed great interest in participating in the eLearning courses run by HL7 Australia.

17 Electronic Health Record (EHR)

Richard Dixon Hughes, NEHTA

The EHR WG is very active within HL7 with some two dozen specifications at various stages of development and usually attracts significant attendance at WG meetings (particularly in the US) and conducts much of its more detailed work through regular teleconferences between WG meetings. EHR WG activities are particularly focussed on functions required in EHR and PHR systems (rather than on the logical content of EHR records or their interchange as messages or documents). Current items on the work program include:

- EHR Systems Functional Model (EHR-S FM):
  - Finalisation of R1.1 as a joint ISO/HL7 specification - one of the in-depth work activities progressed by the EHR WG in Kyoto (see below);
  - Production of major second revision (R2) - planned for completion Sep 2011 (hopefully as joint HL7/ISO standard).
- Continuing production of EHR-S Functional Profiles (as reported below)
- Personal Health Record Systems Functional Model (PHR-S FM) - Issued as a DSTU in May 08, this specification is of increasing interest as a definition of the functions to be supported in a PHR system.
- Work on production of further PHR-S Functional Profiles (as reported below)

- HL7 EHR Interoperability Model (EHR-IM) and EHR Life-Cycle Model - consideration is being given to the integration of these current DSTUs into the next generation of the EHR-S and PHR-S functional models and other relevant documents, rather than confirming them as separate standards in their own right. (See report on EHR Interoperability WG below for more about these topics).
- Tooling - model and profile support. Charlie Mead gave a presentation on SAEAF to the EHR WG in Kyoto, discussing the possibility of using SAEAF viewpoints to reorient future versions of the EHR-S FM, PHR-S FM around a services framework

The EHR WG took particular advantage of the Kyoto location to maximize international feedback on the various topics it is progressing.

Action: Watching brief for future development and include in educational material to inform the Australian healthcare community.

17.1 EHR Systems Functional Model (EHR-S FM)

The EHR-S FM identifies functions that may be required in an EHR system (in this context, “EHR system” refers to a clinical information application used in a health facility or practice). The model is applied by producing more detailed “profiles” identifying which particular functions and attributes “SHALL”, “SHOULD” or “MAY” be present in an EHR system claiming to meet the needs of a particular user domain and/or jurisdictional realm.

The EHR-S FM was first published as an HL7 DSTU in July 2004 and became a full ANSI/HL7 standard in February 2008. Australia contributed much of the early international input but in recent years the standard has tended to increasingly reflect US needs as it is now heavily used in the United States, driven by the activities of the Certification Commission for Health IT (CCHIT) which has sponsored the creation of a series of US-realm profiles now used to certify various types of systems for use by providers.

Revision 1, the approved ANSI/HL7 version of the EHR-S FM has been submitted to ISO/TC 215 for acceptance as an ISO International Standard; however, HL7 is also in the process of developing an extensively updated Revision 2 (R2). The ISO process also threw up required changes that were not part of the original US standard. At HL7 and ISO meetings in Sep/Oct 2008, a compromise position was reached under which a proposed Revision 1.1 containing key changes is being put out through JWG/JIC processes for parallel ballot in both HL7 and ISO. The joint ballots corresponding to the ISO/DIS stage closed in April 2009, with significant support for proceeding to adoption; however, over 40 participants submitted some 290 comments to reconcile. A final draft is now being prepared for final ISO/FDIS and HL7 ballot.

For some of the ISO countries (notably the UK, which voted negatively - and also Norway) there is concern about the conformance issues in that the normative content of the EHR-S FM standard cannot be directly applied to assess conformance of an EHR system without considering the requirements of the relevant profile. It has been argued that the normative requirements are therefore not normative; however, the standard has been widely and successfully applied through the use of profiles, in accordance with the requirements of Chapter 2 of the standard (Conformance Clause), which was drafted on the advice of the US conformance accreditation authority (NIST).

The reconciliation process was commenced by the HL7 EHR WG in Kyoto and is to continue through an accelerated series of twice-weekly teleconferences with the goal of completing reconciliation by 5 June and having an updated draft ready to submit for parallel ISO/FDIS and ANSI/HL7 normative ballot by 8 June (subsequently amended to 11 June). If achieved, this should enable the final votes to be concluded in time for finalisation at the HL7 Plenary in September and the ISO meeting in October (noting that the ISO Central Secretariat shuts down for most of August).

Action: Australia needs to consider carefully our requirements in this area in order to influence the vote.

Groups to whom this may be of interest: NEHTA and Jurisdictions implementation clinical information systems.

17.2 EHR-S Functional Profiles (FPs)

The functional profiles that have been registered for download from the NIST website (http://xreg2.nist.gov:8080/ehrsRegistry/index.jsp) are as follows:

- BH FP. Behavioural Health Functional Profile, Version 1, Sep 2007
- CH FP. Child Health Functional Profile for EHR Systems, Version 1, Oct 2007)
- EHR/CR FP. EHR for Clinical Research Profile, Release 1, May 2008
- EDIS FP. Emergency Department Information System Functional Profile, Registration Release 1, May 2008 (Development Version 1.4)
- LTC FP - Long Term Care - Nursing Nome EHR-S Functional Profile, Release 1.0, July 2008 (Draft pending ASPE review)
- LEHR-S FP. Legal EHR-S Functional Profile. Registration Release 1 (v1.0) Jun 2007. It has been suggested that the records management and evidentiary support functions in this profile need to be reflected in R2 of the EHR-S FM, rather than being published as a separate profile.

HL7 functional profiles are increasingly being used to identify changes to systems required to comply with US Government e-Health incentive programs. The following additional EHR-S functional profiles were identified on the EHR WG work program discussed in Kyoto:

- VR CP. Vital Records Clinical Profile. This specialised US-realm FP is being led by CDC/DHHS with a view to getting more uniform reporting of clinical and statistical information related to births, deaths and stillborn births across the 50 States in the USA. Although there was very low attendance in Kyoto from US Federal and State government agencies, good feedback and strategic approaches were offered to the VR Functional Profiling team over several quarters of detailed discussion. The VR profiles work was also discussed in some depth at the PHER WG.
- An Australian perspective was put forward - suggesting that the work needed to be mindful of international work on identifiers and identification processes and that many of the US-specific details of the VR CP would need to be generalised for if it were to be considered that they may be promoted from the profile level into the EHR-S functional model itself.
- Pharmacy Functional Profile. Project is approved with work underway aiming at an informative ballot in for the January 2010 ballot cycle.
- Standalone Pharmacy Profile. Project is approved with work underway aiming at an informative ballot in for the May 2010 ballot cycle.
- Mobile Health Care Record Profile - being planned, yet to be approved
- Claim for Payment Profile - being planned, yet to be approved
- Public Health Functional Profile - being planned, yet to be approved
- Dental Functional Profile - being planned, yet to be approved

Action: Australia needs to consider their need and strategy, or otherwise, to contribute to and influence this activity.

Groups to whom this may be of interest: NEHTA and DOHA.

17.3 Personal Health Records Systems Functional Model (PHR-S FM)

Following the release of the Personal Health Record – System (PHR-S) Functional Model as a DSTU last year, feedback is now being sought from practical implementation of the PHR-S DSTU and its use to develop PHR-S functional profiles. This feedback will inform its progression to a full ANSI/HL7 normative standard, after the 2-year trial period concludes in May 2010. CCHIT and various US authorities are reported to be showing considerable enthusiasm for use of the PHR-S FM as a tool for defining acceptable PHR functionality for maintenance of health records by citizens.

17.3.1 PHR-S Functional Profiles

The first PHR-S FP, dated Oct 2008 and registered with NIST for download is the Health Authority-Based PHR-S Functional Profile, which provides a list of capabilities a health authority should consider when selecting a PHR-S to provide PHR functionality to its constituents.

The document was sponsored by Trilogy Integrated Resources and also describes the PHR-S that they claim to have deployed in over 400 state-, county-, and city-based health authorities for their residents. The document is in draft form and has yet to be progressed through the consensus process.

Action: Given recent comments of the NHHRC in this country, it may be of value for Australian interests to perform a gap analysis of the high-level requirements for a PHR-S in this document with those previously proposed to support "shared EHR" functions for Australians under Health*Connect* and with ISO 18308 or, if available, NEHTA's proposals for an iEHR architecture.

Groups to whom this may be of interest: NEHTA and DOHA.

The following additional PHR-S functional profiles were identified on the EHR WG work program discussed in Kyoto:

- Health Record Bank Functional Profile - Project approved with work underway
- Payor Based PHR Functional Profile Project approved with work underway. This profile seeks to address the question: "What are the rules that apply to downloading claims data into a PHR?"
- Clinical Research Functional Profile - being planned, yet to be approved. Inspired by the EHR/CR - this profile will address the capture of clinical research information in the PHR environment.
- Provider Based Functional Profile - being planned, yet to be approved. This FP will describe the special requirements involved in PHR systems that are portals into EHR systems.

17.3.2 Alteration of Professionally- Sourced PHR Information

The PHR team within the EHR WG is developing this white paper to address the issue of completeness and accuracy of information held in PHRs and the possible safeguards applicable, given that current PHR implementations are not designed to be an authoritative or legal database of professional document. The work program indicates that the paper is aimed for publication early in 2010.

The main question relates to the situations and processes by which an individual may alter professional contributions to their PHR record. Relevant use cases and potential functions/semaphores for managing changes to entries were discussed in the Kyoto meeting.

17.4 EHR-S FM and US Government Programs

Gora Datta presented on a range of topics including his current work with the HSAG (Health Services Advisory Group) in California, which is funded by CMS (Centers for Medicare and Medicaid Services) under the 9th CMS Scope of Work (SOW) for Quality Improvement Organizations (QIOs). The goal is to help physician practices to improve the quality and appropriateness of their services and the health of the community through better use of EHR systems to derive quality measures. Key points included:

- Even though health care in the USA is nominally "private", the US government still meets over 50% of the overall cost, therefore there are significant benefits to both the Government and to patients in moving toward a pay for performance (P4P) model of care (compared with service-based payment).
- A carrot and stick approach is being pursued under which primary care physicians can receive substantial incentives (of up to $44,000 per physician) for adopting EHR systems today. The "stick" is that they will not be able to do business with the Federal Government beyond 2011, if they are not using an EHR system. By 2014, they must be using an EHR system that is certified (based on an HL7 EHR-S Functional Profile).
- The CMS 8th SOW was a three year US Federal Government program that included provision of financial incentives to encourage clinical practices to buy and instal EHR systems (similar to the Australian PIP program).

- As a core part of this process, CMS have been operating a Physician Quality Reporting Initiative (PQRI) for several years which is reviewed and updated each year. Eligible practitioners that participate in the program have been receiving incentives of 1.5% of fees payable.
- The 2009 PQRI consists of 186 quality measures - and has many elements similar to the Australian primary care practice improvement programs.
- For 2009 and beyond, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) makes the PQRI program permanent but incentive payments will only continue to 2010 (but at 2%).
- MIPPA legislation makes incentives and grants available with a view to gaining improvements against four strategic imperatives:
  - Measuring and reporting performance
  - Adoption of health IT
  - Redesign of care processes, and
  - Transforming organizational culture.
- Bids for the 9th SOW grants opened in 2008 and are made on a State-by-State basis for specific initiatives supporting the 9th SOW theme of "Prevention". An example of the improvements being sought in the California project is to help practices use their EHR system to improve core preventive behaviours. For example, to ensure routine capture of information about vaccinations on presentation at the practice (noting that many vaccinations are externally provided through pharmacies, schools or workplaces etc.) The aim is to better estimate protection levels, handle epidemics and avoid duplication.

[In the week after the Kyoto HL7 meeting, the CCHIT announced its approved 2009-2010 criteria for certification of Ambulatory (office-based), Inpatient (hospital-based), and Emergency Department EHR systems and also for its newly developed stand-alone Electronic Prescribing certification. CCHIT also announced that it will be publishing a companion guide mapping its criteria to the characteristics of a qualified EHR [system] as described in the American Recovery and Reinvestment Act (ARRA).]

17.5 EHR Interoperability Work Group (EHR-I)

The EHR-I WG (http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG) is a sub-group within the EHR WG, led by Gary Dickinson and is progressing work on the following, all of which were presented and discussed in Kyoto:

- The **EHR Interoperability Model (EHR-IM)**, which was published as an HL7 DSTU in Feb 2007, builds on earlier work on trusted end-to-end flow of EHR information through multiple clinical information systems. It makes 9 key assertions about the formation, integrity and use of the information presented in an electronic health record, identifying 85 characteristics by which the achievement of its defined notion of "interoperability" may be tested in relation an a particular instance. The model articulates a series of concepts and tests based on all healthcare delivery being represented as a series of "Acts" (or Actions) each of which results in an "Act Record" forming an immutable part of a person's persistent "legally qualified" EHR.
- The original view was that EHR-IM Acts equate to Acts defined for the HL7 v3 RIM but this approach did not prove popular so the terms health care "Actions" is being phased into more recent specifications.
- Because the EHR-IM requirements are general in nature and are heavily oriented toward "process interoperability" and record integrity (rather than the structures and bindings needed for semantic interoperability) the EHR-IM overlaps the functional requirements for record keeping specified in the EHR-S FM, PHR-S FM and the LEHR FP.
- The main use of the EHR-IM DSTU has been to assess the ability of CDA r2 to support authentication and information integrity (published separately as a DSTU "EHR-IM reference profile for CDAr2" in July 2008)
- For reasons indicated below, it is currently proposed to integrate requirements from the EHR-IM into R2 of the EHR-S FM and the normative version of the PHR-S FM, rather than taking the existing DSTU forward as a separate standard.

- **EHR Life-Cycle Model** - This was published as an HL7 DSTU in March 2008 and is closely associated with the EHR-IM. It identifies key points in the generation, transformation, extraction and handling of a person's EHR information and sets out high level requirements for maintaining information integrity at these points.
- For reasons indicated below, it is currently proposed to integrate requirements from the EHR Lifecycle Model into R2 of the EHR-S FM and the normative version of the PHR-S FM, rather than taking the existing DSTU forward as a separate standard.
- Maintenance of the **white paper "Coming to terms: Scoping interoperability for Health Care"** originally published in Feb 2007.
- The EHR Record Metadata Review. This activity is being led by Michelle Dougherty of AHIMA, who led development of the Legal EHR-S Functional Profile. It seeks to identify what specific metadata needs to be held at the individual record and entry level to enable the needs identified in the EHR-IM, LEHRS FP, EHR-S FM, PHR-S FM and CDA r2 specifications to be met. The work is ongoing and volunteers were sought to participate in weekly teleconferences.
- **ONC/HITSP/AHIC Use Case Simplification Proposal**, which has been presented in a number of forums as well as at the EHR WG in Kyoto. The approach being suggested is to establish a library of common health care delivery Actions (with associated Action Record requirements) to address the plethora of conflicting lower-level requirements in AHIC use cases (which were developed in isolated specialist silos - with little cross-communication). The approach proposes that use cases be specified according to a top-down hierarchy: Use Case → Scenario(s) → Event(s) → Actions(s). The idea is that every use case resolves to a defined set and sequence of actions, where each Action is a discrete unit of service - corresponding to an Action Record. In theory, many of the same elemental Actions occur in different clinical domains and their description and records should therefore be reusable in different use cases. HL7 has no official position on these proposals which have not been put forward for adoption on the HL7 work program.

Many people, particularly those in the vendor community, are unsure of whether these particular HL7 products provide sufficient additional intrinsic value to support a separate stream of standardization work. They are also particularly concerned at suggestions that this might lead to yet another type of compliance regime, which is assumed in much of the EHR-I WG documentation.

The value of EHR-IM and other activities of the EHR-I WG was being seriously considered and discussed at all levels of the HL7 hierarchy at the Kyoto meeting. The consensus among key players appears to be that some elements of this work are potentially unique, have merit and represent viewpoints that need to be considered and incorporated into relevant HL7 standards, particularly R2 of the EHR-S Functional Model and the next generation of the PHR-S Functional Model; however, the most of the concepts are not sufficiently different, unique or independent to justify the EHR-IM and associated documents being retained as separate standards in their own right. This supports the prevailing view in the EHR WG that these documents will not be carried forward as separate standards but that their requirements will be incorporated into R2 of the EHR-S FM (and subsequent update of the PHR-S FM).

Action: Australia should determine a position on this issue for further focused input.

Groups to whom this may be of interest: NEHTA

17.6 Other EHR WG presentations and discussions

- **HL7 SAEAF and application of EHR-S FM**. Charlie Mead, Chair of the HL7 ArB and one of the leads on the HL7 Services Aware Enterprise Architecture Framework (SAEAF) project addressed the EHR WG - offering an approach for "Understanding Complex Models" - based on SAEAF viewpoints. He suggested that the EHR WG consider enrolling the EHR-S FM with the SAEAF team as a "Services Specification Project". He noted that this may help to resolve some of the scoping issues raised by the EHR Interoperability Model and its potential integration into the EHR-S FM and, also, provide a more granular set of profiles and conformance criteria that can be mixed and matched to address specific PHR-S and EHR-S requirements.
- **Diabetes Data Strategy Project** A joint meeting of PC and EHR Working groups discussed how to progress development of a diabetes data set/template to support acute care (primary use), research

and public health reporting (secondary use) purposes. For more detail on the project see section 15 of this report.

- **Role-based Access for shared EHR**. In relation to access control for health information, Bernd Blobel stressed in a joint session with the Security WG (see section 33.2 below) that work on RBAC in HL7 (and other groups) also needs to take into account requirements stemming from :
  - *ISO/TS 22600 Health Informatics - Privilege Management and Access Control*,
  - *ISO/TS 21298: Health Informatics - Functional and Structural Roles*, and
  - The use of a language-based approach (as distinct from a parameter-based) approach to the representation and interpretation of security policies and the results of recent European research studies and proposals for information privacy and access control.
- **Using the HL7 Behavioural Health FP in The Netherlands.** Dr Robert Stegwee reported on the use of the HL7 Behavioural Health FP as the basis for defining common requirements of Behavioural Health EHR systems for use in The Netherlands. The aim of the work was to overcome fragmentation and a lack of innovation in the market (with over 16 different vendors and many different customer groups).

  The project involved the establishment of an agreed common set of requirements for the behavioural health systems market in the Netherlands. The key output was a reference model, consisting of a process model and a requirements specification with a focus on clinical-care-provision and clinical support (rather than administrative) aspects of the EHR system. The initial phase of the project was completed in six months with the resulting specifications being widely applied for acquisition and certification of new generation BH systems across a range of care settings in The Netherlands.
- **National HIE project supporting private healthcare in Brazil**. Carlos Figueiredo presented on the TISS 2.0 project which extends the existing system to provide greater functional and semantic compatibility and interoperability across a diversity of independent administrative systems supporting the delivery of private health care across Brazil. The system services over 220,000 providers and organisations, processing around 80 million transactions per month for purposes of authorisations, claims billing and reimbursement and assists evaluation of health care services from a clinical, epidemiological administrative perspective and health service planning. Further information (in Portuguese) is available from the project website:
  http://www.ans.gov.br/portal/site/_hotsite_tiss/materia.htm

18 HL7 Standards and Interoperability

J. Davis and K. Veil

Action required: Review V2.x vs V3 vs CDA issue at IT-014-06-04/05/06 meeting Feb 2&3

Groups to whom this may be of interest: NEHTA

Australian organisations from whom a domain-expert would be appropriate: NEHTA

19 Individual Case Safety Report (ICSR) SIG

T. Connell-Clark, S. Chu and A. Bond

The ICSR produced a ballot package on Adverse Event Reporting, for HL7 August/September ballot. The ballot materials are already in the ISO ballot pool.

The scope of the “adverse reaction” package is very wide, including reporting on foods, cosmetics, clinical trials, as well as patient care related adverse reactions. The model is complex – contains a modified “clinical statement” pattern – change requests on clinical statement pattern will be required. It also includes modelling of the substance “transportation” event.

Members of the Patient Care TC raised the issue that the ICSR adverse reaction model had included changes that “violated” the clinical statement pattern. Patient care has an “Adverse Reaction” topic – there are certain commonalities between the two activities. Patient care has a set of mini “patterns” that specifies how the clinical statement pattern can be used to report/capture adverse reactions information. It was

suggested that ICSR examine the “Adverse Reaction” topic produced by Patient Care and use it to inform the revision of its work to avoid major “negative” ballot comments.

Action required: The “Adverse Reaction” topic is one that is critically important to NEHTA’s clinical archetype model and its reuse in many clinical structured document templates. NEHTA staff members not only need to keep a close watch on its development but also actively participate in influencing its development and revisions.

Groups to whom this may be of interest: NEHTA, Jurisdictions and Health Care Organisations implementing clinical information systems.

Australian organisations from whom a domain-expert would be appropriate: NEHTA, Clinical Professions.

20 Health Care Devices

This WG did not meet in Kyoto.

21 Imaging Integration

This WG did not meet in Kyoto.

22 Implementation & Conformance

J. Gilbert

IC initiated work to begin educating other committees about the IC and how the work relates to other committees and how moving forward the other committees can work with IC to move forward conformance work to be aligned. IC will contact committees which are doing implementation and conformance work within their groups, i.e. writing specifications:

- EHR
- ArB
- MnM
- Vocabulary
- SOA

Proposal #605: conformance levels: IC are working on integrating more detailed explanatory information about conformance into the HL7 documentation to help clarify the usage and meanings of terms. This work will also introduce the concept of conformance documentation levels, which allows vendors and purchasers to specify the level of conformance documentation and detailed specifications which implementations are built upon and incorporates/assumes a process to compare/test the documents. The work is originally proposed for HL7 v2.8 but will also be relevant for V3 and CDA.

SAEAF and ECCF and IC: Charlie Mead presented the background on SAEAF: RM-ODP and more detail on the Enterprise Conformance and Compliance Framework (ECCF). The ArB are trying to align the terms: conformance, compliance, consistency, traceability, compatibility with current HL7 documentation. Charlie Mead has taken HL7 2.7 chp.2b and proposal #605 and perhaps others to synchronize the different terms and to align with the concepts. (SAEAF and ECCF documents are on the ArB wiki site).

Strong discussion about the different concepts in behind – accompanied by the usability of RM-ODP. RM-ODP as it is used is not sufficient: some of the drawings in the ECCF document and the PPT are wrong, e.g. as source-target relationships get lost and some of the links are defined as "plug-ins into the cells".

Here the model provided by Bernd Blobel is much more applicable. Charlie will re-read the appropriate documents.

IC will go through the SAEAF, ECCF document and make comment to the ArB.

Joint IC meeting with SOA*:* Discussion with SOA group regarding conformance compliance in relation to their new EIS, specifications are starting to be developed; they were thinking these would be conformance profiles, though after discussion agreed to name them services specification.

Joint IC meeting with Vocab*:* Binding Syntax – Refers to binding of terminology to models and how you implement terminology conformance in v3. The binding syntax section was previously in the core principles document and has been noted that this should be contained in a conformance section and not core principles. Discussed that a new conformance section should be written, probably two as some parts need to be normative and some informative. IC will write a project proposal.

23 Implementable Technology Specifications (ITS)

G. Grieve, others

23.1 Joint HL7/CEN/ISO 21090 Data Types

The main focus of the ITS work group was to complete the ballot resolution for the ISO healthcare datatypes so that ISO 21090 could advance to the ISO FDIS and last ballot cycle for HL7. This was completed, and the FDIS has since been prepared.

A major policy decision for HL7 was that the ISO datatypes will no longer be a DSTU (draft standard), but a full normative standard, in the recognition that it doesn't really make sense to share the development of a standard with ISO that ISO regards as a full standard, and HL7 only as a draft, and also in recognition of the long development of the standard and thorough review including implementation.

23.2 Future revision of ITS standards

In addition, the work group reviewed work plans for the future. Including decision made shortly after the meeting, the work group plans to release a modified ITS R2 to enable the adoption of datatypes R2. This will remove the more ambitious proposals from ITS R2 such as reshaping; they will be deferred to a future release. There will also be a datatypes R1.1 that pre-adopts some of the datatypes R2 features in the existing framework. Having so many versions is somewhat unfortunate, but was the only way to build a consensus for moving forward. Summary of current versions:

R1	Existing datatypes (as adopted in CDA R2)
R1.1	Alternate local extension mechanism, and adoption of data types R2 features. May be adopted in existing specifications (such as CDA R2) by trading partner agreement
R2	Full datatypes R2, and revised architecture to provide better support for schema based code generation (schemas will be a proper description of the wire format)

The work group is also seeking proposals for future development, and is particularly considering a representation based on JSON (JavaScript Object Notation - lightweight interchange format) in response to requests from stakeholders.

A serialisation process that allows business analysts to edit instances of v3 ITS XML instances in Eclipse was reviewed and discussed. This work, which was done in collaboration with Loyd McKenzie for Canada Infoway, enables editing of V3 instances using business level terminology.

Charlie McKay indicated his belief that HL7 are alienating a whole group of enterprise architects (EAs) that are not engaged with HL7's industry-specific approaches and architectures. Healthcare CEO's understand the importance of standards and for large scale implementations require short term expert EAs to come into solve a problem. They are given business requirements and are required to produce a solution in three months and are therefore unable to spend three months learning health specific standards and architectures - rather than hitting the ground running to ensure successful implementations. HL7 products, services and tools need to be better tailored for this audience.

In discussing the evolution of ITS it was noted that the XML message specifications have been improved considerably but are still too complex, large, bloated and don't look like the XML that would be produced if it were written manually. Some of this seems to stem back to the initial modelling.

24 Infrastructure & Messaging (InM)

G. Grieve

Infrastructure and Messaging struggled to get quorum at Kyoto. An informal meeting was held to review proposals for v2.8. There are a couple of significant proposals, the most important of which is the proposal to introduce v3 nullFlavors to v2. This has significant benefits but also substantial flow on effects to implementers, so InM will be seeking wide input to this proposal.

InM did meet officially to consider the Behavioral Model work, which has progressed and is starting to look promising. ArB will work with Orders/Observations to start developing practical examples. The committees represented at this meeting agreed that we need to have a behavioural model, but questioned whether we should develop one. Since none of the existing models appears to meet our requirements, we decided to seek another more appropriate SDO to collaborate with on the development of the Behavioral Framework - possibly OASIS or OMG with other options to be canvassed.

25 Laboratory, Orders and Observations

Laboratory WG did not meet in Kyoto. Activity on the related Clinical Statement activity is reported at section 12 above.

26 Marketing Council

M. Walker, K. Veil, T.Connell-Clark, V.McCauley, J. Gilbert

26.1 HL7 Marketing Plan

The first revision of the *PR, Marketing and Communication Plan 2009-2010* (Marketing Plan) is available under "documents" for download from the HL7 Marketing Council page on the HL7 website. In responding to ARRA imperatives, the current revision of this document has a strong US perspective but it is understood that HL7 intends it being extended to better address international perspectives and related marketing initiatives (initially for Canada, Europe and Latin America) and is seeking increased international involvement in this process. Plan includes areas such as:

- Branding campaign – unlocking the power of healthcare information
- Leading line for any promotion …
- Action plans
    - Branding campaign
    - Communication plan – press releases (need to be global)
    - Press kit
    - Who can speak on behalf of HL7 Inc
    - Virtual press room
    - Forward marketing

The HL7 Financial Plan for the US, prepared by the HL7 Board and executive team was also discussed at the Kyoto WGM and raised concerns among many of the Affiliates that their requirements for HL7 standards would be set aside in favour of HL7 focussing on the needs of the US Administration.

26.2 Ambassador Program

Through its Ambassador Program, coordinated by the Marketing Council, HL7 now has 20+ Ambassadors and 9 Standard Presentations:

- Service Orientated Architecture (SOA)
- Personal Health Record – Shared (PHR-S)
- Electronic Health Record – Shared (EHR-S)
- Clinical Document Architecture (CDA)
- Continuity of Care Document (CCD)
- Introduction to HL7 V3
- Clinical Genomics
- Pharmacy and
- Business Benefits of HL7

It was proposed that to ensure the continuity of high quality that the number of presentations be kept to a limited number however in line with this three more were proposed and accepted:

- HL7 V2
- Patient Care and
- Decision Support

Max Walker has been assigned the responsibility, with the help of others in the Australian contingent, to draft the HL7 V2 presentation and Max Walker along with Vince McCauley are likely to join Klaus Veil as official HL7 Ambassadors in the near future.

26.3 HL7 UK Business Strategies

Charlie Bishop, current Chair of HL7 UK, discussed some of the responses of the HL7 UK Affiliate to changes in its operating environment, particularly the reduced role of HL7 UK in standards development, with the UK NHS CfH program now leading investment in standards development. L7 UK have therefore refocussed their efforts on marketing of HL7 and education, such as through HL7 road shows in the past 12 months (see: http://www.hl7.org.uk/marketing/roadshow/2009.asp). The road show involves a full day of activities, characterised by:

- Objectives:
  - Promote HL7 and HL7 UK
  - Raise awareness of HL7 standards
  - Increase membership
- Key features:
  - Three geographically spread venues
  - Attendance open to all
  - No charge – generally free for members
- Funding objective was to break even with all costs (including venue hire, speaker travel cost and event management) to be covered by sponsorship - with 6 sponsors at different levels of engagement. Sold HL7 v3 Primers for half price.
- Event Schedule, includes:
  - Key note speaker (NHS CfH)
  - 3x Case Studies on integration standards featuring sponsors and their customers
  - 2 x Tutorial/Workshop (in parallel) on CDA and IHE XDS
  - Discussion panel

- **Outcomes**: 200 delegates across 3 events + 6 sponsors (vendors) + small profit (just above breakeven). 20 new members for HL7 UK (10% reduction in membership rate for registering within a month of attending event.

With around 200 current members, the **HL7 UK Membership Structure** has three types of members:

- Personal member – £130 and 1 vote/members
- Organisation – £650 and 3 votes/organisational member
- Benefactor – £1300

26.4 HL7 India Membership structure

The recently reinvigorated, HL7 India (http://www.hl7india.org/) has several different levels of membership, which may be useful to look at for Australia. The levels and rates are:

- Individual – 5000 R (Rupees)
- Organisation – 10000 R
- Benefactor – 40000 or more
- Complementary – Free

Groups to whom this may be of interest: HL7 Australia Board and membership.

27 Medication Management (Pharmacy WG)

J. Davis, C. Lynton-Moll, S. Chu, R. Dixon Hughes

The Pharmacy Working Group is mainly focused on HL7 V3 messaging however they have agreed to cover V2 questions on Wednesday as requested by Australian representatives. The group covers the Medication Domain and the Pharmacy Domain. The Medication Domain has its own DMIM.

The Pharmacy Domain covers common order topics and is not necessarily medication specific as pharmacists can also dispense devices i.e. bandages, etc. We have been successful in getting HL7v2 pharmacy messaging re-established as a topic for discussion during subsequent Working Group Meetings.

Action: These activities are directly related to priority areas of National e-health strategy and as such it is essential that the Department of Health and Ageing continue to support participation in these international working group meetings.

The Pharmacy Working Group have a number of use cases defined (and are identifying additional ones) which may be of great interest to Australia as they are likely to cover many of the same use cases we have agreed to document as part of IT14-06-04. In addition they have also implemented digital signing of the HL7 V3 prescription message so again we should look at how this has been implemented to see whether a similar implementation can be applied to V2.

Action: Ongoing participation is required in this work area, and there is also a need to bring this information back into the Australian community to ensure adequate input and implementation preparation.

27.1 Use of CDA for pharmacy/ medications

A joint session was held with Orders and Observations (OO) to discuss the use of CDA or messaging for pharmacy orders and the disparity between laboratory orders and prescriptions/ pharmacy, with the following being noted in relation to defining where to use and where not to use CDA (in preference to messages):

- **When to use CDA:**
  - To replace the paper order carried by the patient
  - To document the act of ordering as a service event
  - To publish the document in a shared infrastructure

  - For query and retrieval by the chosen fulfillers to avoid manual transcription
  - For documents that are persistent and accessible to other authorised parties.

- **When not to use CDA** - To handle the workflow between the filler and placer including status change and content update

Some of those present thought that CDA was appropriate for laboratory ordering but that messaging was the correct method for prescriptions/pharmacy. **Other discussion around the topic** included:

- A clarification - the choice for prescriptions in The Netherlands is messages not documents
- Standards selection for prescriptions (Rx) was neutral - it is of concern that there is a battle between documents and messages
- Bigger worry that CDA schemas for Rx/laboratory and equivalent v3 message payloads are different
- Perspectives from OO (Orders & Observations)
- Larger investment in place is now driving use of CDA documents for Rx itself - particularly in community settings
- Implementers of Rx prefer a consistent approach across institutional and community settings
- England started Rx as messages
- Need to start with specific user requirements that may yield preference for different solutions.

The main concern was that HL7 appears to be developing two different standards for the same thing (i.e. CDA and v3 messages for pharmacy and laboratory) but the payload content specifications are different for the CDA documents and v3 messages (i.e. the pharmacy CDA document does not have the same content as the pharmacy message specification). This has resulted in talks about providing mapping between the CDA and message equivalent content.

Analogy: If you write a letter it is a document. You then put it in an envelope and put a stamp on the envelope to send it and it then becomes a message but the content has not changed. So why is the content different in CDA and a message?

The following concerns were identified:

- It is of concern that Rx and laboratory use cases with strong similarities come to different conclusions when addressed in CDA and messaging paradigms - but it is unclear why this is so.
- Different countries are coming to different conclusions on whether to use CDA or v3 messages for laboratory (e.g. Canada vis-à-vis countries following IHE [XDS?] on the use of messages or CDA to support laboratory workflow)
- The fundamental problem of continuing an inconsistent approach to modelling payloads for documents (CDA) and messages.

It was agreed that Pharmacy and OO/Laboratory WGs should attempt to resolve the issues as follows:

- Need to raise the problems more widely within ArB, Structured Documents, OO, Pharmacy, MnM, CS etc as it is starting to hurt HL7 and those seeking to implement it consistently in ways that foster interoperability.
- Since we have parallel efforts (lab CDA content, lab result) - use these as a sample to work through and seek measures to resolve the issues.
- Identify what needs to be changed on either side to bridge the gap
- Work out how to incorporate a message payload in a document without redesign
- Recognising that the CDA schema is stable and that “simple” is not a path to “simple/easy interoperability”. Inability to address the root causes only moves use-case-specific specifications into implementation guides (however - such guides would need to be normative to resolve the issue).

27.2 HL7v2.x pharmacy messages

Discussion of HL7v2 message issues went well with Pharmacy WG accepting that although they are v3 focused, v2 should not be forgotten as v2.x prescription messaging implementations are going to be around for quite a few years yet.

Australian delegates gave some background on **the Australian situation** then went through our issues with the following **outcomes**:

- Issues relating to authority prescription approval number and prescription valid-until date will be taken to OO WG, as it was considered that these two items were valid for both prescriptions and orders.
- It was proposed that the prescription type i.e. whether it is PBS, RPBS, AUTH, PRIV etc. was probably more required for billing/reimbursement purposes than to actually belong to the drug/medication RXO segment and it was suggested using the billing (BLG) or finance segments. Neither of these segments are currently used in the Australian context however it may be possible to use the insurance IN1 segment instead.

The Pharmacy Work Group has said that they are happy to discuss any future v2 pharmacy message issues as required. We need to investigate the full use and need for the send-to-patient and previous-authority indicators so that we can determine whether they are really required and, if so, identify the correct segment in which to place them. Moving forward, they have requested our participation in defining use cases and processing with regard to institution and hospital pharmacy to ensure that whilst defining v3 all our needs are identified and covered. They are currently expecting this work to occur around May 2010.

Action: Identification of Australia's approach to inclusion of billing information in processes for Drug/Medication messaging – NEHTA , Standards Australia, HL7 Australia, prescription exchange services, Medicare Australia, DoHA PSB, IHE Australia.

During the IHE update it was suggested that an IHE technical framework in conjunction with v2 messaging could be used to assist with pharmacy in the hospital setting - but France who are the ones progressing IHE for Pharmacy would only consider creating an IHE framework for v3.

Action: Consideration of IHE profiles for v2 messages: NEHTA, HL7 Australia, IHE Australia.

27.3 Progress with Other Key Requirements

Medication Identification Services

There was some discussion regarding Medication Identification Services to provide a standard methodology for searching for products. The Medication Identification Services would be a re-use of the Entity Identification Service. The benefit would be that if all service provides implemented the same EIS then users would have the ability to search all available directories. The assumption is that you would need to have a standard product catalogue and standard terminologies.

Send to Patient Indicator

"Send to patient" is still used sometimes, for example, authorities for repeat prescriptions of increased quantities of Schedule 8 drugs cannot be obtained by phone and must be obtained in writing by sending the prescription to Medicare Australia for approval. It is also still optional for doctors to send the script in for approval even if it could be approved by phone. Some doctors do this as they don't want to waste time sitting on hold to MA.

Previous Authority

In the early days, it may not have been easy for the approval person to see if it had been approved before and therefore able to be "rubber stamped" on subsequent prescriptions.

Relationships to IDMP and AMT work

The Pharmacy WG also discussed common medication types, looking into how this fits into the Identification of Medicinal Product (IDMP) work originally sponsored by ICH and being progressed actively through ISO/TC215/WG as a Joint International Committee (JIC) project. Despite being a joint project, IDMP has been controversial and HL7 engagement with the work has been patchy. This could have implications for Australian Medicines Terminology (AMT).

Identification of v2/v3 gaps

Pharmacy WG is instigating a mapping exercise between v2 and v3 message specifications and requirements to see where issues lie and to ensure that anything missing in v2 is covered in v3.

27.4 Common medication model

The Pharmacy WG has developed a "common medication model". This model is based on the medication domain message information model (HL7 DMIM) published earlier. Since the publication of the DMIM other groups have voiced their requirements and presented similar models to cover areas such as immunization, non-medicinal products (such as point of care testing devices, e.g. BSL test strips, surgical consumables such as bandages, etc), and ordering. The different groups decided that the various models need to be harmonized into one single model which resulted in the creation of the "common product model".

It is designed to support:

- Order of medicines
- Order of non medicinal products
- Dispensing
- Administration of medications

The task at hand now is to examine whether this common model is harmonized or in line with the "clinical statement" pattern, the "common order" and various domain specific "order" messaging models produced by "Orders and Observations".

There is also a need for other harmonization efforts – e.g. with the IDMP (identification of medicinal products) project – a joint initiative by HL7, CEN, and ISO to harmonize an information model/structure for representing medication information, with the "common product model" as the starting point.

SNOMED-CT will be the candidate terminology to populate the harmonized model.

27.5 Proposals for new Pharmacy WG projects

There are two "new proposals"

27.5.1 Medication Identification Services Proposal

This project requirement is conceptualised in terms of a web service whereby a user can call up a web service, send the appropriate parameter values and request relevant medication information to be returned. Use case example:

> *A user may want to know the Australian, or Japanese medication identifier and associated scientific information for a specific medication such as "amoxicillin 250mg".*
>
> *The web services would return relevant detailed information about the medication in question.*

The proposal suggests that the scope of the project needs to be further defined, including the standard specifications to be developed for identifying the types of services available, the type of parameters and values required or accepted, and the type of information that may need to be returned to the user. However, it is not clear that the WG has all the resources required to deliver the required outputs. It was suggested that this "proposal" would be discussed further in future conference calls.

27.5.2 IHE profiles for eRx, dispensing and medication administration

France submitted an IHE white paper for development of IHE profiles to support electronic prescribing and dispensing reporting with the possibility to expand the scope to medication administration. The care settings would cover both acute care and also community settings.

The profiles would need to identify the standards to be used and decide to use either messaging or CDA.

France is requesting contributors/participants from HL7 to support the development of the technical framework. This proposal will also be discussed further in future conference calls.

Groups to whom these proposed projects may be of interest: NEHTA , Standards Australia, HL7 Australia, prescription exchange services, Medicare Australia, DOHA PSB, IHE Australia.

28 Modelling & Methodology (MnM)

G. Grieve

MnM performed ballot resolution for three ballots:

- **Abstract DataTypes**. The abstract datatypes (joint with ISO as ISO DIS 21090) passed ballot, and reconciliation was completed. However due to a controversial substantiative change, a further ballot will be required, limited to that single change.
- **RIM**: a number of significant negatives will lead to extension and clarification of the documentation in the RIM, including documentation of some informal lore. In particular, the somewhat ill-clarified notions of "structural" and "immutable" attributes will be clarified
- **Core Principles:** further development leading to a new ballot. At some stage in the future, the core principles document will be incorporated into a wider set of documentation including the SAEAF document

In addition the committee carried out its normal role of providing consultative and facilitative advice to committees, particularly over cross-committee issues.

29 Patient Administration (PA)

K. Veil

The agenda of the PA Work Group was achieved, albeit both regular co-chairs (USA VA & McKesson) not being able to attend due to travel restrictions. PA had wisely at the previous WGM elected 2 interim co-chairs (Klaus Veil & Jay Zimmerman, Canada) and the required quorums were met.

Work on v2.8 and v3 was undertaken, with one focus being v3 out-patient encounters which have not been worked on since 2005 and so are not fully modelled.

PA members commented that while the work progressed somewhat slower due to the absence of the experienced v3 co-chairs, they felt the WGM was productive and their goals were achieved.

30 Patient Care

M. Walker, D. Rowed and K. Veil

31 Patient Care WG and Patient Referral

M. Walker, D. Rowed and K. Veil

Patient Care (PC) WG deals with the clinical content of HL7 communications in areas such Problems, Diagnoses, Assessments, Goals, Pathways, Concerns (formerly ‘Conditions’), Care Plans, and Referral.

It principally concerns itself with HL7 Version 3 message development, as well as generic modelling of the concepts through the Detailed Clinical Model (DCM) projects of HL7 and ISO. It has been a lead team in the Clinical Statement work and works with the Clinical Statement (CS), Structured Documents (SD), Clinical Decision Support (CDS) and Orders and Observations (OO) WGs to ensure uniform approaches are used across their subject areas.

It therefore has close relationship with other specialized clinical and public health domains, many of which started out as Special Interest Groups (SIGs) under PC sponsorship. These include: - Patient Safety (PS),

Public Health and Emergency Response (PHER), Community-Based Collaborative Care (CBCC), Cardiology, Paediatric Data Standards as well as the Clinical Interoperability Council (CIC).

Its principal v3 ballot work is around the Care Provision messages which generalize referral and collaborative care communication. This work was led by Australia and is informed by our referral work. The main artefacts are in DSTU stage.

31.1 Continuing support for HL7v2.x clinical messages

PC WG remains responsible for Chapters 11 and 12 of the HL7v2.x standard, which address clinical patient care messages and referrals. These two chapters have been maintained by Australia through IT 14/6/6 and incorporation of Australian-sourced content into the international standard via the CBCC and PC working groups.

Australia continues to use and develop HL7 v2 messages and has made major enhancements to this standard to meet stakeholder requirements. Its value to us centres on its widespread deployment and support together with its simple, implicit but adequate dynamic model for clinical communication

Its weakness is in its poor expressivity for content but this has been addressed in Australia with version 2.7 extensions and more recently the use of archetyped data within v2 messages.

There is a need for more support of our V2 work at HL7 and making more people aware of the value of using it for clinical messaging.

One of the current co-chairs of this PC had issued a somewhat irregular view that "V2.x has been deprecated" which is not in line with HL7.org Board policy and had slowed down the inclusion of Australian V2.x content into the v2.x Standard. Following a delegation to the committee by representatives of the Australian contingent it was agreed that Patient Care would resume official responsibility for HL7v2 Chapters 11 and 12 (Referral & Discharge Summary and Patient Care). With the election of a second V3 co-chair (Ian Townend, NHS) and a new V2.x co-chair (Klaus Veil, Australia - interim, until confirmed at the next WGM) we have been able to mitigate this issue.

There will now be dedicated time at future meetings for v2 work of interest to Australia and, particularly in association with CBCC WG, on enhancing Chapters 11, and 12 for v2.8 and the Collaborative Care Message.

Action: If this continues to be a priority for Australia – sufficient focused support must be available at the next meeting to ensure that the issue is successfully pursued.

31.2 Progress of v3 work in PC WG

At the Kyoto meeting PC WG achieved ballot resolution on v3 work covering:

- Health Concern (i.e. Problems)
- Care Composition, and
- Assessment Scales

Other current v3 work includes:

- Taking Patient Care Provision from DSTU to Normative.
  This includes: Care Transfer, Query, and Care Record Structures
- Care Plan structures,
- Adverse reactions.
- Definitions and modelling around Diagnosis, Observation, Concern and Problem.

31.3 DCM Developments

Patient Care WG is the main driver of the “detailed clinical model” development discussions and most of the HL7 contribution to this work takes place at PC. See also the separate section on Detailed Clinical Models (DCMs) at section 14 of this report.

The HL7 community appears to have arrived at a general agreement that the "Clinical Statement" pattern (as discussed in section 12 above) will be the central and harmonized structure for communicating all clinical content, whether HL7v3 messages or CDA is used. It also appears that there are movements to push the use of "clinical statement" not only for messaging, but also to inform the specification of EHR storage/contents. As the clinical statement pattern is still a relatively "generic" container it is the general opinion of the PC WG that content-specific constraints are required. "Detailed Clinical Models" (DCMs) are promoted as the logical specific constraints that can be applied to the clinical statement pattern.

DCMs are presented as detailed logical models for individual clinical concepts that are technology and platform independent. They represent clinical concepts in the following formats:

- A detailed description of the clinical concepts with definitions, versioning, authorship, custodianship, and other relevant meta data about the clinical concept in a MS WORD document
- The same contents can also be represented in a SPREADSHEET document

These documents are intended for supporting iterative development of the concepts until general consensus is reached, although it has been argued that more effective online collaborative tools should be used.

Once a specific DCM has reached general consensus level, it can then be represented as UML diagrams. At the present stage, it is proposed that Enterprise Architect (EA) be adopted as the tool for this purpose.

The DCMs are abstract/logical models. They need to be "transformed" into either HL7v3 templates or *open*EHR archetypes before they can be used in, for example, a CDA document, v3 message or archetype-based information exchange. A set of tools are required to perform the transforms. It was proposed that the following processes and tools could be considered:

- From the EA UML, XML data of the model can be extracted
- Handcrafted XSLT is created to convert the XML into Encore XML/XMI
- Another handcrafted XSLT is created to convert the Encore XML/XMI into *open*EHR archetypes and/or HL7v3 templates

At the time of the discussion only a couple of handcrafted XSLT's were available to achieve these transformations. This raised serious questions of

- the labour-intensive nature of the handcrafting exercises, hence the viability and scalability of this approach;
- the error prone nature of handcrafted tools.

No solution/satisfactory approach could be reached at the meetings, although Medical Objects from Australia asserted that it already had the tools which could be used to perform the transform.

Ten clinical concepts had been selected by the Patient Care TC for DCM development:

1. Length
2. Weight
3. BP
4. Heart frequency/pulse rate
5. Breathing
6. Body temperature
7. GCS
8. Apgar
9. Barthel
10. Braden

According to the Patient Care TC, these DCMs were close to completion and were available at the following website: http://www.hl7.org/Library/Committees/template/DCMTop9_V_03E59.ZIP.

The development of the DCM concept needs to be observed and monitored closely. NEHTA may want to input or influence international efforts on DCM developments as they impact on its clinical archetype development as reusable components in the various structured document templates.

Another topic that is considered of significant interest to NEHTA clinical archetype development is the work on "problem/diagnosis" severity and certainty modelling. There is still no agreement on how to effectively model these two qualifiers that have significant impact on a clinician's interpretation of the values of a

patient's problem and diagnosis. A close watch will be maintained on the HL7 mailing list and subsequent meetings on how the modelling works evolve.

Although Australia is not currently using any Patient Care v3 messaging formally, the stakeholder input and modelling used by HL7 internationally for its V3 work and technology-neutral DCM work is of importance to our content modelling for EHR, eReferral, Discharge and Collaborative Care Communication, and proposed local adoption of CDA.

32 Public Health and Emergency Response (PHER)

Max Walker, Richard Dixon Hughes

Attendance at PHER WG sessions was significantly reduced at this meeting, given that most of those active in the PHER WG are employed by State and Federal Government agencies in the USA and cannot obtain funding for international meetings. Nevertheless, there was a small contingent from the Centres for Disease Control (CDC), which has carriage of work on the Vital Records (VR) Functional Profile, which was discussed at several sessions - some of them joint with the EHR WG and another as host to the SOA WG.

Australia has convinced PHER that their scope should be expanded from US Realm to International. The idea is to establish core data sets and./or attributes with additions allowed for localization. This will start with Vital Statistics (Birth & Death Certificates) and a joint presentation between US & Australia is to be scheduled for the next Affiliates Meeting with the aim enlisting broader participation in this project.

In the initial overview session, PHER reaffirmed its areas of interest and activity, which includes::

- Public health registries - Immunisation, Cancer, etc.
- Tuberculosis
- Vital records
- Public health reporting
- Public health case management
- Outbreak management

32.1 Canadian Panorama Project

Co-chair, Joginder Madra (Canada) outlined how various PHER aspects are brought together within the "Panorama" project, developed in British Columbia, but now endorsed for roll-out as a common solution sponsored by Canada Health Infoway. Key features include:

- It has major components for essential public health business applications: - Communicable disease case management, Outbreak management, Immunisation registry, Work management, Notifications management and Inventory.
- These components are supported by common business services: - Clinet index, Provider index and Location index - with all components (and external information exchanges) supported by standards-based interactions over the Common Services Bus.
- It is BOTH a point-of-service application and a registry application
- A layered approach to client/patient identification - as there is an overlap with social care, where many PHER clients have concerns over the privacy of protected information about themselves. Clients may exist in the Panorama indexes that are not part of each jurisdiction's registry (but jurisdictional registries are accessible from Panorama).
- Other particular strengths include the call/recall functions

32.2 Vital Records Functional Profile (VR FP)

The project centres on collection of (high-quality) data from the clinical stakeholders and be able to pass it on to the Vital Statistics stakeholders. Various elements of HL7 activity support this:

- HL7 VR Domain Analysis Model (VR DAM)

  - Serves to identify the birth and death registration work flow processes and stakeholders utilizing an HL7 recognized format – unified modelling language (UML)
  - Serves to guide future design and implementation efforts for standardizing the electronic data exchanges between EHR and VR systems, NCHS and other public and private information systems

- HL7 Electronic Health Record-System (EHR-S) VR Functional Profile, which has the following goals:
  - facilitating EHR systems capturing vital records (Birth, Death and Foetal Death) data at the point of contact or point of care
  - specifying the functional requirements needed for data exchange among providers, states, local registrars and Federal agencies

Issues included consideration of whether a given DAM is "correct", HL7v3 experts in joint sessions advocated that it would be better to map each DAM to the RIM (which is a 1:1 verification effort), rather than mapping each DAM to all other DAMs (which is an n:(n-1) verification effort). Furthermore, it would be good to originate the various elements of a given DAM from existing D-MIMs. For example, a "person-who-is-a-nurse" who collects Vital Records data has already been defined as a "person-who-is-a-nurse" who can collect any nurse-originated data.

Michelle Williamson of CDC, outlined the requirements for reporting births, deaths and foetal deaths in the USA. In presenting to HL7, CDC and the Vital Records (VR) Functional Profile project team are looking for information from other countries as to what is captured on vital records certificates and the systems functions and business processes used to manage and use this information.

Williamson introduced a 119 page document on Vital Records that identifies issues of consistency across the models and sought advice on how they might be rendered in the SOA environment. US Veterans Affairs are keen to internationalise the model.

It was considered that the decision as to whether to pass this information around as messages, documents or services is an organisational decision. HL7 needs to concentrate on providing compatible solutions to these problems. Dr Andy Bond suggested that the general principles should be: document centric is suited to information at rest; look at functions that surround each business interaction; then identify the logical collections of functions that need to be supported by each type of service - recognising the possible need to mix and matching elementary service functions in different use-case contexts.

A VR service should be engineered on what is there now - it does not look very demanding - but it is important to identify the "interactions" - what it is that you want to do.

More detailed advice on assistance on specific VR FP descriptions and conformance criteria that are of concern to the VR project team were given in joint sessions between PHER and EHR WGs hosted by EHR. These discussions focussed on the wording of particular conformance criteria

Australia has convinced PHER that their scope should be expanded from US Realm to international. The idea is to establish core data sets and./or attributes with additions allowed for localization. This will start with Vital Statistics (Birth & Death Certificates) and a joint presentation between US & Australia is to be scheduled for the next Affiliates Meeting with the aim of enlisting broader participation in this project.

Action: This extension requires support and input from appropriate organisations in Australia.

33 Security / Privacy / Access Control

Richard Dixon Hughes, Julia Davis, Heather Grain

Of the three Security WG co-chairs, only Bernd Blobel was able be present in Kyoto with the two US-based co-chairs, Mike Davis (US Veterans Administration) and Glen Marshall unable to be present.

The Security WG met for a total of 1.25 days, with much of the time being spent on review and discussion of activities being progressed by related groups in other SDOs, in particular ISO/TC215/WG4 (Security, Privacy and Safety).

33.1 Privacy and Access Security Services (PASS) Project

The main current work being undertaken by the Security WG is the Privacy and Access Security Services (PASS) project. The Kyoto meeting received a progress report from the PASS project but was unable to do any detailed work on the project as Gila Pyke and other key members of the project team were not present in Kyoto. It was noted that work on the project is being actively progressed via a series of regular project teleconferences. Currently there are two main work streams - Access Control and Audit Trail. For more information, see the PASS Wki-site at: http://hssp-security.wikispaces.com/.

33.2 Role Based Access Control (RBAC)

The principal involvement of the HL7 Security WG in the area of "Role-based Access Control" (RBAC) has so far been based on how HL7 can support the requirements of the INCITS 359-2004 RBAC standard, strongly endorsed by NIST. (INCITS is the the US-based InterNational Committee for Information Technology Standards).

Bernd Blobel gave an excellent review of security-related issues in a joint meeting of EHR WG with the Security Work Group. The EHR WG noted Bernd's first-hand knowledge of EHR security issues as a principal author of key ISO TC215 standards and his role compiling a 400-page report for the German Government, surveying security policies of many countries. His presentation included the following points:

- Security is a now "core" aspect of EHRs, which is inseparable from other aspects of the EHR and its use to support clinical activities.
- EHR systems therefore need to be able to interpret security policies automatically and control access to EHR information based on: "roles", the "type" of data and its proposed "use".
- Organisational data security and access policies can be consistently applied within the boundaries of a single organisation but, without standards-based approaches, that consistency vanishes when EHR information begins to move across organisational and geographic boundaries (as between EU countries).
- Access and security policies are needed that can span geographies and can be formalized into machine-understandable formats (so that EHR systems can apply those policies transparently and automatically).
- Key ISO standards relevant to HL7 work in this space include *ISO/TS 22600 Health Informatics - Privilege Management and Access Control*, a three-part specification addressing electronic access to clinical information; and *ISO/TS 21298: Health Informatics - Functional and Structural Roles*.
- There may be potential benefits from the creation of a "policy warehouse" providing the ability for each user organisation or country to access the warehouse (to post the rules of the EHR-senders, and to consume the rules of potential EHR-recipients).
- "Policy-Domain" might be a better term than "Jurisdiction" in HL7's discussions of these issues.

Bernd offered to hold a joint meeting with the EHR WG and Structured Documents WG on Wednesday Q1 at the September 2009 WGM in Atlanta, and speak about the Policy-Domain concept. EHR WG discussion focussed on:

- The desirability of the R2 release of the EHR-S FM supporting a Policy-based approach
- The potential for EHR WG to create a White Paper that explains the Policy-Based Approach. Such a paper would include an informative background, a normative section, and some Informative example (i.e., profiles), and
- The potential for establishment of a (global) profile for the Policy-Based Approach; that could be used to derive further profiles (i.e., "constraints") for each "Policy-Domain" (i.e. jurisdictional realm).

33.3 Reports on other security and privacy protection projects

- **HL7 Security Cookbook**. There was no further progress reported in relation to preparing an HL7 security "cookbook".

- **Liaison with ISO/TC215/WG4 Security**. In relation to projects being undertaken by WG4, the HL7 Security WG:
  - Noted the status and progress of all WG4 activities in areas such as pseudonymisation, anonymisation, privilege management and access control (PMAC), audit trails, directory services, and functional and structural roles.
  - The HL7 Security WG was concerned that the scope of the ISO 27789 Audit Trail specification was too narrow, if it was to accord with HL7's work on the topic (HL7 Audit Trail Messages, based on RFC 3881). The WG resolved to ask HL7 to initiate a joint project at JIC to harmonize the HL7 work with the ongoing activities around ISO 27789 Audit Trails.

    However, it was also noted that the scope of ISO 27789 was deliberately kept narrow to avoid replicating material from RFC 3881, which would create potential for inconsistency. HL7 should be encouraged to consider the same question and should reference, rather than replicate, other standards' contents.

- **Other projects around the world.** The following are among the other projects presented and discussed by the Security WG as part of an update on progress around the world:
  - Work on PKI infrastructure in Japan and local standards on the use of digital signatures and encryption for CDA and other clinical documents
  - A series of Japanese publications providing guidelines on managing security and safety of clinical information systems
  - A large scale project within the EU to pilot EHR sharing and ePrescription services including infrastructure services (ID services for patients and health professionals).
  - The European interoperability project - Calliope
  - Certification - after finishing quality labelling and certification criteria definitions, EuroRec Institute is defining a process for certification by appropriate authorities in the EU Member States (and is looking to communicate with CCHIT in the US on this)

- **Relationships with other HL7 WGs**. With respect to relationships with other groups inside HL7, the Security WG was particularly concerned about the need for coordination of work affecting structured documents/CDA, the status of the SAEAF Project and need to be involved in the preparation of Alpha Projects. Specific liaison and joint sessions would continue t o be promoted with CBCC, EHR, SOA (on PASS) and Structured Documents (CDA).

33.4 Privacy Policies Control and Consent Directives

H. Grain

Community-Based Collaborative Care (CBCC) are addressing vocabulary requirements of HL7 models for electronic privacy policies and consent directives (e-policy and e-consent) – the Consent Directive Domain Analysis Model (DAM). Vocabulary harmonisation proposals are being prepared and will need to be carefully reviewed to ensure that they reflect Australian requirements.

Privacy process difficulties and other matters covered during general discussion of privacy issues in Vocabulary WG joint sessions included:

- The process whereby patient updates are sent to the central EHR system – using dual digital certificates, EHR system must check it is communicating with a valid provider and the provider's system must check that the patient details are correct prior to posting.
- Update push /pull. Consideration of the following use case. Patient on a waiting list at hospital A at address 1, patient changes address notifies Medicare where their core demographic is updated. The patient expects that the national system is now updated. How does the hospital use the new address when notifying the patient that they have reached the top of the list?

  In Germany – institutions aren't allowed to share this information unless the patient returns to the organisation, at which point it can be automated.
- In Austria, a decision was made 2 years ago to develop a national EHR based upon IHE and HL7 CDA, LOINC, DICOM. So far the infrastructure for communication of payment is in place (Health

information medtrack) based upon smart card for patient and provider. At the moment it only guarantees that the patient has insurance but is not used to carry any other information. Not all practitioners are included, and no hospitals. It is based upon contracts with the insurance companies. Basic infrastructure is due by 2012 for thorough patient and practitioner identification. If you want to work or live in Austria you must register and will therefore be on a central registry, a copy of this will be created for healthcare that will form the basis of the EHR. There are political issues with establishing this system and funding is required.

Various countries commented that there is a need to 'sell' the benefits of EHR projects to counter over-emphasis on the privacy and security – what will they do for the average health care provider or patient and how they make information interchange safer and more effective.

34 Service Oriented Architecture (SOA) and HSSP

M. Walker, V. McCauley, D. Rowed and A. Bond

Overview of SOA/HSSP process

The SOA working group is the HL7 International side of the joint HL7/OMG Health Services Specification Project (HSSP). In addition it provides [web] services-oriented input and expertise to other HL7 Committees and Working Groups. Current HSSP work can be viewed on the HSSP wiki at http://hssp.wikispaces.com.

The SOA WG has responsibility within HL7 for managing the HSSP process, whilst individual content WGs have responsibility for the domain content of the resulting service specifications.

A service specification in the HSSP is initiated at HL7 with registration of a formal HL7 project. A detailed platform independent specification is then developed by HL7 using the standard balloting process for a Draft Standard for Trial Use (DSTU).

Once the specification has passed ballot it is handed to OMG where a task force is formed including at least two health software companies prepared to implement the specification. A platform dependent specification is then completed and implemented by at least two vendors. Feedback from the implementation experience informs the specification, resulting in a feedback loop which usually runs for at least 2 iterations.

The completed specification is then balloted and goes though a detailed independent analysis similar to defence of a postgraduate thesis. After passing OMG final ballot it is handed over to a Finalisation Task force for documentation completion and is placed in a formal standards maintenance process. The output of the OMG work is then handed back to HL7 for final ballot as a normative ANSI/HL7 Standard.

It is strongly recommended that all except the casual reader should look at the HSSP Overview Powerpoint presentation which has been prepared by the SOA Committee to explain its work and the current status of work items - available from the HSSP wiki site by following the download link on the "About HSSP" page: http://hssp.wikispaces.com/standards.

34.1 Current SOA/HSSP component service status

The current status of services specifications currently under development is shown in the table below (taken from the HSSP Overview PowerPoint) presentation:

Asset	Purpose	Functional Spec-DSTU (HL7)	Technical Spec (OMG)	Functional Spec-Norm (HL7)	Implementation Availability
Entity Identification Service (EIS)	To manage identities and identifying traits (e.g., MPI)	Complete	Complete	In Ballot	Commercially Available
Retrieve Locate Update Service (RLUS)	To manage location and retrieval of healthcare content	Complete	Complete	Expected 9/2009	Commercially Available

Asset	Purpose	Functional Spec-DSTU (HL7)	Technical Spec (OMG)	Functional Spec-Norm (HL7)	Implementation Availability
Decision Support Service (DSS)	To analyze patient data and assess against knowledge rules.	Complete	Expected 9/09	Expected 5/2010	In development
Common Terminology Service (CTS II)	Defines behavior for managing/maintaining terminologies	Expected 5/2009	TBD	-	-
[Healthcare] Audit Service (PASS Audit)	Security-oriented service to manage audit record	Expected 9/2009	TBD	-	-
Human Services Directory (HSD)	To find providers & services in allocated areas, e.g., referrals.	Expected 9/2009	TBD	-	-

- Entity Identification Service (EIS) – Following the successful creation and acceptance of the OMG EIS specification, there was a "for comment" ballot closing in June 09 prior to the EIS specification being released for full ANSI/HL7 normative ballot in the September ballot cycle. As there were no substantive negative ballots at the time of the Kyoto meeting, it was considered likely that EIS will pass the current ballot cycle. The OMG Specification includes a platform specific implementation of IHE PIX/PDQ as a specific instance of EIS.

  Vince McCauley noted that EIS should be considered by NEHTA as an interface into the provider directory part of UHI.

- Retrieve, Locate, Update Service (RLUS) – has completed work at OMG and is ready for HL7 final ballot immediately prior to the September WGM. The HL7 ballot documentation is currently being prepared. The OMG implementation specification includes IHE XDS as a platform specific instance of RLUS

- The Human Services Directory Service (HSDS) - based on the HSV/HSD project in Victoria is also being standardised through HSSP in a project being led by Max Walker. He estimates that the HSD Functional Specification and associated documentation in HL7 is 95% complete and this will then be peer-reviewed by the HSSP community. There have been some minor modifications following engagement by NEHTA. This service is now expected to go to DSTU ballot in the HL7 September ballot cycle.

- Clinical Decision Support Service (CDSS) – completed HL7 DSTU ballot. There have been some minor delays in OMG and the OMG Technical Specification is now due to be completed by September 2009 with possible final HL7 Ballot at the May 2010 WGM.

- The Audit SFM has been created and nears completion. The Security WG refer to ISO 27789 – Audit Trails for Electronic Health Records. An SFM for Access Control is also underway but is immature at this stage.

34.2 Practical Guide for SOA in Healthcare

This completed document (Parts 1 and 2) was released in December and can be accessed at http://hssp.wikispaces.com/practicalguide. It documents the HSSP process and the Service Development Framework (SDF) used by HSSP. It is a remarkably accessible document and is also recommended reading.

The document is currently being revised to include information learnt from the recently completed first full HSSP cycle and to incorporate the relationship with HL7's Service Aware Enterprise Architecture Framework (SAEAF).

The revised document will contain more detail about how a platform independent service can be developed into a particular service instance implementation including how to specify conformance criteria, service behaviour and shared terminology. In particular it will be extended to include analysis of HITSP, HSSP, HL7 SAEAF, US Federal Enterprise Architecture, and other industry reference sources to elaborate a more mature healthcare SOA Reference Architecture.

34.3 Relationship of HL7, OMG and SAEAF

One of the concerns arising from the HL7 adoption of SAEAF was that service development work would be undertaken more in HL7 Committees and lead to a weakening of ties with OMG, despite the fact that the HSSP process has been working well.

The CEO of OMG Richard Stacey again attended some of the SOA committee meetings and the HL7 Board meeting. A further 2-year bilateral agreement was signed to formalize and extend the current arrangements between HL7 and OMG.

The SOA group spent considerable time at this meeting educating those committees involved with clinical and administrative content about what SOA is and how SOA can be incorporated into the current work plans of those Committees.

There is still the mistaken view that services are an alternative to messages given the traction that messages have gained as an implementation tool in HL7 over the years. Adding to this confusion, there are ongoing overlaps with the SAEAF work that may mislead some stakeholders within HL7. The existing SOA SIG slide sets portray services, messages, and documents as alternative paradigms that don't appear to allay fears that this is indeed an alternative technical approach. SAEAF has approached this issue by relating all back to the viewpoints of analysis provided through RM-ODP and the layers of abstraction through MDA.

Some time was taken looking at the role of the Service Functional Model (SFM) used within the HSSP process and as part of the RFP process then undertaken by the OMG. This again adds to some confusion as to where it fits alongside the SAEAF framework.

34.4 Proposed project for integration of application processes

David Rowed described a need for integrating independently supplied vertical application processes in use within one health care facility or decomposable patient care application, where SOA utilization may facilitate a new development approach and encourage more flexible, scalable solutions.

The scenario would be EHR services supporting Medication Management, CDS, and interacting with Communication, e-Referral, Document management, Pathology, Care Planning etc. Each component could be separately supplied and selected according to scale and business requirements of the health care facility. The existence of SOA profiles might encourage industry to provide, and clinicians to expect, this type of application partitioning and consequent functional optimization. There was strong support for this at the meeting.

Ken Rubin noted that this is within the scope of HSSP and is looking for David to progress with an initial Charter document. David also raised the proposal with Andy Bond in support of the NEHTA services agenda.

It was suggested we look at a few interactions initially. We would need an HL7 WG to support it, and interested stakeholders to develop it in detail. In subsequent discussions with William Goossen (Patient Care co-chair) it was indicated that this would be appropriate for support by PC WG. Other WGs would also be asked to consider what interactions are involved between their application processes.

A project funded by the Australian Commonwealth Government carried out by IBM Services (the GP Computing System Functional Specification, 1997 available from the General Practice Computing Group GPCG) identifies, defines and organises all of the key application processes in primary care and would be a good starting point to define SOA interactions.

35 Structured Documents (SD) and CDA

V. McCauley,

The Structured Documents committee is in charge of the HL7 Clinical Document Architecture (CDA). CDA has so far been through two releases. Release one specified detailed document header information using the HL7 Reference Information Model (RIM) but the document body was mainly text.. Release 2 provided the capability of expressing richly encoded clinical content in the body (including but limited to the clinical statement) and a process for deriving a human displayable document. Templates were also defined for constraining CDA documents for specialized purposes.

Due to conflicting parallel streams, I was only able to attend a single CDA session; however, many of the important issues are addressed elsewhere, [Editor's note: Incompatibility between CDA and other HL7v3 information models and structures and the question as to whether there HL7 should define a preference for CDA or v3 messages to address particular use cases have become heated topics of debate as covered elsewhere in this report. See also under: Medications Management/Pharmacy (at 27.1) Patient Care/ DCM (at 31.3), Templates (at section 36) and Clinical Statement (at section 12).

Work continues in conjunction with the Templates Committee on defining and implementing a shared HL7 repository for Templates and other artefacts required to successfully implement interoperable CDA documents with rich clinical content. Finding resources to move this work forward has proved difficult. However, it is now proposed that the repository also contain *open*EHR Archetypes (and possibly OpenEHR Templates) and hence may use the *open*EHR Clinical Knowledge Manager currently available on the web for archetypes.

Two new initiatives have been launched. *"Show me your CDA"* is an area where implementers can see other implementations and exchange ideas www.showmeyourcda.net (see under IHIC conference at section 4 above).

An online registry of CDA products and services has also recently been deployed – see:
https://www.phddotnet.com/cdareport/Home.aspx

36 Templates

Richard Dixon Hughes, Andy Bond

The HL7 Templates WG has played a secondary role since publishing Release 2 of the Templates DSTU in February 2008; however, the time is now coming to:

- Review the Templates DSTU for possible promotion to the status of a fully normative ANSI/HL7 standard in light of implementation experience
- Identify and report on the business requirements for an HL7 templates repository. Such a report would support the tooling initiative and identify potential requirements for a templates repository that would support HL7's engagement with the joint ISO/HL7 DCM (Detailed Clinical Models) project, which is being led by William Goossen (as per report on the DCM project in section **Error! Reference source not found.**).

Much of the Templates WG activity at this meeting was conducted as the junior partner in joint meetings with Structured Documents (SD) and other WGs; however an extra early-morning session dedicated solely to Templates WG business was held between 7 and 8 am, which was attended by Richard Dixon Hughes and Grahame Grieve from the Australian delegation.

The co-chair position previously occupied by Ian Townend of UK NHS CfH had fallen vacant and those with an interest and active engagement with HL7 Templates and CDA were encouraged to apply. The WG was pleased to receive a nomination from Richard Kavanagh, also a senior Systems Architect from the CfH programme, who was elected for a two-year term.

Templates was also host to a well attended joint session with Structured Documents (SD), Patient Care (PC) and Vocabulary WGs during which the following two presentations were given as background to proposed work on requirements for a templates repository:

1. A presentation by Cecil Lynch of Ontoreason (clynch@ontoreason.com) on *"Template Registry OWL as an Option"* with the following being among the points covered during the presentation and discussion:

    - A demonstration of open-source OWL-based tools for maintaining clinical models (templates)
    - The tools include an inferencing engine that works with "listeners" in real data flows
    - The tools allow users to test whether one (template) model is a child or equivalent of others already registered in its repository, or whether it represents a semantically different entry.
    - The tools are written in the Beta version of OWL-2 and they are being used at IMHC, where they currently support ontologies encompassing SNOMED CT, Rx-NORM and LOINC.
    - OWL ontological analysis can be applied across a range of template/modelling paradigms, including openEHR, DAMs etc.
    - Stan Huff (IMHC) suggested that HL7 should consider the value of using these mature industry-standard technologies rather than various "new" technologies that are being invented by other players in this area.

    During discussion it was suggested that the presentation had been educational, that the tooling shows great potential for adding an 'ontology' layer to a templates registry but would probably be used in conjunction with a templates registry, rather than providing the registry. The ability to document and present templates in a user-friendly form was also emphasised.

2. A presentation by Bob Dolin on "*CDA Implementation Guides for CDA Release 2 - CDA for Public Health Case Reports"*.

    The approach uses an Access Database generating CDA Implementation Guides and supports different types of templates including content for: Document, Section, Clinical Statement, and Supporting Information.

Dr Andy Bond and Dr Stephen Chu of NEHTA and Richard Dixon Hughes were among some 36 people that attended this second meeting.

Both meetings considered how to progress the templates repository project, with the following being noted:

- An HL7 project scope statement had been prepared and submitted for TSC approval to carry out a: *"HL7 Templates Registry Business Requirements Analysis"* project, with the intent of: *"Developing consensus about the necessary business processes and policies to register artifacts in a Template Registry to be developed in a subsequent project."*
- The project output will be business requirements specifications for input into a subsequent HL7 Templates Registry development project which may be a sub-project of the current HL7Tooling initiative (for the Shared Artefact Repository component).
- The project will perform research, analyse and document business requirements sufficiently to ensure template artefacts can be successfully registered accessed and maintained throughout their life cycle, based on a minimal set of requirements for registering and accessing templates from various template repositories supporting a variety of cooperating organizations (e.g. HL7 v3 templates, HL7 CDA templates, NHS templates, *open*EHR/13606 archetypes, DCMs, IHE, etc.).
- Business aspects to be considered include: governance, endorsement and maintenance of template information, jurisdictional differences, Intellectual Property (IP) rights, rights to use and restrictions on access and use, requirements for maintenance and on-going support (in terms of capacity resources, and tools).
- There is a concern (particularly expressed by incoming HL7 Chair, Dr Bob Dolin), that the project needs to have achieved meaningful progress and initial outputs within 6 months and needs to address the SD WG's immediate need for tooling to more easily create, manage, harmonise, catalogue (etc.) the templates needed for the CDA r-2 implementation guides.
- This is a very high priority in the US at this time, and these tools are needed within the next 6 months - given the US Government's emphasis on standards integration in supporting the computerisation of medical records.

- The project needs to work both top-down from the business requirements and bottom-up from existing and emerging approaches to ensure that the end results are practical and realistic as well as covering the required field.
- The project is being led by Mark Shafarman, with around 15 to 20 potential active participants.
- The work is being progressed via an ongoing series of weekly teleconferences with a major discussion having been held on 17 April at which an outline of the document, sources of information and potential contributors were identified.
- The work is potentially relevant to national and international implementation initiatives (NHS, Canada Health Infoway, NCTIZ, CEN, NEHTA, US National Interoperability Initiative-HITSP, ISO, IHE, NIST)
- The work should be of interest to NEHTA and, subject to agreement from Dr Andy Bond, it was suggested that Sara Gordon (who recently joined NEHTA after having worked with NHS-CfH) may be the most appropriate contact.
- There was some discussion of the difference between a templates registry (index) and a repository (store) - with Grahame Grieve (Australia) noting that the project needs to focus on requirements for a hybrid "registry/repository" since both are required and the distinction to a user is likely to be annoying and artificial, even though the capability may be actually delivered as a series of component service.
- The project needs to address CCD templates as well as those being developed for other CDA applications.
- The WG resolved that:

> *"The WG should collate existing and documented templates, no matter the different styles of templates in use, together with how they are being created, used and maintained. This information should be added to the HL7 Wiki."*

37 Tooling

R. Dixon Hughes, G. Grieve and H. Grain

A high level plan for tooling was produced late last year. Funds to execute this plan are a significant element of the HL7 Finance Proposal to the US Government and other major HL7 stakeholders (see CEO Report in section 5.4).

HL7's tooling initiatives have to address three key business functions in an integrated manner:

- Managing ballots and standards development (including documents)
- Automated support for users of HL7 standards and products (e.g, automated schema generation) - this aspect is not yet well supported.
- Certification and conformance against HL7 standards products

While the HL7 tooling plan addresses all three aspects, the immediate focus has been on the first element in accordance with a high level plan to migrate the HL7 modelling repositories and standards publication support to a new environment.

It has been hard to come to grips with the cost of achieving these goals. The current (original) mHL7 tools were all produced by volunteers, in many cases to support themselves in their role as editors. They were not robust, well understood, well integrated or well supported and have become a cause for concern.

The approach to date has been to build on the work and generous contributions of the UK-NHS and Canada Health Infoway but this has clearly demonstrated that the investments needed to complete the tasks within a reasonable time are not within presently available HL7 resources and, given changing priorities for them, are not expected to be available from those who have supported the work to date - hence the request to the US Government.

The plan and its projected benefits for tools to facilitate enhanced product balloting & production, user creation of implementation specification and certification and testing tools have been well received.

If HL7 receives the funding that it is seeking, then it expects to be able to roll out comprehensive tooling inside 2 to 3 years focussing on consolidating the following eight streams (in accordance with the pathways detailed in the diagram set out at the end of this topic):

1. Publications database and editing and conversion tools
2. Design of static models and templates, which has largely been addressed by the recent UK NHS-CfH development initiative
3. Tooling for representation and management of v3 standards in XML format down to the desktop
4. Integrated publisher/facilitator desktop tool
5. v3 message generator (model driven)
6. Miscellaneous supporting tools - instance example generator; model validation and testing; static model refinement; ballot differences; generalised desktop tool
7. Vocabulary maintenance and integration with terminology services
8. Repositories/registry for standard artefacts (potentially linked to DCM project outcomes).

It was noted that, while the specific requirements of SAEAF are still being instantiated, the tooling development project's requirements will be specified to support and align the HL7 Services Aware Enterprise Architecture Framework.

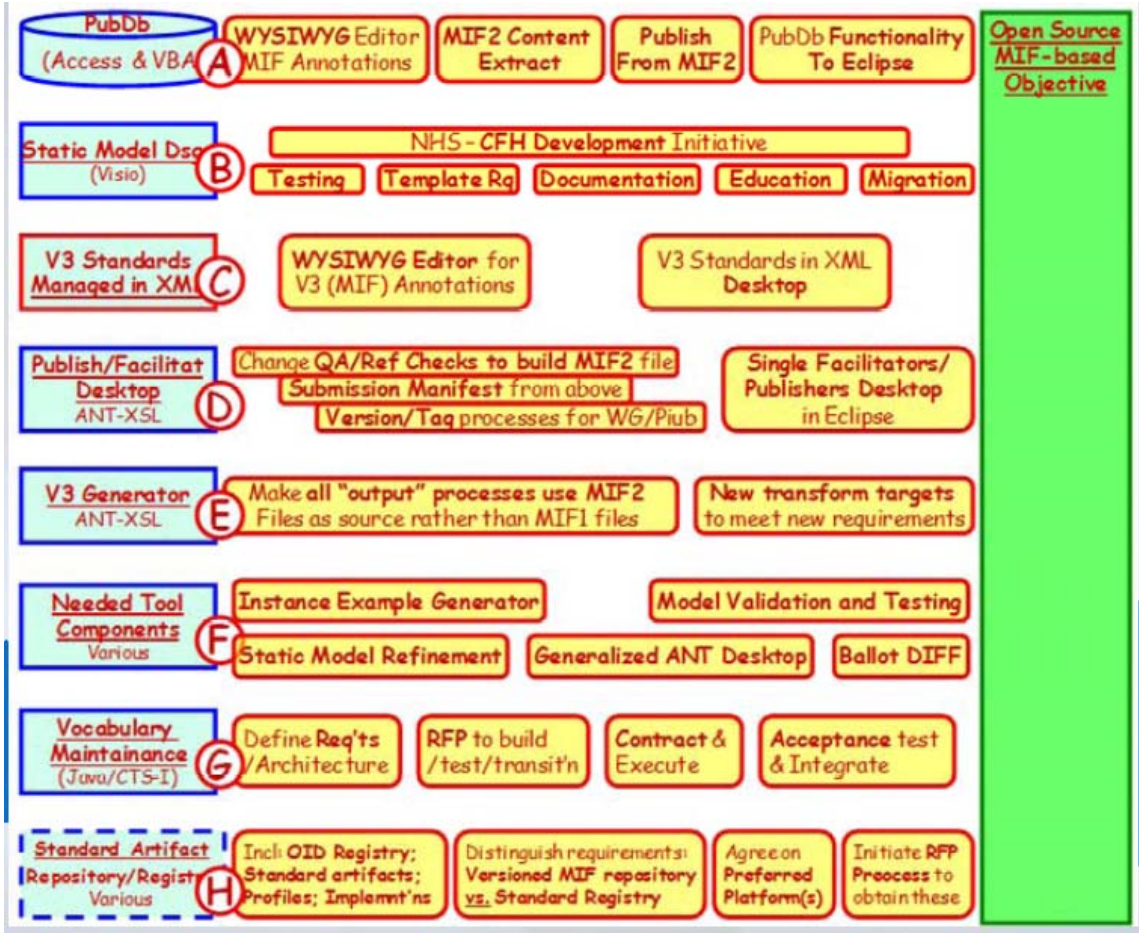

Figure 2 Development pathways for HL7 Production/Publishing tools project

38 Vocabulary WG (Vocab)

H. Grain

The Vocabulary Working Group met with near normal numbers and all 5 Co-Chairs were present.

Facilitation is a major issue for Vocabulary as WGs who build models need to understand how vocabulary relates to their activities. The Vocab Facilitator works with the committee and helps them to do terminology correctly in their work: - Which terminologies to use? How to get terms added to SNOMED-CT? How to represent binding requirements to meet the business case? etc.

The facilitators have several responsibilities

- When a committee is proposing terminology that is included in a ballot, the Vocab Facilitator prepares the appropriate templates and documentation for harmonisation and the Facilitator also attends the harmonisation meetings, where they answer questions that might arise in the meeting about the proposed vocabulary elements.
- When a change is made to a proposal during harmonisation that requires model changes and an agreement is made at harmonisation that change is taken back to the working group for incorporation.
- Facilitators may attend vocabulary tutorials for free
- Facilitators are strongly encouraged to provide guidance on how to improve the process of vocabulary management, tools and harmonisation processes.

38.1 Harmonisation process

Forms for vocabulary tooling harmonisation are available from the Gforge site. Also make sure that you are using the most current version of Rosetree.

Three weeks before harmonisation there is a need to provide the cover page (summary) of the work to be included, to ensure that the work is on the harmonisation agenda.

Before the meeting you need to have all of the forms complete. Be aware of the mechanism for binding and value set usage as this is a key issue for most groups.

38.2 Representation of composite concepts of badly behaved terminologies

Though it is highly desirable to use a well constructed and governed terminology it is recognised that the world of health care has to operate in an environment where many terminologies and code sets are used that do not behave in an ideal manner. The issue is where there are codes systems where there are no rules for post coordination, and concatenation is the only option.

From a linguistic perspective, well behaved compositions can be seen as fusions of predicate expressions with complements yielding composite expressions. The predicate provides semantic selection constraints on possible complements (e.g. one cannot kill a sausage), while the complement adds more specificity to the expressions. SNOMED-CT provides a relatively well evolved set of rules for such fusions.

This problem is particularly relevant to the use of MedDRA but also to other representation systems. There could be multiple groups needing to extend their vocabulary. This is a little different as existing concepts are used and combined. There are three options:

- You only use what the terminology has
- You are extending using what the terminology has
- You are adding to the concepts that the terminology has

Another alternative is to develop a list of CUIs, apply for SNOMED-CT concepts to represent local requirements and replace the CUIs when a solution is provided.

One of the purposes behind registering a code system is that you can register in a publicised place important information about the code system. If you want to create a code system that is implicitly an extension to an existing code system. If someone wants to use a different mechanism, this process using OID registries can be used without restricting people's coding needs.

Example: metastatic gingival cancer – not clear whether the gingival cancer is secondary to another, or whether the cancer in the gingiva has metastasised.

Motion: The vocabulary committee recommend the use of a local coding system to handle concept completeness, that the code system be registered with an OID to encourage reuse.

Motion: A section shall be added to the core principles document describing general approaches to handling deficiencies in existing code system such as: content coverage, compositional expressions, appropriate data type representations and the use of the registry to support the approach.

Further discussion required with MnM on the data type impacts on recommended processes for handling 'bad terminology'.

38.3 Vocabulary Model for HL7

The question arose on a vocabulary call/list serve as to whether there is a source of truth model for HL7 vocabulary, should it be a technically implementable model, or a technical model? The problem is that there are multiple models none of which totally meet the defined need, though CTS is the closest. Issues for further discussion include:

- Who should be responsible for the vocabulary model for HL7?
- What is the scope of the model?
- Should it be a conceptual model? Should it be a platform-independent model?
- What is the relationship of any vocabulary model for HL7 in context of the other vocabulary model artefacts of which Vocab WG are aware?

The core principles document defines what vocabulary means in HL7 and a vocabulary model is intended to be a technical framework on which the tooling required to support implementations and ballots of HL7 material.

The original goal was to create an artefact robust enough to support vocabularies generally. The CTS project and it's progeny focused on a model of terminology to suit the wider need, or to meet the needs of the HL7 community only. CTS1 was limited to represent HL7 requirements only – it was a pruning of the initial draft to provide only HL7 specific functionality. CTS2 is to restore the breadth of functionality intended for a shared artefact for HL7 and elsewhere.

Declaring the MIF as the model would compromise a goal of achieving a partnership with OMG and a multipurpose tool to meet HL7 needs as well as the broader community.

Requirements to meet our requirements a model must:

- Provide a single point of access to look at the model so Vocab understand how vocabularies are constructed
- Identify what code can I put here (binding)
- Identify the value set to use.

There was strong support for the broader scope.

Motion: That the scope of the vocabulary model defined and published by HL7 should be a superset of HL7 needs, providing a common framework and model for vocabulary representation and binding throughout healthcare and potentially other domains.

This includes but is not limited to: terminology and ontology use in healthcare messaging, services, electronic medical record systems, and HL7 models. A common terminology service (such as CTS2) is intended to be a representation of this broad scope.

Discussion: this motion is consistent with the original intent of CTS work was to provide both a framework and model and a set of services to operate against that framework and model. The vocabulary elements of core principles now represent some of the material that was in CTS1 and is no longer in CTS2.

Vocab WG is building a standard that represents both HL7 and the broader need of other healthcare standards organisations. There was concern that contributors such as Lloyd were not present.

Motion: That the vocabulary working group initiate a project to produce a publishable model as described in the motion above and correlate that artefact to the existing HL7 models, based on identified requirements.

Discussion: It was considered that vocab may declare CTS2 as the current model meeting this need. This will require considerably more discussion. The scope is to be defined at publication time.

38.4 International Standards Knowledge Management Tool (SKMT)

H. Grain delivered an update on the SKMT including the glossary which is of particular concern to the Vocab WG.

The process for initial inclusion and ongoing maintenance of terms into the glossary was discussed and a process similar to that used at ISO (where the terms must be in the glossary prior to ballot) was accepted. Scope statements have been prepared to include this into the HL7 work program.

Criteria should be developed to determine what documents should be included from HL7 into this tool. There is a need to determine how to reference definitions in the structure of HL7 documentation going forward. There was discussion on what should be in scope eg: DAM & DMIM definitions – are they in scope? This was referred to the Technical Steering Committee.

- URL for the tool – http://www.cred.ca/skmt_glossary
- Currently the tool contains
  - 1700 terms
  - 1900 definitions
  - 86 documents
- Current HL7 glossary is mainly focused on v2.

38.5 Common Terminology Services (CTS)

CTS2 Ballot reconciliation was a major activity of this meeting. It was accepted that CTS2 becomes a SAEAF Alpha project. An informative Platform Independent Specification will be added to the released specification package. The ballot comments that elicit Platform Independent Specification type content will be added to it after inspection for requirements and possible inclusion into the Conceptual Specification (SFM, DSTU).

It was recognised that including the level of detail necessary to robustly represent hL7's fine-grained vocabulary requirements is likely inappropriate in the high level requirements document proposed, a separate HL7 conformance profile should be created and balloted in parallel with the CTS II requirements. The CTS II requirements could then reference the HL7 profile as 'one of the profiles' that would need to be supported by the RFP solution, allowing for the existence of other profiles as well. RFP submission would of course be dependent on both the base CTS II spec and the hL7 conformance profile successfully completing ballot. It was agreed that the suggestion is good. Availability of a conformance profile would be useful and will be developed.

CTS2 is the second version of the clinical terminology services work. It currently consists of an SFM but has caused some concern during conversations with the OMG ontology group as the OMG group look to try and generalize the CTS approach. It was agreed within the OMG that a Platform Independent Model (PIM) would be provided alongside the SFM as informational guidance as to the required service outcome. It was also agreed that CTS2 would become a SAEAF alpha project.

Implications for NEHTA: The HSSP work continues to mature and as such these specifications should be tabled as interface options for NEHTA work. In particular, UHI should look to EIS as a base interface specification for the services work. NEHTA should also evaluate the HSD specification. Canada and the UK are both looking at a terminology service as part of their ongoing investment in terminology services. NEHTA also needs to evaluate this proposition.

Considerations: The issues raised at this meeting represent issues of implementation and governance of terminologies in clinical systems and in administrative systems. Many of these issues are not well thought through in Australia, or at least they are not clearly represented in our e-health initiatives as issues to be resolved.

Action: Consider how these issues impact the implementation of clinical terminology in our e-health systems and the modifications needed in vendor products to support them.

Groups to whom this may be of interest: NEHTA, Health Department Implementers, Health Care Organisations, MSIA and terminology implementers.

38.6 Concept domain naming rules

A motion from Harmonisation requested that Vocab and InM be consistent with naming of concept domains and value sets registered with HL7.

If you are browsing concept domains in RoseTree it is obvious where these fit, but when looking at a model or other attribute it is useful to be able to identify what type of thing you are looking at and to provide assistance on where to find more details through improved capacity of search facilities to be able to use the name structure more effectively to support searching.

If you need to make a constraint on a model we need guidelines on selection of a human readable name. The intent is to have the name indicate semantic category. For every coded attribute in the RIM there is a single concept domain for that coded concept. When those attributes are used in subsidiary models there is a desire to constrain that further.

It was agreed that domain naming rule conventions be established according to the following **draft rules:**

When naming Concept Domains, the following naming conventions will be applied:

- Concept Domain names shall begin with the applicable parent class name (Act, Entity or Role).
- Concept Domains shall end with “Type”.
- They start with the class name the end with type and may have different patterns between.

Examples:

Domain = ClassName + DomainNameSuffix

DomainNameSuffix = PrintName + “Type”

Sub-domainName = ClassName + DomainNameSuffix

ActSupplyType

ActPharmacySupplyType (a sub-domain of the ActSupplyType)

38.7 Core Principles

Much of the meeting sought to clarify and resolve issues from the Core Principles ballot reconciliation. This document seeks to clearly describe the rules for vocabulary and modelling when developing HL7 standards and also support consistent implementation. This process provides rules and supports greater consistency in the representation of terminology and terminology binding to a model.

Action: Australian organisations involved in the implementation of terminology should provide input to this document in order to ensure it meets our needs, but also to educate and inform our terminology governance organisation and vendor community.

Groups to whom this may be of interest. NEHTA, Health Care Organisations, MSIA and terminology implementers

38.8 Gello

A presentation by Andrew McIntyre on Gello was given to the Vocabulary WG seeking advice on potential relationships to CTS2.

Gello is similar to OCL2 with additional extensions to deal with HL7 requirements and doesn't include inappropriate features from OCL. Gello grew out of Guideline Interchange Format (using Arden syntax) – the objective was to be more object-oriented and to have a better interface to clinical data interchange. It is completely read only and cannot change the EHR and is able to stand alone and is therefore safe to execute.

The option is to create a virtual interface into the clinical data and any decision support should be able to run. Often used by decision support mechanisms to assist decision making.

Looking at ways to interact with the concept model it was presented that if you allow Gello to access CTS then you have a scriptable way of doing validation without hard coding. Gello can check against the patient's preceding history to check whether history is the same, though they may be coded in different coding systems. The objective / request is to give Gello CTS access.

Vocab WG have the concept of HL7 defining the place for value sets. If Andrew would like a rule set capability to persist some Gello definition rules to persist this that could be part of the platform independent model of CTS2. We are looking for ways to enhance the rules definition base without breaking functionality. CTS has to understand the rule to be able to deliver the value set. There must be a set of rule types to support this.

38.9 IHTSDO tooling

A memorandum of understanding has been established with IHTSDO identifying how the two organizations can collaborate and work together. Vocab WG sought HL7 HQ agreement to load the MOU onto the HL7 the web site.

Bob Dolin and Russ Hamm are the liaisons between IHTSDO and HL7. They have been working with Ed Cheetham and John Quinn to outline potential collaboration points and in initial discussions identified the IHTSDO workbench as a potential area to begin discussions. We are trying to figure out how we would work together.

IHTSDO put out an RFP to develop a workbench to support all requirements for terminology and workflow management. Vendors were encouraged not to respond to the whole package but to target their areas of expertise. Successful candidates have been selected. This work supports authoring and access to content, including subset referencing etc. Bob Dolin believes that he can use the workbench to output xml value sets and using the rule transforms generate material that would greatly ease the harmonization activities of HL7. It may be fairly easy to do a transform of the core MIF file and suck in HL7-authored vocabulary out of the MIF file into the vocabulary. It isn't as clear how to load the subset structures to input the value set definitions. As there are approximately 3,500 value sets this must be an automated process. There is the potential for this to replace HL7 tooling. The issue will be the capacity to load everything into the tool, needing import capability to bring in the substructures.

It will be necessary to identify the extensions (if any) required to support HL7 tooling requirements. HL7 membership to the workbench is being organized to allow analysis. The method for this evaluation is being established.

Because this will be the primary metadata management, the LOINC project will be included in this activity if/when they are included with relationships to SNOMED-CT.

Functionality is available to have multiple review and reconciliation management.

Vocabulary WG requirements for IHTSDO tooling include: Potential extension points such as: CTS interface into the workbench.

Should there be a coordinating body for change requests to IHTSDO? or should all requests from the HL7 community go through a central point?

38.10 Business requirements for harmonisation

The Vocab WG considered and updated a number of processes required for harmonisation of new standards, in order to review and ensure that all processes are clearly defined and that the capability to achieve the requirements is provided. This requires HL7 and the Vocab WG being able to support the following hierarchy of capability:

1. Vocabulary maintenance requirements
    a. HL7 code system authoring and curation
        i. V2
        ii. V3
        iii. external
    b. HL7 value set authoring and curation
        i. V2
        ii. V3
        iii. external
    c. Terminology binding authoring and curation
    d. Concept domain authoring and curation (functional requirement includes RIM relationships).
        i. V2
        ii. V3
    e. Concept domain binding authorizing and duration
        i. V3
2. Vocabulary requirements
    a. Terminology entity search/browse
    b. Vocabulary entity import/export
3. Change Request Management (Harmonization proposal) development and curation (this function acts as a trigger to any of the vocabulary maintenance requirements))
    a. Change Request Search / Query
    b. Change Request Submission
    c. Change Request Review
4. Quality Assurance
    a. Identification of errors

38.11 Ongoing activities with IHE

A report was provided by Sylvia Thun (form Germany) on IHE activities. In IHE, each committee is chaired by an industry and a user representative. Current work profile items include:

- Sharing value sets. – SVS profile provides a means through which healthcare systems that produce clinical or administrative data can receive a common, shared nomenclature managed in a centralized fashion. Within the code system they are now recommending specific code sets. The profile describes a mechanism of retrieving a value set from a value set.
    - Some possible metadata defining a value set are:
        - Value set code
        - Value set name (description) – unique in the domain
        - Value set date created
        - Value set date revised
        - Value set OID
        - Value set version

  - The CTS model doesn't include a code in the definition. The name appears to be used as a code in the use case.

- IHE terminology profile – Frank Oemig
  - A common terminology for IHE must be established – independent of the used/underlying standards!
  - Glossary containing a list of words – this work should be harmonized with the common glossary
- ICD10 – 11
  - SNOMED-CT ontologies, CLaML
  - European smart open services – epSOS. This uses ICD10 which is the most common platform in Europe. People from IHTSDO and WHO are talking, if ICD11 is built upon SNOMED-CT, it is likely that SNOMED-CT will become the base in Europe.
  - CLaML ISO 14463. This is an xml standard used for interchange of classifications, it includes ICD, ICPC, ICF, and others. This work supports the development of classifications and maintenance of publication and usage.

  Note: HL7 requires functionality to support import and export in ISO adopted terminology representation standards such as CLaML
- IHE Pharmacy specification. This is new work from France and Germany, talking about semantics within IHE. On the technical side they will use CDA for e-prescribing and e-dispensing and are discussing which semantic standards they should use in the profile.

38.12 TermInfo

TermInfo documentation provides implementation and messaging guidance for v3 terminology support. There has been little contribution of late, and this was of concern to the community at the meeting – however the intent to ballot the document as Normative was strongly supported as a mechanism to progress work that was seen as both useful in and of itself but also highly instructive. The intent to consider how these issues can be addressed in v2 was still an issue but one to be considered as a result of ballot comments.

Action: Australian needs to consider this document at ballot and to represent any concerns or request regarding v2 requirements.