IT–014 Health Informatics Committee

Australian Delegation Report

HL7 Working Group Meeting

Phoenix, Arizona, USA, January 2010

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

- *Andrew McIntyre (Medical Objects)*
- *Andy Bond (NEHTA)*
- *David Rowed (Delegate)*
- *David Rowlands (Delegate)*
- *Grahame Grieve (Jiva Medical)*
- *Heather Grain (Delegate)*
- *Hugh Leslie (Delegate)*
- *Max Walker (DHS Victoria)*
- *Richard Dixon–Hughes (Delegate)*
- *Sarah Gaunt (NEHTA)*
- *Stephen Chu (NEHTA)*
- *Vince McCauley (Delegate)*

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1. INTRODUCTION

The benefits that the Australian Healthcare Community derives from Australian representation at international e–health standardization meetings such as this regular Working Group Meeting of HL7 International are significant and ongoing. It is vitally important to ensure that relevant Australian positions are 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 and that Australians are able to perform influential roles within the organisation.

The Australian delegation at the HL7 meeting in January 2010 included representatives from the National E–health Transition Authority (NEHTA), from the Department of Human Services Victoria, as well as members attending on behalf of their employer organisations. The contributions of delegates and other representatives in the Australian team were invaluable. This collaborative approach represents a very positive step in the national and public interest and allows the achievements of the delegation to be enhanced through mutual backup, support and input.

This report identifies priority areas for the strategic engagement of parties who have an interest in the national e–health agenda, the management of health information and its application to quality/safety of healthcare; and provides an update on areas identified in previous reports as requiring ongoing input.

This report has been produced as a result of the input of the Australian delegation and in particular those delegates (listed as "delegates" in the attendance list) which were co–funded by the Department of Health and Ageing (DOHA). Without the support of DOHA, Australia's contribution to the meeting and its ability to respond to the various issues discussed in this report would have been severely hampered.

Information is presented by topic, with areas of specific concern to Australian stakeholders being highlighted along with suggested action for consideration by those stakeholders. Contacts are provided for those who would like further information or to participate in further work. 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.

All proposed activities will be reported back to their 'home' sub committee within IT–014 for further consideration. These subcommittees are open to any one who wishes to join discussions or learn more about the topics summarised in this report.

For details of IT–014 subcommittees contact Andrew Caswell of Standards Australia (andrew.caswell@standards.org.au) or by telephone on (02) 9237 6012.

2. INTERNATIONAL ATTENDANCE AT THE WORKING GROUP MEETING

Analysis of pre–registration documentation showed that this meeting had 501 participants from 22 countries.

There were 12 Australians at this HL7 meeting most 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.	6
Total:	12

Table 1 Delegation by funding source

The delegates receiving DOHA funding were selected through an independent review panel process run jointly by representatives of NEHTA, DOHA, HL7 Australia and Standards Australia. The resulting delegation was strongly experienced but it should be noted that an increase in the number of areas of interest to Australia and continuing expansion in the breadth and depth of HL7 activities covered at the meeting put severe strain on the ability of the Australian team to cover all relevant topics at a desirable level of detail.

One attendee who was new to the meeting process was able to be substituted into the delegation as a backup when another delegate was unable to attend. Due to specific mentoring prior to the meeting, this delegate was able to fulfil the required tasks well. The process of encouraging and mentoring new people

needs to be continued if Australia is to protect its investment in standards development and the skills available within Australia.

The delegation's capacity to deliver the intended outcomes of participation, information distribution back to Australia and to influence developments supporting Australian requirements is enhanced by having a delegation of experienced people balanced with some "new blood" who can both challenge the processes and increase the pool of understanding of these complex issues in Australia.

On this occasion, two of the Australians holding Co–Chair positions on HL7 International work groups were unable to attend the meeting, (one for personal reasons and the other because of limits on the number and priority of delegates that could be funded) – these two Co–Chairs have previously been key to ensuring that practical Australian requirements for HL7v2 messaging, including recent extensions, continue to be supported; however, their inability to attend reduced the delegation's ability to engage with and influence the HL7v2 agenda, with some adverse consequences emerging that now need to be addressed.

Figure 1 indicates the investment being made by the international community to participate in, learn from and influence the development of standards at HL7. The figures shown represent attendance by country at this meeting compared to the average attendance over the previous year. In particular, it is noted that Canada has more than doubled their attendance over the last 12 month. The UK and the Netherlands have also increased their involvement. Australian participation is steady and relatively strong, although our ability to influence outcomes is, to some degree, degraded by greater participation from other strong countries.

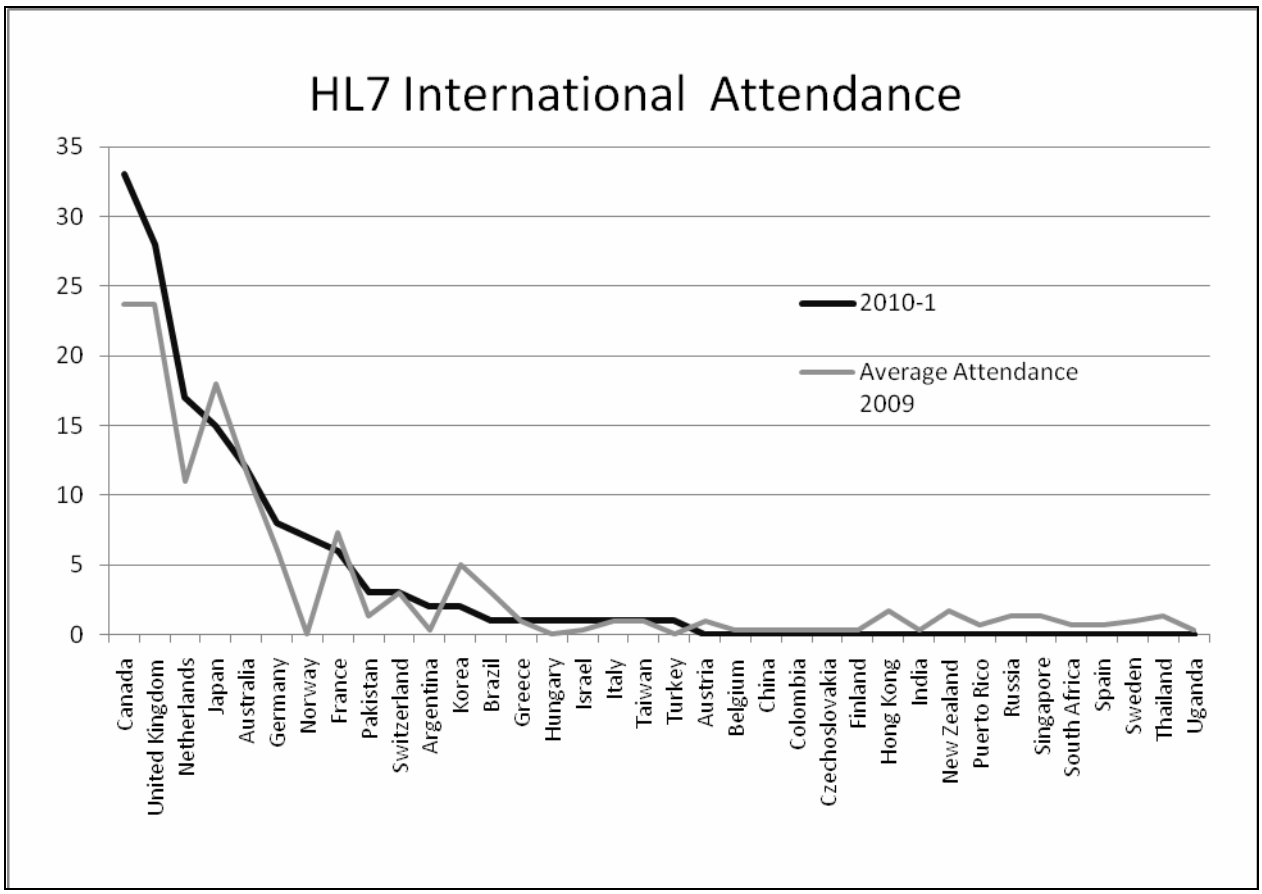


Table 2 International attendees (from outside the USA)

These international attendees are largely funded to attend by their employer or as employees or consultants on national programs – in many cases funded to influence HL7 developments and to return expertise to their own country and employers. The funding provided by employers and national programs does not offset the voluntary nature of much of the work which must be done on weekends and evenings, out of work time, but does indicate the value attached to the activities by employers and national programs.

USA traditionally has the largest number of attendees; however the international meetings and influence, and their government changes this year have impacted their attendance. Table 2 shows the influence of USA attendance on total attendance for the meeting.

	2010 Jan (USA)	2009 Sept (USA)	2009 May (Japan)	2009 Jan (USA)
USA attendance	362	373	78	234
Total attendance	525	514	221	343
% of USA attendees	69%	72.6%	35%	68%

Table 3 Attendance from the USA as % of total attendance

Action:

Develop a mentoring strategy to extend the number of Australian e–health practitioners familiar with HL7, its standards and its processes. Examine how to gain benefit from its products and participation in its activities.

3. MEETING LOGISTICS

HL7 International Working Group Meetings cover 7 days, with formal meetings normally running from 8am to 5pm but with many additional meetings outside these hours – some commencing as early as 6:30 am and others up to and sometimes past 10pm.

Table 3 on the next page shows the meeting schedules for some of the more significant of the 63 different work groups, committees, Board and Council meetings.

The Technical Steering Committee also holds a major meeting to coordinate work on the initial Saturday and it is common for some affiliated bodies to meet on the Thursday, Friday and/or the final Saturday – these additional activities are not reflected in Table 3.

The Working Group Meeting is not a conference – it is an extensive program of working meetings (including meetings of the groups identified in Table 3), that meet with the aim of developing HL7 standards and implementation guides, improving HL7 products and processes, coordinating HL7 work and progressing the organisational activities of HL7 to meet the needs of stakeholders – considering the needs of both stakeholders that attend the meetings and those that are in the wider community. Although engagement outside working group meetings is strong (particularly through regular, often weekly, teleconferences) the ability to influence outcomes requires physical presence at the meeting.

Tutorials are also offered and these are of great value both to new comers and to older hands, to bring them up to date on generic changes made that may not be discussed in their individual committee areas such as vocabulary submission requirements.

In Table 3, 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.

	Sun	Mon	Tue	Wed	Thur	Fri
Affiliates Council	X				X	
Architectural Review Board (ArB)	X		X	X	X	
Board of Directors		X				
Technical Steering Committee (TSC) (Also Sat)	X	X	X	X		
Affiliates' Council	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	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				X
Tooling	X		X		X	
Vocabulary	X	X	X	X	X	X

Table 4 Meeting Schedule highlighting areas of major Australian interest

4. AUSTRALIANS IN LEADERSHIP POSITIONS AT HL7 INTERNATIONAL

Leadership positions at HL7 International are determined by ballot or by Board appointment, with ballots for Work Group Co–Chairs being held at the Working Group Meetings. Most positions are on a rotational basis and have a two–year term with no limit on consecutive terms. According to of the *HL7 International Governance and Operations Manual* (section 09.02.04.03) Co–Chairs who do not attend two consecutive Working Meetings may lose their position.

Positions held by Australians in the HL7 International Community are identified in the table below.

An *** next to a name indicates that this person missed the January 2010 meeting, and may be at risk of losing this position, if they miss another.

Working Group or Committee	Position	Status	Person
Advisory Council to the Board of HL7 International	Chair	Current position – with access to board activities and board members.	Richard Dixon Hughes
Architectural Review Board	Member	Continuing invited appointment	Andy Bond
	Member	Continuing invited appointment	Grahame Grieve
Community Based Collaborative Care Working Group	Co–Chair	Re–Elected	Max Walker
Grants and Contracts Infrastructure Committee	Member	Continuing invited appointment	Richard Dixon Hughes
Implementation and Conformance Working Group	Co–Chair	Current position	Jane Gilbert ***
HL7 Internationalization Task Force	Member	New invited appointment	Richard Dixon Hughes
Organisational Relations Board Committee	Member	Continuing invited appointment	Klaus Veil ***
Product Strategy Task Force (V2/ V3 Task Force)	Member	Continuing invited appointment Continuing invited appointment	Richard Dixon Hughes Grahame Grieve
Modelling and Methodology Working Group	Co–Chair	Current position	Grahame Grieve
Patient Care Working Group	Co–Chair	Current position	Klaus Veil ***
Structured Documents (Developers of CDA)	Co–Chair	Elected	Grahame Grieve
V2.x Publishing Working Group	Co–Chair	Current position	Klaus Veil ***
Vocabulary	Co–Chair	Re–Elected	Heather Grain

5. HL7 INTERNATIONAL – STRATEGIC ENGAGEMENT

At various sessions during the week, the Chair of HL7 International (Bob Dolin), the CEO (Dr Charles Jaffe), CTO (John Quinn), Technical Steering Committee (TSC) Chair (Charlie McCay) and others gave presentations on some of the strategic issues and directions being addressed by HL7 International.

All slide decks presented to the membership in general sessions can be downloaded from the HL7 website:

www.hl7.org/documentcenter/public/calendarofevents/wgm/phoenix012010/General_Session_Presentations.zip

Key points noted from these presentations and other discussions with members of the HL7 leadership team include:

- To reflect its growing importance as a global organisation and with the encouragement of its stakeholders from around the world, in December 2009, the peak HL7 organisation changed its official corporate name from "Health Level Seven Incorporated" to "Health Level Seven International Incorporated" and its associated operational name to "HL7 International". This change was officially announced at this meeting.

- In addition to changing the name of the HL7 organisation, other significant progress being made on internationalisation of HL7 includes: the opening of a European office in Brussels, progressing the registration of HL7 International as a corporate entity operating in Europe and revitalization of the Internationalization Task Force to examine new governance and membership models for HL7 as a global organisation.

- HL7 continues to respond to the recent US Stimulus and health reform packages – which are focussed on spending a total of US$34 billion over the next few years on the uptake and "meaningful use" of e–health solutions in the United States. HL7 continues to be well received by ONC1 and other relevant US–Government agencies (NIST and NLM) and is preparing a "Proposal to license HL7 intellectual property" for submission to the US Government, the proceeds of which should help to fund longer–term development and maintenance of HL7 standards (to the benefit of all HL7 users).

- As a consequence of developments in e–health regulation in the USA, especially the Interim Final Rule (IFR) on standards, specification and certification criteria for EHR technology, HL7 has managed to progress dialogue with IHE, EHRA/HIMSS and HITSP (ANSI) about harmonisation and collaboration of their work and presenting a common front to the regulators. Under this regime, HL7 will develop all required standards and implementation guides and IHE/EHRA will concentrate on facilitating, testing and demonstrating standards–based interoperability to progress shared priorities (for the USA).

- Long–term issues of concern to HL7 Australia and other international affiliates such as the relationship between affiliates and HL7 International, equity in fees charged and the terms on which members and Affiliates may access HL7 International's intellectual property are being considered by the Internationalization Task Force which has been reactivated by the Board.

- There is a trend toward CDA being used where HL7 messages were intended (particularly for prescriptions) – guidance is urgently required as some jurisdictions seek to apply CDA universally and others have sought to disallow health records being populated with structured clinical data extracted from CDA documents (allegedly on safety grounds).

- As HL7 seeks to collaborate at a global level with a wider range of global health informatics SDOs, the national affiliates are also being asked to ensure that they reach out to national ISO/CEN standards bodies and groups representing IHE, IHTSDO, CDISC, GS1 and other HL7 global partners operating in their countries.

- In the US, NIH/NCI has openly stated that it will use SAEAF as the basis for developing its next generation Enterprise Architecture and will develop tools and artefacts that will also benefit HL7 and other users of SAEAF.

- HL7 is considering the adoption of a quality plan to help it manage its development and production processes to ensure more consistent quality in all aspects of its business including development and production of standards and management of its workflow. The nature of the quality plan and the assignment of organisational responsibilities for its achievement are currently being debated at the TSC, Board and among senior HL7 personnel.

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

[1] ONC – Office of the National Coordinator for Health IT. NIST – National Institute for Standards and Technology. NLM – National Library of Medicine.

6. HL7 ROADMAP DEVELOPMENT

The Roadmap Committee (Chaired by HL7 International CEO, Dr Chuck Jaffe) has responsibility for maintaining the HL7 Roadmap in light of experience and changing demands in both the internal and external environment. With input from the Advisory Council and other stakeholder groups the Roadmap Committee has revised the strategic initiatives for 2010. The revised initiatives as approved by the HL7 International board in December 2009 are as follows:

- Lead the development of global technical and functional health informatics standards.

  Description: Assume a leadership position in the development of global technical and functional health informatics standards for electronic health records, personal health records, health information exchange, and clinical data representation.

- Streamline the HL7 standards development process.

  Description: Optimize HL7 internal processes to more efficiently deliver global and realm–specific standards in response to new "customer" requirements.

- Facilitate HL7 standards adoption and implementation.

  Description: Contribute (often in collaboration with other groups) solutions that make HL7 implementation easier.

- Define an overarching and internally consistent interoperability framework.

  Description: Maximize data reuse by ensuring consistency of representation across HL7 specifications.

- Ensure broad and encompassing stakeholder engagement in the standards development process.

  Description: Ensure a clear process whereby stakeholders such as clinicians, technical experts, and policy makers can contribute to the development of HL7 standards.

- Align HL7's business and revenue models to be responsive to national bodies while supporting global standards development.

  Description: Profiler–Enforcer organizations, most notably at national levels, have emerged as the largest (but not only) users of HL7 intellectual property and source of funds for standards development, standards tools, and standards implementation guides. HL7's governance, organizational structures, product strategy and revenue models (including IP rights and fees) must evolve to reflect this reality while retaining the fundamental principles of collaborative working and ANSI approved processes.

One of the main issues facing HL7 is how to operationalise the strategic initiatives, with a view to:

- Aligning the board of directors, staff, TSC and HL7 membership in pursuit of a shared HL7 vision and direction through implementation of the roadmap and strategic initiatives.
- Allowing HL7 members and stakeholder groups to influence the roadmap.
- Clarifying roles and responsibilities of the CEO, CTO, the board, the TSC, the HL7 membership and the Roadmap Committee in relation to the roadmap and strategic initiatives.
- Defining the end–to–end process for strategic initiatives and roadmap items – addressing how items are proposed, triaged, prioritized, funded etc.
- Ensuring that roadmap tasks tie back to the strategic Initiatives.

There are insufficient resources to undertake all potential "roadmap projects". At the January 2010 meeting, the Roadmap Committee met to review and to commence the process of assigning priorities to potential projects – using a series of relevant subgroups within HL7 to review rankings and recommending priorities for endorsement by the Roadmap Task Force.

To ensure progress against the strategic initiatives it is proposed that:

- three "SMART objectives" are to be defined for each of the six strategic initiatives. (Note. SMART objectives have metrics that are Specific, Measurable, Actionable, Relevant, and Timely), and
- preliminary mapping of project milestones to the revised initiatives will be undertaken by HQ staff.

Implications:

Australian interests including HL7 Australia, NEHTA, MSIA, IHE Australia, IT–014, jurisdictions and AHML need to consider the HL7 strategic initiatives and roadmap projects from time to time with the objective of ensuring Australian needs and priorities are reflected in them.

7. CEO REPORT

The CEO of HL7, Dr Charles ("Chuck") Jaffe MD, PhD, presented reports to the International Council on 17 January 2010 to the general membership at the morning of 18 January 2010 and to the Board of HL7 International in the evening of 19 January 2010. In these reports he highlighted the following points of importance to HL7 and its Affiliates, under the main themes of strategy, outreach and funding.

7.1 PROGRESSING INTERNATIONALISATION OF HL7

Specific activities aimed at progressing the internationalization of HL7 have been actioned:

(a) Changing the legal name of HL7 to Health Level Seven International Incorporated (and to trade as "HL7 International").

(b) Opening a European office for HL7 in Brussels and taking steps to register HL7 as an organisation operating in Europe.

(c) Reactivating the Board's Internationalization Task Force. The Task Force will examine potential new governance models to address from HL7's increasing engagement with national e–health programs and, also, residual One Member One Vote (OMOV) issues.

For more information see the article by Chuck Jaffe on page 5 of the January 2010 edition of HL7 News, available online at:

www.hl7.org/documentcenter/public/newsletters/HL7_NEWS_20091221.pdf

7.2 ON–GOING DEVELOPMENT OF THE HL7 ROADMAP

In December 2009, following a review of the roadmap process, the Board of HL7 International approved updated strategic initiatives for 2010. Under the Chairmanship of the CEO, the Roadmap Committee is now working on prioritisation of "roadmap projects needed to achieve the strategic initiatives and is also assigning SMART objectives to measure achievement of the strategic initiatives – as reported in more detail in section 6 above.

Funding proposal to ONC/DHHS

US stimulus funding to accelerate HIT spending has provided leverage opportunities for HL7. A financial submission for licensing and maintenance of HL7 Intellectual Property in the USA was put to ONC/DHHS some months ago and continues to be discussed with key government stakeholders (ONC, NLM and NIST) and has been progressively adjusted in line with their feedback.

The main submission is now referred to as the "Proposal to License HL7 IP (Intellectual Property" and will be submitted this quarter – probably for one–off funding under ARRA – with a second proposal being required for "ongoing maintenance and development of HL7 products (for use in the USA). Hopefully these arrangements will facilitate HL7 work priorities and global availability of HL7 products without inhibiting its ability to address international needs.

Implications:

HL7 Australia and IT–014 to monitor and make considered responses at senior levels of HL7 (and potentially seek Australian Government to approach US Government) as implications for Australia and the international community become clearer.

7.3 HL7 ANNUAL REPORT

The first ever HL7 annual report will be produced in time for widespread distribution at the HIMSS convention on 1–4 March 2010 and will include:

- reports from the HL7 leadership
- technology achievements, Work Group achievements and ballot results
- Conference and Workshop reports
- HL7 achievements internationally and new international members, and
- financial statements and contact information.

7.4 HL7 INTELLECTUAL PROPERTY (IP) POLICIES AND PROTECTION

A task force has been set up to review possible changes to IP policy, management of IP and enforcement, which may involve retention of legal counsel to assess the status of HL7's IP, enforcement and licensing regimes and opportunities for "rights" enforcement.

7.5 OUTREACH – ONC/DHHS

HL7 International has frequent contact with the ONC and those involved in the Health IT standards and policy committees. Now that Dr Doug Fridsma has been appointed Director of Standards at ONC, he is expected to be HL7's principal point of contact with ONC.

Dr Fridsma gave a presentation to the HL7 membership at the general session on 18 January 2010 which mainly focussed on operation of the current regulatory review processes.

HL7 will be submitting comments on the Interim Final Rule (IFR) on *standards, specification and certification criteria for EHR technology*, which was released on 13 January 2010 and becomes effective in February (although it may subsequently be amended in light of comments received during the current comment period.)

Further commentary on government–sponsored e–health initiatives in the USA are reported in section 11 below.

7.6 OUTREACH – IHE AND HITSP

Recent regulatory events in the USA have stimulated closer cooperation between HL7, IHE and HITSP. A basis for communication between the three groups and an appropriate division of responsibilities have been agreed following a one–day meeting on 8 January 2010 sponsored by EHRA/HIMSS at Siemens in Pennsylvania. Five outcomes were reported from the meeting:

- A single deliverable for CCD will be developed, using existing HL7 and IHE content.
- A standards and implementation "life cycle" concept (and white paper) will be developed. (This should have utility outside the USA.)
- The process for developing Implementation Guides will be better defined.
- A CCD deliverable (as defined above) will be piloted.
- The organizational governance necessary to produce unified, consistent, unambiguous implementations will be defined.

Implications:

The ability for IHE International to operate effectively, work with the entire supplier community and to collaborate equally with HL7 and other SDOs is of importance to Australia (albeit the initial focus seems to be in the USA). This latest step is seen as a positive move in what has been long–standing area of difficulty (see previous WGM reports).

7.7 OUTREACH – NCPDP/PHARMACY

NCPDP and HL7 International are working on an MOU to establish a united approach. There is exploding demand for e–health interoperability in the retail pharmacy sector as it performs an increasing range of primary care functions. A major technical issue has been an NCPDP desire to use CDA for exchange of dynamic prescription data (rather than HL7v3 pharmacy domain messages). HL7 planned further discussions with NCPDP later in the week of the WGM to progress the MOU and technical approach.

HL7 and NCPDP are also collaborating as the lead organisations in the US SDO Collaborative Organization (SCO).

7.8 OUTREACH – (US) NATIONAL QUALITY FORUM (NQF)

HL7 has been working with NQF on a project to identify standards and technology needed to implement the ever–evolving content of national clinical quality measures in implementable specifications. While execution of a formal MOU has not been a priority up to this point, NQF is now eager to complete an MOU with HL7 to avoid disruption of the current project, should ONC/DHHS not renew the HITSP contract (which has been supporting the NQF standards project).

Outreach – Clinical Community (CIIC)

The principal vehicle for HL7 strategic engagement with the clinical community is through the HL7 Clinical Information Interchange Collaborative (CIIC), formed after HL7's "Bridging the Chasm" event in April 2009. This event 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.

A follow–up meeting of the CIIC has now been deferred twice due to difficulties with funding; however, a request has been made to ONC – which is being considered.
Recruiting clinical input from the international community has begun to yield modest results with the leaders of HL7's international community being encouraged to pursue this activity vigorously.

Implications:

HL7 Australia to work with Australasian College of Health Informatics and NEHTA in considering clinicians from Australia for potential involvement in CIIC.

7.9 OUTREACH – LIAISON WITH CDISC

HL7 has a liaison with CDISC in the area of clinical trial and research data interchange and supported the entry of CDISC to the JIC. Becky Cush, CEO of CDISC serves on the HL7 International Board and also participates in JIC – with existing CDISC standards being harmonised with other work as they are developed into a full international standard as a JIC project with HL7 support.

7.10 OUTREACH – LIAISON WITH US–NIH/NCI

There is strong interaction between HL7 and the National Cancer Institute (NCI), where SAEAF is being used as the basis of the NCI Enterprise Architecture and functional profiles and standards are being developed based on a range of HL7 technologies to support and report on Ambulatory Oncology practice across the USA.

There is potential for the NCI Enterprise Architecture to be adopted more widely as a model throughout US National Institutes of Health (NIH) and the DHHS.

7.11 OUTREACH – US FEDERAL HEALTH ARCHITECTURE

HL7 is working with US–DoD and US–DVA and other federal agencies on standard EHR content architecture, components and interchange formats for health information managed by US federal government agencies.

7.12 OUTREACH – SUPPORT FOR EU INITIATIVES

HL7 has been involved in providing information and support to the European e–health INTEROP and epSOS projects, in addition to being present and prominently supporting a range of European health informatics activities and national HL7 affiliates in Europe. In addition to recent establishment of the European office, formation of "HL7 Europe" is expected to occur in March 2010 at the EU High–Level Conference on e Health in Barcelona – and will enable HL7 to participate directly in more EU activities.

7.13 OUTREACH – WHO / HEALTH METRICS NETWORK

Exploring how HL7 standards, methodologies and capabilities may be cost–effectively applied.

7.14 GRANTS AND FUNDING – ROCKEFELLER FOUNDATION INTEROPERABILITY GRANT

In partnership with the WHO, American Medical Informatics Association, ONC and others, HL7 has been participating in work to develop and demonstrate an interoperability framework to overcome fundamental problems of information re–use in the Global South economies.

Phase I activities included successful completion of the Bellagio Conference in Italy, involvement of Ugandan representatives at the January 2009 HL7 WGM and HL7 is now completing the final activities, which includes approximately $75K for publication of a final Phase I report.

A Phase II proposal is under review at the Rockefeller Foundation aimed at a follow–up conference in Rwanda and more work on standards and interoperability architecture – with Rockefeller Foundation yet to make planning decisions on value, content, duration and objectives.
Other grant/funding opportunities.

Other opportunities for grants/funding of interest to HL7 International include:

- AHRQ (Agency for Healthcare Research and Quality) – grant request for Paediatric EHR work.
- Opportunities to apply for funding under the DHHS SHARP (Strategic Health IT Advanced Research Projects) program, which has $60M to fund projects conducting focused research in critical areas where breakthrough advances are needed to address existing barriers to the adoption and meaningful use of health information technology. Activities such as the HL7 tooling initiative are potential candidates for this funding.

7.15 ENCOURAGING GREATER LOCAL COLLABORATION BETWEEN SDOS

In his presentation to the International Council on Sunday and subsequent comment to the Affiliate Chairs, the CEO particularly noted the importance of global collaborations between HL7 and IHE (and other bodies such as ISO, CEN, CDISC, GS1, IHTSDO) being reflected at the local level by collaboration between the HL7 Affiliates and the national/regional representatives of IHE, ISO and the other bodies. He noted that poor communication and problems for the entire stakeholder community can be minimised by ensuring that Affiliates are also active in their outreach activities and are not insular.

8. CTO REPORT

The CTO, John Quinn, reported to the Affiliates, the Board, the TSC and to the general membership, focussing on the following.

8.1 ARB/SAEAF

The Services Aware Enterprise Architecture Framework (SAEAF) and the associated "Alpha Projects" are a priority for the Architecture Board (ArB).

Development and publication of SAEAF documentation is progressing well since the decision was taken to hire a professional technical writer and prepare the documentation in the DITA document management tool. More detailed comments on the progress of SAEAF are reported below in the section on SAEAF.

The increasingly close relationship between HL7 and the US National Institutes of Health (NIH) National Cancer Institute (NCI) is particularly significant for wider development and acceptance of SAEAF, with Ken Buetow of NCI writing to HL7, making points, generally along the following lines:

- NIH/NCI Center for Biomedical Informatics and Information Technology (CBIIT) has decided to use SAEAF as their framework to specify Version 2 of their Enterprise Architecture – more specifically to develop their semantic, security, and technology/tooling infrastructure.
- As a consequence, all of the NCI development teams will be defining, designing, developing, and deploying software using SAEAF constructs, in particular the Enterprise Conformance and Compliance Framework (ECCF) and the Behavior Framework (BF).
- The Information Framework (IF) and Governance Framework (GF) are also expected to play significant roles, when they become available over the next few months.
- The CIO of the NIH (NCI's parent body) has indicated that he would also like NIH to adopt SAEAF.
- It is the joint goal of the NCI and the NIH to work with the Federal Health Architecture (and other national projects) to adopt SAEAF with the aim of all having a common framework from which they can achieve scalable, tractable interoperability.
- NCI is currently actively working with the HL7 team developing SAEAF and encouraging HL7 to place the continued funding of this effort on the "high–priority" list to avoid unnecessary diversification that will hinder interoperability.
- Building a core of shared knowledge, approaches and tooling is essential to provide the foundations for uniformity of architecture while allowing localization to individual organizational units and systems.
- NCI CBIIT views the development of relevant tools as critical to success of their mission and, therefore, plans to aggressively fund and develop these tools – which they are willing to share with other interested organizations including HL7.
- The essence of the NCI partnership with HL7 is envisaged to include HL7 taking the lead on development and maintenance of core SAEAF content – documenting it in the SAEAF Book, with NCI CBIIT developing a set of tools for managing SAEAF–derived semantic content (models, artefacts) which they would be willing to share with the larger SAEAF community.

It was noted that HL7 itself is also using SAEAF to develop its own Enterprise Architecture and that these two projects, along with the Alpha projects will strongly inform further development of SAEAF.

8.2 HL7 TOOLING

Over 90% of planned work on tooling projects in 2009 was delivered, with the following being among the budgeted items having been satisfactorily completed or expecting to be complete by 31 January 2010.

The main work still outstanding has been in the area of OID Registry content cleanup, where two packages have been delivered with one package and some entries still to be completed. Availability of resources and information needed to clean up historical entries is a challenge.

The focus has been on fixing tools required for publication and every–day activities (e.g. OID Registry). It was reported that the improved tooling for publication is already having an effect with the time for HL7 to produce the annual normative edition of V3 is expected to be reduced significantly in 2010 and to less than 3 months in subsequent years.

The focus in the next cycle will be on the adoption of a static model designer (SMD) based on one of the two options offered by the UK NHS and US Veterans' Affairs. The other proposed focus going forward is conformance profiles for application of EHR–S FM.

The "Tooling" budget for 2009 covered both HL7 HQ infrastructure components (notably, ongoing software licenses for the HL7 web site, Gforge and re–hosting of Gforge) and HL7 tooling products, which gave a false impression of the resources available for new HL7 product tooling.

The preliminary estimate of cost for the 2010 budget for tooling is $US 243K, which is expected to include work in the following areas:

- **Operational Activities** including: SAEAF editor, planning and coordination support, vocabulary harmonization support, enterprise DITA tool
- **SMD (Static Model Designer) implementation** including software enhancement, making v3 MIF2–driven, training material, completing OID registry update
- **Implementing enhanced XML processing** including XML Validator (replacement for current outdated software)
- **Defining requirements for shared artefact repository**, including pilots of: template registry, templates design
- **IHTSDO workbench implementation, HL7 SNOMED CT subset, IHTSDO workbench enhancement**: MIF enabled import/export , HL7 Vocab Harmonization configuration
- **Open Health Tools (OHT) packaging and deployment**, and
- **Innovation Project**.

8.3 NEW MEMBERSHIP APPLICATION PACKAGE

In 2009, HL7 HQ implemented the GoMembers' membership and meetings management web–based application package – which was brought in after the previous unsuccessful Ascentium development was discontinued.

The GoMembers implementation has been largely successful with a range of post–implementation issues reported as being worked through over the coming months. However, in December, GoMembers was taken over by CDC Software, and although the takeover has had some impact, it is not expected to significantly affect finalisation and support of the HL7 membership management system.

8.4 HL7 TECHNICAL COLLABORATION AND LIAISONS

The CTO abbreviated his reporting of technical collaboration and liaison activity, noting that more detailed reporting of these activities was now the focus of the reconstituted session on *"HL7 activities with other SDOs"* convened by TSC in Q4 on the Sunday – replacing the former HL7/ISO/CEN collaboration group. He highlighted some of the more important liaisons in which he had recently been active:

- Gforge re–platform.
- Vocabulary Harmonization expenses; Vocabulary algorithmic update and clean–up; IHTSDO Workbench evaluation for Vocabulary Change Management Requirements.
- Static Model Designer Requirements and Testing (by 31 Jan).
- OID registry upgrade (by 31 Jan).
- Upgrade of XML processing (final report by 31 Jan).
- CTO Support for Tooling Project Coordination and Planning and W3C Copyright resolution.
- The Joint Initiative Council (JIC) and ISO/TC215 liaison and activities – which continues to require undue time and effort.
- In the US–realm, collaboration through the SDO Collaborative Organization (SCO) is progressing but is proving to be slower than expected.
- The key members of this organisation are HL7, NCPDP, X12, ASTM, CDISC and ADA, with NLM (SNOMED), LOINC, GS/1 and WEDI as potential members. Observers include major users of standards including – ANSI, FHA, SSA, HITSP, IHE, ONC, TC215/US–TAG.

- HL7 continues to support SCO (including providing the next Chair) but it is hard for individual SDOs to make firm progress until more of the domestic US regulatory program is in place and the standards to underpin the ONC e–health standards and compliance agenda are clearer. HL7 took the opportunity of being in Phoenix to arrange discussions with NCPDP (the current SCO lead organisation) about progressing SCO activities.

- A recent significant move has been HL7 and OACIS moving forward on standards for disaster response, ambulance and first responder – particularly targeting the needs of ambulance services in the US. This may also be of interest to Australia.

8.5 HL7 QUALITY PLAN

HL7 International is to take up the suggestion that it develop a Quality Plan. The concept was discussed and developed in several sessions hosted by the Technical Steering Committee (including the Co–Chairs forum on the Monday evening), with the following being some of the points debated:

- What is meant by "quality" in the HL7 context? What aspects of HL7 activities should it address? How big is its scope? For example, should it address clarity of purpose, lack of ambiguity, cross–artefact consistency, comprehensibility and usability of HL7 products, medical correctness, clinical safety of artefacts etc?

- Initial discussions focussed on product quality – ensuring that products: meet requirements; are timely, consistent, comprehensible and easy to implement; and adhere to HL7 internal standards.

- An effective plan should be continuous and ensure that quality is built into all aspects of the product lifecycle – as HL7 proposes, plans, designs, defines, publishes, reviews, reconciles and distributes its products.

- Harmonization, balloting and publication are key check points for quality assurance.

- Who should be responsible for it? Initially, it was proposed that the Quality Plan be "owned" by the CTO and/or TSC but this evolved to recognition that, to be effective, "quality" has to be an organisation–wide ethos, involving the following roles:

  - Sponsor – the Board of Directors of HL7 International
    To provide organizational legitimacy and policy

  - Overseer – TSC (Technical Steering Committee)
    Ensures that the program is defined, manned and pursued. Also the point of “final appeal”

  - Arbiter – Architecture Board (ArB)
    Review rules and acts as “court of review”, should it be necessary

  - Manager (of quality process) – Publishing Work Group
    Sets specific expectations, validation suites, reports, and assures that ballots and editions meet these expectations

  - Quality Reporters – Facilitators, Work Group Leaders, Balloters, Customers, Identifies Opportunities for quality improvement; places where established rules conflict with ability to get work done; places where rules are being “bent” or worse.

  - Implementers – Each and every HL7 participant
    Takes the action to make it right or not do it wrong in the first place.

- Implementation of a quality plan involves establishment of a quality culture (inspection and vigilance), tools for inspection and quality management and a broadly–based quality reporting regime [hopefully integrated through formal quality management processes].

Martin Entwhistle (NZ) noted that HL7 NZ would be keen to consider how such a plan could be applied for the adoption and adaptation of HL7 for local use.

It will be important to consider how this will apply to/affect Australian HL7 localisation.

9. HL7 INTERNATIONAL BOARD MEETING – OTHER MATTERS

The board of directors of HL7 International met on 19 January 2010 from 3:30 pm to 10:30 pm. Matters not covered in the CEO and CTO reports above (and elsewhere) included the following.

9.1 INNOVATION COMMITTEE

An Innovations Committee led by Board–member, Ken Lunn (NHS) has been established to find methods for encouraging innovative approaches and solutions. An invitation to submit video presentations was issued in December 2009. There were 12 responses to be reviewed at the January meeting – which are hoped to bring in more ideas. During discussion, it was noted that:

- Use of video presentations meant that the ideas live beyond their initial presentation at a WGM.
- This initial response proved that it is a useful means of raising innovative ideas – continuation of the initiative was supported.
- It was generally agreed that it is important to have a process in place to capture innovations and pick up on industry best practice.
- TSC is keen to take the innovation concept forward with incubator projects.
- There needs to be a clear distinction between what is real and what is innovation – with processes to manage the creative tension that will be created between the status quo and awesome change.
- There may be up to 40 new concepts at the next WGM and by then HL7 hopes to have a process for propagating, assessing and developing innovative ideas.

9.2 EDUCATION COMMITTEE PROPOSAL TO DEVELOP HL7 TEXTBOOKS

There was substantial discussion of a proposal from the Education Committee to develop an HL7 textbook series, with commissioned authors, funded by a combination of HL7 internal funding and external grants. Key points included:

- There is currently a variety of learning materials in use, including both HL7 and externally–developed materials, whose quality and depth vary widely.
- The Education Committee considers that HL7 educational activities have a significant effect on the way HL7 operates and how its products are used, and that healthcare IT needs an authoritative HL7 learning source.
- A series is proposed in which Volume 1 would cover V2, V3, CDA, and EHR–S FM, to be developed by July 2011 and fund the development of later volumes, which would focus on more specialized topics (e.g. SOA applications).
- There was support for the overall concept but concern about the issue being raised directly at the Board without a proper business proposal and input from the TSC and Finance Committee.
- It was noted that publication of text books is a competitive marketplace in which it is hard to make a profit, particularly for printed editions. The production as an e–book might be preferable but, in any case, the costs of writing, editing, and overhead of review process need to be identified and recovered. The content of later volumes also needs to be identified.
- The wisdom of HL7 seeking external grants to compete directly with members and HL7 affiliates that are already in the market was questioned.
- The Education Committee was asked to scope the proposal as an HL7 project and submit the project and costed business plan for consideration through the normal project approval process.

9.3 TREASURER'S REPORT

2009 Financial Results

The 2009 accounts are still being finalised; however the year–end forecast is as follows:

	YE Forecast	Budget	Variance (F/U)	As a %
Revenue	$3,872,655	$3,689,785	$182,870 (F)	+4.96%
Expenses	$4,181,587	$4,807,603	$626,016 (F)	+13.02%
Surplus/Deficit	($ 308,932)	($1,117,818)	$808,886 (F)	
Reserves	$3,696,611 =10.8 months	$2,958,612 =7.5 months	$737,999 (F)	

HL7 had deliberately set out to invest in key projects and incur a deficit budget for 2009 – reducing reserves to progress organisational priorities. As things eventually transpired, the likely result is much closer to break–even than originally proposed, largely because of lower levels of expenses. Specific aspects contributing to the result included:

- organizational membership dues were $73,870 (4%) better than budget of $1,831,988
- individual membership dues were $9,132 (3.8) lower than budget, continuing the downward trend
- country (Affiliate) dues were 33% better then expected at forecast of $186,359
- HL7 continued to reap the benefits of ≥$300k windfall due to Intel's decision to continue funding the CEO's compensation, and
- discretionary CEO spending was substantially less than budgeted.

2010 Budget

The proposed budget for 2010 is as follows:

	2010 Budget	2009 Budget
Revenue	$3,639,445	$3,689,785
Expenses	$4,451,034	$4,807,603
Surplus/Deficit	($811,589)	($1,117,818)
Y/E Reserves	$2,885,022 (7.8 months)	$2,958,612 (7.5 months)

- Members – As of January 1, 2010, there are 499 organizational members (up 60 from the previous year); 29 benefactors (down 3 from last year who converted to organizational membership); and 422 individual/student members (down 33 from the previous year).
- Grants/Contracts – $140,000 in grants/contract revenue was budgeted for 2009 with $194,028 being forecast for year–end. AHRQ provided unbudgeted funding of almost $49k to go towards the expenses for the "Bridging the Chasm" meeting which accounts for the difference.
- Meeting attendance – Both the January and September WGM attendance was around 500. The May WGM attendance was less than 250.
- WGM/Plenary Revenue – $910,423 was budgeted in 2009; yearend forecast is $872,540 ($38K less than budget), of which:
  - Jan (Orlando) WGM generated $359k
  - May (Kyoto) WGM generated $160k ($17K less than budget), and
  - Sep (Atlanta) Plenary generated $352k ($19K less than budget).

- WGM/Plenary Expenses – $1,034,844 was budgeted in 2009; yearend forecast is $909,000 ($126K less than budget), of which:
  - Jan (Orlando) WGM cost $326K
  - May (Kyoto) WGM cost $263K ($76K less than budget), and
  - Sep (Atlanta) Plenary cost $320K ($50K less than budget).
- The average US WGM surplus was $60K; the average non–US WGM deficit was ($10K) – with the surplus being applied to infrastructure and keeping dues reasonable.
- A Board Committee is investigating opportunities to address non–US WGM performance.
- Education/Summits/Workshops exceeded projections – reaping $398,395 in revenue, $88K more than the budget of $310,375. Forecast expenses were $161,482, which is $35K less than the budget of $197,158. Overall profit is $236,913 ($123K better than budget).
- The distance learning program generated $108K in eLearning course fees, which is $63K more than budgeted.
- The 2010 budget is based on an 8% increase in membership and meeting registration fees.
- The January (Phoenix) and September (Cambridge, Mass) meetings are expected to generate $376K in revenues, with the May meeting in Rio budgeted for revenue of $286K (break–even).
- Following adjustments for carry–forwards, the 2010 budget was expected to be presented to the Board for ratification at its next meeting.
- The Board thanked the Treasurer, Hans Buitendijk, for his report.

9.4 POLICY COMMITTEE

The recently formed Policy Committee, Chaired by Don Mon, is still discussing its role and developing its mission, charter and processes for bringing recommendations to the Board. Discussion centred on:

- The committee's differing views on where it might fit into the advocacy continuum – from informing entities about applicable standards through to the shaping of public policy.
- The Committee is also working on the area requiring immediate attention: an appropriate HL7 response to the US Government's NPRM and IFR (see section 11 below), through a transparent approach, with final sign–off at the Executive Committee.
- The Board noted that, while HL7 might be a valuable facilitator, it should remain neutral on issues that don't relate to HL7 as an SDO. No matter how strongly HL7 may feel about a particular issue, HL7 needs to be careful about making public statements that are not related to its professional role as an SDO. In some circumstances, the right outcome might be a considered recommendation not to make a statement.

9.5 INTERNATIONAL WORK GROUP ASSESSMENT TASK FORCE

Hans Buitendijk reported back to the Board on the activities of the task force which had been set up by the Board to "assess the success of International Work Group Meetings and provide recommendations on how to move forward with Work Group Meetings outside the US".

The task force (TF) had significant international representation comprising: Hans Buitendijk (Chair) (US), Jill Kaufman (US), Michael van Campen (Canada), Catherine Chronaki (Greece), Charlie McCay (UK) and Mark McDougall (HL7 HQ).

The TF reviewed the financial outcomes of the four recent international WGMs (Nordwijkerhout, Cologne, Vancouver and Kyoto) and developed a process aimed at understanding the factors affecting international WGMs – conducting a survey to identify the needs, objectives, issues and challenges as perceived by key groups within HL7, namely: the Chairs of committees and WGs, Affiliates, the Board and HL7 Headquarters.

The following are among the outcomes:

- There is value in face–to–face meetings as they are an important venue for networking, chance meetings, and extended discussions. There is a fear of being out of touch if HL7 does not hold face–to–face meetings. Video and virtual meetings are, as yet, not a satisfactory substitute.
- Regional and national participation has been important to a couple of groups and WGMs held outside the US have helped with international engagement and reducing US centric perceptions.
- The conclusion is that WGs should continue to foster opportunities to increase global engagement.
- The data indicates that fewer attendees from North America attend meetings at venues outside North America but EU participation does not rise substantially when EU. The situation in Asia/Pacific and South America is unclear but is probably similar. Therefore, HL7 should:
  - schedule WGs close to the location/region with the highest WGM attendee representation, and
  - stay near major airports and cities.
- Key participation drivers are: A compelling business case; Cost justification; Agenda content; and Co–Chair availability.
  - Therefore: Reinforce the business case at an affordable cost through PR.
- Timing:
  - stay warm
  - avoid holidays in the host country
  - January in US has typically been best time for WGM attendance and May has been the worst, and
  - therefore avoid January for non–US meetings unless there is an exceptional business case.
- Recommendations:
  - ensure Co–Chair participation in all face–to–face WGMs
  - improve marketing
  - improve financial break–even opportunity
  - optimize location and timing, and
  - publish findings and recommendation to membership.

Subsequent discussion at the Board resulted in:

- Agreement to endorse the TF recommendations and initiate the necessary activities to implement them (with the TF to be discharged on completion).
- A request that the role of selecting international WGM venues revert to the International Council.
- Suggestions that the Co–Chair rules be reviewed to require attendance of Co–Chairs at international WGMs need to be balanced against restrictions on international travel by government employees from the US (which might preclude their being Co–Chairs).
- Suggestions that HL7 look at the cost and business case for having more remote access to these meetings.
- Agreement to pursue consideration of the outcomes at subsequent Board meetings.

In his later presentation on the work of the IWGA TF to the Affiliate Chairs (sitting as the International Council), Hand Buitendijk put particular emphasis on the following aspects:

- The need for all WGs to nominate Co–Chair and/or interim Chairs to enable WG business to continue at international WGMs. Affiliates need to respond by ensuring that relevant experts from outside the US take on Co–Chair roles.
- The need for clear marketing plans to be developed for all WGMs (not just for non–US meetings):
  - identifying business cases for target audiences

- addressing the overall cost to participants (not just meeting costs)
- programs to increase awareness in the area where the meeting is being held
- producing retrospective marketing reports and promoting what was achieved, the value of meeting and the location, and
- follow–up recruiting of new attendees to participate in future WGMs and improve the relevance of WGMs.

- And particularly for non–US meetings:
  - peer–to–peer invitations/contacts (e.g. veteran's health, national programs)
  - pro–actively addressing concerns such as security and total cost, and
  - improving the financial break–even and local commitment through local sponsorship of the WGM.

The International Council noted the IWGA TF recommendation to market future WGMs heavily, especially those held outside North America. HL7's internationalization is now at a critical stage and demonstration of the effectiveness of standards meetings outside the US is a critical success factor. A Task Group was created to advance this topic (D Rowlands to assist).

Implications:

Australia 2011 WGM Committee to note findings and ensure that key points are addressed for the proposed meeting in Sydney in 2011.

9.6 PRESENTATIONS BY EXTERNAL GROUPS

Health Story (an HL7 Associate)

Associate Professor Judith R Logan MD of the Oregon Health and Science University presented to the HL7 Board on the Health Story project, which portrays itself as a non–profit industry alliance of healthcare vendors, providers and associations.

Approximately 1.2 billion clinical documents are produced in the United States each year. Dictated and transcribed documents make up around 60% of all clinical notes. These documents contain the majority of physician–attested information and are used as the primary source of information for reimbursement and proof of service.

The project aims to bridge the gap between a physician's need for fast and easy methods of creating clinical documentation (most of which is based on dictation/transcription in the USA) and the health care enterprise's need for structured and coded information in the electronic medical record to support meaningful use. The ultimate vision is that all clinical information required for good patient care, administration, reporting and research will be readily available electronically, including information from narrative documents.

The founders of the initiative were the Association for Healthcare Documentation Integrity (AHDI), Medical Transcription Industry Association (MTIA), American Health Information Management Association (AHIMA) and M*Modal and is being managed by Alschuler Associates, LLC and Optimal Accords.

The primary output is support for the development of HL7 CDA implementation guides (IG) for common types of documents, with the following being available for download via the www.healthstory.com website:– (a) Consultation Note, (b) History and Physical Note, Operative Note (as DSTUs); (c) Diagnostic Imaging Report, (d) Care Record Summary and (e) Discharge Summary (in draft/ballot). Work is currently proceeding on: (f) Procedure Note (Endoscopy Report), (g) Unstructured CDA documents, (h) Billing and Reimbursement Requirements, and (i) Progress notes. As part of its Health Information Exchange (HIE) certification regime for 2011, CCHIT has called up HITSP (document C/84), which references both the consultation note and the history and physical note.

In addition to assisting health care institutions to capture information better, the standardization and adoption of these electronic documents is expected to assist the exchange of clinical documents between organisations. Looking forward, their goals are to:

- maintain a strong coalition with HL7
- increase market demand for specifications
- sustain technical specification development

- earn national endorsement, and
- foster widespread adoption.

Health Story works almost exclusively with the Structured Documents WG within HL7. Some members of the Board were concerned to ensure that experts on domain groups were being consulted and involved in the development of specifications related to their domain areas.

Some US–based e–health consulting firms with strong HL7 links appear to be gaining significant market exposure and opportunity by their close association and support for Health Story; however, on balance, HL7 and its wider stakeholder community appeared to be deriving significant benefit from the Associate Charter Agreement between HL7 and Health Story and its continuation should be supported.

No specific Australian action is proposed on the basis that all relevant Health Story material eventually works through to (US–realm) CDA R2 implementation guides, which are known to NEHTA and other relevant stakeholders in Australia.

Mohawk College

Ted Scott (Dean of Applied Research) and Professor Duane Bender introduced Mohawk College, which is located in Ontario Canada, where it operates the Mohawk Applied Research Centre in Health Informatics (MARC–HI), which is building an EHR Reference Implementation based on Canada Health Infoway's published pan–Canadian standards using the EHRS Blueprint.

Work on this project has the endorsement of Canada Health Infoway and is being funded by the Canadian government to 2014 through a $2.4 million grant from the Natural Science and Engineering Research Council of Canada (NSERC). There is also collaboration with private sector partners, who have provided seed funding and in–kind donations for specific research projects. The work is guided by a Project Advisory Board which consists of representatives from various project stakeholders.

The front end of this project is provides an HL7 Version 3 messaging environment that:

- This project allows adopters to experiment in a living laboratory without constraints of privacy, security etc, rather than in a live healthcare environment.
- Provides a preliminary conformance testing environment.
- Provides a standards testing and quality assurance environment.
- Has the capacity to influence HL7 V3 messaging standards through evidence based experimentation (XML transport).
- It accelerates tooling development and the provision of software components that can be directly integrated into commercial applications.

The project has attracted a range of related RandD projects outside the core funded project.

As part of this work, Mohawk is developing the Everest Framework, a suite of HL7 V3 messaging API software technologies to simplify access to the EHR – which is providing productivity gains of one to two orders of magnitude for vendors integrating existing products onto the Infoway HIAL access layer.

These are similar to the experiences of the UK NHS with respect to reference implementations for vendors communicating via the NHS Spine.

Later in the meeting, the Board discussed the most appropriate nature for a relationship with Mohawk College and other community–based research organisations developing reference implementations of HL7 technology. It was concluded that this type of relationship was outside arrangements covered by the standard HL7 MOU (which governs relationships with other SDOs) and Associate Agreements (Trade Associations). It was decided to go back to Mohawk and identify what the basis of a new type of agreement should be for prototyping services.

Presentation on patient safety (Maureen Baker, UK NHS)

There are a range of standards for safety management in safety critical industries. This presentation from the UK NHS argued that designing health interoperability approaches ought to be subject to the rigour of formal approaches to safety design.

Common issues include inconsistent units of measure and reference ranges, truncated instructions (especially to mobile devices), etc.

NHS Connecting for Health is designing safety controls during design activities that include: assigning safety roles and responsibilities; hazard identification; clear safety targets, reporting systems, etc.

There was discussion as to whether HL7 should develop a formal safety management approach. This will be considered in HL7's quality Plan (as discussed in section 8.5 above).

10. HL7 PRODUCT STRATEGY – V2/V3/CDA TASK FORCE

At the September 2009 WGM in Atlanta, a strategic task force (TF) was convened to identify the challenges within the current HL7 V2/V3 and CDA approaches, identify options for addressing these challenges, and develop a plan for moving forward. A member of the HL7 Board, Dr Stan Huff of InterMountain Health Care (IMHC), was engaged by the Board to Chair the task force and the other members of the task force are:

- Hans Buitendijk
- Jane Curry
- Dennis Giokas
- Grahame Grieve
- Ed Hammond
- Richard Dixon Hughes
- Becky Kush
- David Markwell
- Charlie McKay
- Frank Oemig
- John Quinn

Australia is well represented on this Task Force by Grahame Grieve and Richard Dixon Hughes.

The V2/V3/CDA Task Force (TF) was established to deal with a range of organizational concerns including:

- HL7 currently supports 3 exchange methods – V2, V3, CDA – but these do not draw on common data types, vocabulary, and semantic models.
- V3 has been successful in some contexts but could be more so – especially in the US. It is complex and difficult to understand and implement – negating some of its proposed benefits.
- V2 and V3 are facing challenges in meeting the industry need for cross–institution and national interoperability.
- How HL7 product development should address the industry shift from message based to service based interoperability.

The need for clarity and resolution of the relative positioning of HL7 V2 and V3 grows more acute. This has been thrown into sharp focus by the omission of V3 messaging from the "Interim Final Rule" and "Meaningful Use" documents released recently which will set the agenda for the e–health initiative in the USA.

The TF met on Q3 Tuesday to review progress with project leader, Stan Huff, and Virginia Riehl, who is a consultant assisting with the work, and to assist them in preparing for their subsequent presentation to the Board of HL7 International. At these meetings it was noted that:

- A problem statement and an options paper were developed with input from the TF (which includes both Grahame Grieve and Richard Dixon Hughes from Australia), the Chair of the Technical Steering Committee (TSC) and the four Steering Divisions (SDs).
- The problem statement and options paper were then used as the basis for telephone interviews with around 45 prominent HL7 members – selected for their ability to provide a range of experiences and perspectives.
- The problem statement and options paper evoked a range of responses – particularly a reaction from some who felt that the documents had discussed v3 problems in depth but failed to acknowledge or build on the successes of v3 messaging.
- The desired scope of the TF's work came up for considerable discussion – the issues are substantial but the approach and level of investment for the current exercise are considerably less than what would be required for HL7 to develop a fully–blown product strategy.
- The project team is comfortable to progress various suggestions that it has received involving:

  - analysing the current state further, particularly learning from V3/CDA successes
  - progressing technical suggestions about what the strategies should be, minimize differences between V2, V3 and CDA
  - providing guidelines on when to use V3 messaging vs. V2 or CDA, and
  - development of possible strategies for further evaluation based on experience to date.

- While the identification of potential "low–hanging fruit" is useful, some of those on the Board and TF (including Dixon Hughes) have the view that the current activity needs to lead into a more comprehensive product development strategy involving proper market research across various stakeholder groups – otherwise HL7 is likely to fall into the trap of "product push". Without such fundamental research, it is not clear that any "v4" would be any more successful in the marketplace than v3. HL7 needs to address the broader issue of product evolution form a truly strategic perspective.

- It was noted that the more comprehensive product strategy was beyond the scope and resources of the current project, but that the formulation of recommendations to go forward with work on such a strategy should be one of the outcomes.

- There is potentially significant overlap between the activities of the TF (driven top–down from the Board), the activities of the TSC and ArB (with responsibility for the HL7 product architecture, projects and SAEAF) and the activities of the new Innovation Committee.

- The initial papers focussed on issues arising from information structure and semantic content, but the work does not address questions about the dynamic model and relationship of V2 and V3 to the SAEAF initiative.

- There is a significant risk of miscommunication and confusion – both within the HL7 community and among its many customers. It was noted that the Board will need to determine how to manage the various documents being produced by the TF. They can be considered white papers with no official approval or the TF can step through them and approve them for broader communication.

- External communication also involves ensuring that the international community understands that this is an international project while, at the same time, there is a need to reach out to key constituents in the US to avoid creating opportunities for challenges to HL7.

- On the broader front, realisation of a product development strategy involves a range of tasks and roles: – development of strategy proposals, evaluation and selection of strategies and identifying how to implement the chosen strategies. This raises challenges of governance – how does HL7 move from a high level strategy to project plan with accountability? Who needs to be involved at each point?

- Ultimately, HL7 will need to identify desired outcomes from the TF and these various other activities and formalise them as roadmap activities and projects – under the governance of the TSC.

- Scope of recommendation – should the TF attempt to define a future state where HL7 supports a single or minimum set of interoperability solutions or where many solutions are supported but content and activities of the solutions are coordinated?

- The way forward is likely to involve a combination of evolutionary and revolutionary steps – but each step needs to be well–founded and manageable. This is analogous to a company that has an existing product and is creating a new product with good communication being essential.

- The Board supported the continuation of the TF and the project within the current scope, noting that the TF will provide further recommendations in 2–3 months regarding the need and approach for a broader product development strategy.

While it is refreshing to see the HL7 organisation make an effort to effect change and address many issues both in the published standards and the way the organisation itself manages the standards process, it remains to be seen whether effective changes can be achieved. It is likely that there may be considerable reluctance within the organisation itself to achieve the changes.

Implications:

The Australian e–health community should keep a close watch on the outcome of this Task Force and its publications so as to make sensible decisions about adopted standards going forward.

11. STANDARDS SUPPORT FOR E–HEALTH REFORM IN THE US

The Obama administration has embarked on aggressive measures to stimulate the planning and uptake of e–health in the USA in association with its commitment to healthcare reform and to stimulate the economy.

The first of these measures were signed into law when President Obama gave assent to the American Recovery and Reinvestment Act (ARRA) on 17 February 2009 and involve total funding for health IT (and related activities) in the vicinity of US$34 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. The approximate split of funds is set out in *Table 5 – Approximate split of funding for US e–health initiatives* (on the next page).

It can be seen that a large part of the total amount is incentive funds for e–health adoption and provision of PQRI quality measures under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Payment is tied to providers being able to demonstrate “meaningful use” of "EHR Technology"

As an example of the support that will be provided by the Obama initiative, private physicians will be provided with up to $50,000 to install accredited software over the next 3 years with decreasing amounts if installation occurs later in the cycle. If accredited software is not installed, Medicare payments will be reduced by 2.5%.

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 DOHA 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**

Table 5 – Approximate split of funding for US e–health initiatives

HL7 is positioning itself to be the primary provider of standards for this initiative.

Two key regulatory instruments – the Interim Final Rule (IFR) on standards, specification and certification criteria for EHR technology and the Notice of Proposed Rule Making (NPRM) on the EHR incentive program were both released on 13 January 2009. The rules set out a staged approach to the adoption and use of Health IT to meet the legislative criteria for "meaningful use".

In relation to standards, for 2010, the IFR has identified HL7 v2.3.1, v2.5.1, CDA R2 and CCD among the allowed standards for exchanging patient summary record content and v2.5.1/v2.3.1 for some other applications – along with the use of terminology appropriate to the clinical domain from SNOMED, LOINC or RxNorm.

It was notable that HL7v3 received no explicit endorsement and HL7 was disappointed that, contrary to prior indications, use of the relatively unstructured ASTM CCR format was also allowed for the present.

Comments may be submitted on both the IFR and NPRM up to 15 March. HL7 is planning its comments at present; however, arguments for change at this stage will need to be backed by strong evidence if they are likely to result in any change being accepted.

HL7's continues to maintain contact with ONC in response to the stimulus and health reform packages and continues to be well received by ONC and other relevant US–Government agencies (NIST and NLM), with the following developments being of particular note:

A draft proposal has been discussed with key government stakeholders in ONC, NLM and NIST and adjusted in line with their feedback.

One–off ARRA stimulus funding needs to be fully committed by 31 March 2010 and is not suitable for long–term maintenance; however, ARRA deliverables can be over an extended period. It is therefore likely that two separate contracts will be required: one for "licensing IP" and another for "ongoing maintenance and development". The second will require a separate justification and funding source.

The main proposal is now referred to as the "Proposal to License HL7 IP (Intellectual Property" and will be submitted to the US Government this quarter – the proceeds of this should help to fund longer–term development and maintenance of HL7 standards.

Dr Doug Fridsma, who has just taken up the position of Director of Standards at ONC addressed the general session on the Monday morning and will be one of the key people dealing with HL7 International on behalf of the US Government.

12. INTERNATIONAL COUNCIL (FORMERLY "AFFILIATES COUNCIL")

The International Council (IC) (which is a forum for discussion of international interests within HL7) met with representatives present from Affiliates in Australia, Austria, Belgium, Brazil, Canada, China, Colombia, Finland, France, Germany, Greece, India, Israel, Japan, Republic of Korea, Mexico, New Zealand, Russia, Sweden, Switzerland, Taiwan, The Netherlands, the UK as well as having Stan Huff present as the inaugural US representative.

A delegation from Pakistan also attended, as well as senior HL7 office–bearers. Apologies were received from the newly elected Hong Kong SAR.

In its Sunday general session, the International Council received reports from: the two directors on the HL7 Board elected by Affiliates; the CEO and CTO of HL7 International, the TSC, Marketing Council and Education Committee and in relation to HQ Liaison along with updates and requests on specific topics of interest. In addition to topics covered in more depth elsewhere in this report, the following were noted:

- The Affiliates Council has been renamed the International Council as part of HL7's internationalization initiative and has been expanded to include a representative of the USA.
- Feedback from Affiliates on the performance of HL7 HQ was positive on all assessment measures – with "customer service" being a clear leader and PR/Marketing Support and the Balloting Website trailing the field (while still being scored positively).
- Brief presentations given by each affiliate delegation present – summarising the current status and activities of HL7 in their country. These are summarised in Annexure A below.
- The European Federation for Medical Informatics (EFMI) is holding its Special Topic Conference in Reykjavik, Iceland on 2–4 June 2010 on the theme: *'Seamless care – safe care. The challenges of interoperability and patient safety in health care'*.
- The focus is on issues arising from the safe interoperability of systems including global standards for patient safety, traceability and accurate data synchronisation. These include socio–technical, technological, financial, legal and cultural challenges in cross–border communication, potentially impacting on patient safety and continuity of care.
- For more information – see:

www.sky.is/efmi–stc–2010–.html

- The South American regional conference held in Uruguay in October 2009 attracted some 350 delegates and was, by all accounts, a success.

- The Chair of HL7 International, Bob Dolin, provided an update on proposed features for CDA release 3, encouraging widespread input from the international community in shaping the features of r3 as it proceeds into ballot. Interested experts may find out further information through the CDA/Structured Documents wiki – there are already around 40 formal proposals for enhancements.

- An associated issue is the current debate on how the so–called "Right Hand Side" of the Clinical Statement pattern should be realised for CDAr3 as people start to exceed the representational capabilities of the existing model. Options include – using the RIM, using the CS model with additions, or extending the CDAr2 model. Experts were encourages to participate in the online ballot on these issues.

- Universal Vital Records: EHR–S Functional Profile – Solicitation of international participation. The origin is public health and the aim is to lay the foundations for e–vitals exchange. Australia has already contributed by providing information via the Victorian Department of Health.

The following are among the topics dealt with in more depth by the Affiliate Chairs at the closed session of the IC meeting held on the Thursday afternoon:

- Update and detailed discussion arising from the findings of the Board–appointed committee commissioned with assessing criteria for selecting non–US WGM locations (for more detail – see commentary on committee report to the Board of HL7 International in section 9.5 above).

- Update on establishment and operation of the HL7 Europe office and formation of a European Advisory Council (EAC) to represent the views of European Affiliates to the HL7 Europe office.

- The EAC will be constituted in accordance with IC recommendations and is expected to be announced at the EU High–Level Conference on e–health in Barcelona in March 2010.

- The European Office is staffed by receptionist who translates calls and emails to HL7 HQ for attention of Mark McDougall, Charles Jaffe and John Quinn. A firm of attorneys in Brussels has been reviewing the constitution of HL7 International to ensure that it permits registration in Europe.

- A report back on outcomes of the Tuesday–night Board meeting – as covered in section 9 above and other sections of this report.

- Discussion of future WGM locations – Rio in May 2010, Sydney in January 2011, and London or Paris in 2012 and improving transparency of the selection process.

- Affiliate Chairs endorsed France's continued activity to secure a WGM for May 2012 in Paris.

- Affiliate Due Diligence Committee (ADDC): – noting proposed changes to ADDC terms of reference and procedure; revised membership approach; Affiliate review process; and confirmation of additional IC member of the ADDC.

- Potential revisions to the Affiliate Agreement. This is expected to take three to six months with time for input to be sought at the May 2010 WGM – resulting in formal recommendations for the October meeting.

- Global Membership Directory – a motion to approve the proposed scope, approach and schedule for global membership directory, allowing affiliates to upload and manage their data was discussed and agreed.

- Internationalization Task Force Update – as reported elsewhere, but with more focus on possible new membership models.

- National Initiatives Project – Overview of objectives and solicitation of interested parties willing to participate in the committee running this project being Chaired by Catherine Chronaki.

- HL7 international is keen to develop a better understanding of the relationships between HL7 and national e–health programs, both organizationally (e.g. is an affiliate a contributor) and in terms of standards involved. A survey will be developed in the first instance (D Rowlands to assist).
- Affiliate Chairs supported a set of budget requests from the International Council budget:
  - $US2,000 to support HL7 attendance at two JIC meetings
  - $US5,000 to help HL7 Europe Chairs without other recourse to funds get to the HL7 Interoperability meeting in Barcelona (this was debated at some length)
  - $US3,000 to publish proceedings of the EFMI special topic conference in Reykjavík, and
  - $6,000 to support IHIC 2010 in Rio.
- $US3,500 is left from the 2010 budget and consideration should be given to projects that might enhance Sydney 2011 (although the purpose of these funds is not to directly support WGMs)

12.1 AFFILIATE MEMBERSHIPS

An affiliate liaison report was presented, during which it was noted that:

- The Hong Kong SAR has joined HL7 since the last meeting.
- Luxembourg was approved by the Board at the January 2010 meeting and will become an Affiliate on execution of the Affiliate Agreement and payment of their fees.
- Entry of Hong Kong SAR and Luxembourg brings the total number of HL7 Affiliates to 35.
- Norway has applied for Affiliate Membership and had a 3 person delegation at the meeting.
- Pakistan had a delegate at the meeting and is in the process of applying for affiliate membership.
- The Philippines is being mentored to commence the process of forming an affiliate.

Hong Kong's membership has raised questions about the geographic scope of an affiliate given that Hong Kong is part of China. There were "mutterings" that HL7 Quebec might be next! This is a sensitive area that will require discussion and resolution in the near future as HL7's membership grows rapidly and becomes more diverse. It was noted that HL7 China had supported separate membership for HL7 Hong Kong, given the differences in their political systems and separate approach to health IT.

12.2 2010 INTERNATIONAL HL7 WGM IN BRAZIL

The May 2010 HL7 International Working Group meeting will be held in Rio de Janeiro, Brazil from 15–21 May 2010. It is to be held in the same location as the ISO/TC215 Health Informatics meeting (which will be held on 9–13 May). It is also proposed to hold the International HL7 Interoperability Conference 2010 (IHIC 2010) on 14–15 May (Fri/Sat) after ISO/TC215 and before the HL7 WGM.

The promotional web site for the 2010 WGM in Rio de Janeiro:

www.HL7.org.au/2010–WGM–Rio.htm

Two seminars were also held. One hosted by HL7 Australia was focused on partners of HL7 delegates who were present at the January meeting, with a view to encouraging their attendance in Brazil in 2010 and at the proposed Sydney WGM in January 2011.

The other seminar was hosted by HL7 Brasil and ran for a full quarter and addressed issues relating to the venue in Rio, the city and its neighbourhoods, the need for Australian, US and Canadian passport holders to get visas within 90 days of their arrival in Brazil (this process can take several weeks). Copies of all the presentation materials have been obtained and will be made available to potential attendees at the Brazil WGM through Standards Australia (or contact Richard Dixon Hughes – richard@dh4.com.au).

12.3 PROGRESSING INTERNATIONALIZATION OF HL7

The change in the legal name of HL7 to HL7 International is effective immediately, and an announcement was to be made with joint press releases, broadly distributed in the US media and through the international press. The January Newsletter article describes the CEO's vision for internationalization.

An Internationalization Task Force has been re–established to address high level topics such as governance, dues and intellectual property (IP). Richard Dixon Hughes has been appointed as a member of the task force.

Plans for the HL7 European office have progressed under the leadership of HL7 HQ with active support from Catherine Chronaki (HL7 Greece). The logistics of incorporation (according to Belgian law) have been initiated. Office space has been leased at: Square de Meeûs 38/40, 1000 Brussels; T: +32 (0) 2 401 61 25; F: +32 (0) 2 401 68 68.

A draft white paper has been written and an issue list developed re the scope of the European office.
The EU pilot office sets a model for other global opportunities, and HL7 International has already been approached to establish an Asia–Pacific office. The success or otherwise of the EU pilot will obviously be a significant determinant of the future.

Implications:

Australia should consider whether we would want to be the Asia–Pac office location, and if so how we could orchestrate towards this – including via a successful Sydney WGM.

13. AFFILIATES DUE DILIGENCE COMMITTEE (ADDC)

This Board–appointed committee has oversight of the processes to evaluate, recommend admission and cancellation of HL7 International Affiliates. Klaus Veil is a member of the ADDC and attended their session at the January meeting by teleconference. Business transacted included:

- Updated Committee Terms of Reference and Procedures were agreed by the ADDC and will now be provided to the International Council (Affiliate Chairs) and the Board of HL7 International for final approval.
- The Affiliate application by Pakistan was reviewed and found to be address the basic requirements. The next step is for more detailed interviews with the applicants – Klaus was 'volunteered' to undertake the interviews.
- The ADDC also discussed closer collaboration with the HL7 International Mentoring Committee and the updating of the "How to become an HL7 Affiliate" slides – originally created by Klaus.
- The Committee will continue to meet monthly by teleconference.
- Working Group web site:

  www.HL7.org/Special/committees/affildued/index.cfm

14. AUSTRALIAN PROPOSAL TO HOST 2011 INTERNATIONAL HL7 WGM

Significant progress was made by the Australian delegation in progressing final approval and arrangements for holding the 2011 HL7 International Working Group Meeting (WGM) in Australia, noting the following relevant background:

- After iterative discussions, presentations and submissions throughout 2009, HL7 Australia submitted a proposal to the HL7 International Board, through its Finance Committee, to hold a WGM in Sydney in either January or May 2011. This proposal was developed with assistance from an Advisory Group comprising three HL7 Australia representatives, representatives from Standards Australia, IT–014 and NEHTA, and two observers from DOHA. David Rowlands Chairs the Advisory Group, which is ongoing.

- The proposal was endorsed by the HL7 International Finance Committee (in November 2009) and Board (in December 2009) subject to (a) the provision of $AU100,000 in local sponsorship, to assure financial viability, and (b) satisfactory exit from existing arrangements in Florida.

- The sponsorship is proposed to be substantially provided by DOHA and NEHTA. At the time of departure for the Phoenix WGM responses to HL7 Australia's requests for these sponsorships were proceeding through the relevant approval processes but had not yet been secured.

- There are significant benefits for Australia in securing the WGM, most notably in exponentially widening the opportunities for Australian participation and in leveraging the attendance of international experts for local education, training and other purposes.

Activities to progress the proposed Sydney WGM included announcements re the meetings' likelihood, marketing Sydney's advantages, appraising HL7 International about progress and assuring them that progress is on track, and initiating a site visit.

14.1 ANNOUNCEMENTS

Repeated announcements were made at the HL7 International Council meeting, attended by over 100 people, that Sydney was the likely destination for January 2011. Informal channels of communication were also used throughout the WGM. HL7 International's published forward schedule still indicates Florida, but this is associated with existing commercial arrangements and cannot be changed until a clear (non–conditional) decision has been made in favour of Sydney. Accordingly, unequivocal messages about Sydney being the January 2011 WGM location remain dependent in the first instance on confirmation of the main sponsorships.

14.2 MARKETING

HL7 Australia funded a reception at the Phoenix WGM to promote international meetings to potential U.S. participants who require further information about the attractions of Rio (site of the May 2010 WGM) and Sydney, and their partners. A culture of success and enjoyment in Rio is likely to increase the prospects of attendance in Sydney. More targeted marketing, via a range of channels, will be developed by the Advisory Group and undertaken throughout 2010 after the WGM is secured.

14.3 APPRAISING HL7

Meetings were held with key HL7 international staff and Board members to ensure they understand the processes and timeframes required for securing sponsorship; and were re–assured that progress is on track. The site visit by HL7 staff was brought forward. The site visit will now occur from 16–20 February 2010 rather than waiting for sponsorship to be confirmed. This will accelerate the overall decision making and notification timetable.

14.4 SITE VISIT

Lillian Bigham, HL7 International's Event Co–coordinator, will undertake the site visit. Relevant meetings, venue assessments and negotiations, Sydney orientation, etc will be arranged by, and Lillian will be accompanied and assisted by, HL7 Australia staff. Meetings with sponsor and Advisory Group representatives will be encouraged.

14.5 ATTENDANCE

Enthusiasm to attend the meeting in Sydney is high (even more so than the next meeting in Rio de Janeiro). Most Co–Chairs have indicated they will be able to attend. A number of groups are actively planning co–located events though HL7 Australia has decided to not bid for the IHIC conference, which is often held immediately prior to the international working group meetings.

14.6 BACKUP

New Zealand remains the "Backup site" in case of political or geographical disaster!

This remains a real issue for HL7 following the September 2009 meeting when the Atlanta area was declared a disaster zone due to flooding, during this meeting and the entire state of Arizona was declared a disaster zone, due to record rainfall. At one stage there were four simultaneous weather alerts for floods, blizzards, mud slides and tornados on the one day, as well a metre of overnight snow. Hopefully Sydney will be kinder.

Promotional web site:

www.HL7.org.au/2011–WGM–Sydney.htm

More info from Rene Spronk:

www.ringholm.de/column/Internationalization_of_HL7.htm

15. JOINT INITIATIVE COUNCIL (JIC) – SDO HARMONISATION

A meeting of the JIC was held in conjunction with the January 2010 HL7 WGM but the outcomes were not separately reported back to the WGM. HL7 is now putting information on its website about HL7's commitments to JIC joint projects and the adoption of HL7 standards by ISO/TC215:

- For information about HL7's collaboration with ISO and others through JIC

  www.HL7.org/participate/isojic.cfm

- For information on the JIC process stages

  www.HL7.org/documentcenter/public/procedures/iso–jic/The%20JIC%20Process%20Stages.doc

- For information on projects underway from HL7 for ISO and JIC approval

  www.HL7TSC.org/wiki/index.php?title=ISO

The original JIC/JWG web site is:

www.Global–e–health–Standards.org

Traditionally, a session has been held in Q4 on the Sunday of each HL7 WGM that focussed on harmonisation activities being coordinated by the Joint Initiative Council (JIC) and the associated "Joint Working Group (JWG)" which is formally constituted as ISO/TC 215/WG 9 and for which Standards Australia provides the secretariat. On the few occasions when WG 9 has met at HL7, it has commenced at this time, immediately after the open session of the International Council.

The principal purpose of this session has been to provide the HL7 membership with an update on projects being progressed or considered as joint projects under the Joint Initiative (JI) Charter for Health Informatics SDO Harmonisation and to allow opportunities for discussion and feedback.

Commencing from this January 2010 HL7 WGM, the TSC has taken over responsibility for running this session, which now also looks beyond the JIC to address the broader gamut of "HL7 Activities with Other SDOs". A series of presentations were given addressing:

- **HL7 activities with CEN TC 251** – comments by Mark Shafarman, Bernd Blobel and Melvin Reynolds pointing out some of the CEN origins of common work (13606, harmonised data types, HISA etc). The ContSys continuity of care work needs to be integrated with several upcoming ISO and HL7 initiatives.

- **HL7 activities with CDISC** – Becky Kush gave a presentation entitled *"Harmonizing Standards Initiatives: An Overview of Collaborative Standards Initiatives for Clinical Research and Healthcare"* in which she outlined CDISC, its background, relationship with HL7 and the role of the BRIDG model, noting that:

  - all CDISC standards will be modelled and harmonized into BRIDG
  - BRIDG is the Domain Analysis Model for the HL7 RCRIM Workgroup
  - HL7 collaborates on harmonization of Terminology and in the BRIDG Advisory Board
  - BRIDG is being balloted through JIC, and
  - presentation available from:

www.hl7.org/Library/Committees/tsc/CDISC%20HL7%20Collaboration–TSC–17Jan10–fin.pdf

- **HL7 activities with DICOM**. Helmut Koenig reported briefly that the MOU between HL7 and DICOM was renewed in 2007 and a joint working group was established. There is close cooperation with Structured Documents, worked jointly on Diagnostic Imaging Reports (DIR Implementation Guide. Corresponding DICOM document is the transformation guide.

- **HL7 activities with IEEE (11073)**. Melvin Reynolds briefly touched on strong collaboration between HL7, IEEE Committee 11073, ISO/TC 215 WG7, IEC/SC42A/JWG7, IHE and Continua Alliance, which is successfully achieving coordination of device connectivity, based on a common 11073 terminology and data models. Connectivity standards are now moving to CDA as well as v2 and are recognised by HITSP specification in the USA. More HL7 expertise is required to advance these projects, particularly support in HL7v3 RIM, CDA Templates and DCM. See:

  HL7_2010–01_Phoenix_HL7_SDO_Coord_Activities_Devices_r1.pdf

- **HL7 activities with IHE**. Keith Boone gave a presentation IHE Report to HL7 TSC in which he summarised the use of HL7 standards in IHE profiles and noted current and new areas of work. See:

  www.hl7.org/Library/Committees/tsc/IHE%20Report%20to%20HL7%20TSC_2010Jan.pdf

- **HL7 activities with IHTSDO**. Russ Hamm noted the two main areas of joint work between HL7 and IHTSDO, namely:

  - The IHTSDO Workbench: HL7 has evaluated the workbench product and considers that it has the core capabilities to maintain and manage HL7's vocab resources and other vocab activities.
  - The next step is for the Tooling and Vocab WGs scope and carry out a pilot project using the workbench. A time had been set at the WGM to develop the project scope – potentially crafting shareable subsets/refsets and recommending SNOMED changes using the workbench. More hands–on experience with the software is a key objective for HL7.
  - TermInfo (specifications for co–implementing SNOMED in HL7 V3 standards). IHTSDO wants to reduce representational gaps in TermInfo and will be working with the HL7 Vocab WG to extend the TermInfo ballot to get input from the IHTSO community and produce the next generation of TermInfo as a joint offering.

- **HL7 Activities with NCPDP**. Sue Thompson, spoke at some length on NCPDP (National Council for Prescription Drug Programs – an ANSI–accredited SDO that grew out of pharmacy claims settlement), the relationship with HL7 through the SCO and the various current SCO projects, most of which have strong input from the HL7 leadership. NCPDP also has close relationships with ASC X.12 for claims transfers.

- One of the other projects involves work with WEDI on implementation of a health identification card.

- Work is expected to start in April/May on a functional profile for pharmacy/pharmacist information interchange to provide criteria for systems certification.

- HL7 activities with OMG. Ken Rubin reported that OMG has been working with HL7 for some time and that the relationship between HL7 and OMG has steadily improved with regular participation at CEO/CTO level in each others activities. This is particularly important for the progression of the HSSP (Health Services Specification Project) in which OMG and HL7 work together in the development and delivery of robust SOA standards for the healthcare sector ,with the following being noted:

  - CTS2 (Common Terminology Service) has passed HL7 publication ballot and is now with OMG to go through their process for adoption as an OMG technical standard – participation is encouraged.
  - HSD (Health Services Directory) also passed ballot this time.
  - DSS passed some time ago and in December was adopted as OMG specification.
  - SOA in Healthcare conference will be around June or July 2010 in Washington DC.

- HL7 activities with ISO/TC215 Health Informatics committee. The HL7 CTO, John Quinn, gave a brief presentation covering:

  - ISO/TC215 Working Group structure

- JIC activities, noting that Kees Molenaar (CEN/TC251 – The Netherlands) is taking over from Ed Hammond as Chair of the Joint Initiative Council (JIC), and
- the need proposed joint JIC or ISO project to also be registered with documentation in the HL7 project system. This is ESSENTIAL if HL7 is to support the work.

- The following JIC projects involving HL7 were noted:
  - ISO 27953 – Health Informatics: Pharmacovigilance – Structure and Data Elements for Individual Case Safety Report (ICSR), HL7 contacts are Lise Stevens and Mead Walker – 2nd DIS ballot passed.
  - Health Informatics – Identification of Medicinal Products (IDMP).
    - ISO TS 11238 – Ingredients/Substances
    - ISO TS 11239 Dose/Unit/Route
    - ISO TS 11240 Units of Measure [Christof Gessner]
    - ISO TS 11615 MPIDs
    - ISO TS 11616 PhPIDs

    It was noted that the IDMP project expired during 2009 and was reactivated with a second NWIP/CD ballot which passed – with 800 pages of comments subsequently being reconciled.
  - ISO/TS NWIP 28379 Health Informatics: Common Glossary for TC215.

    Deliverables: Glossary and Document Register User Guide and Standards Knowledge Management Tool (SKMT) Web Site.

    Project Insight No 495 – Vocabulary WG – Leader: Heather Grain.
  - ISO/TR NWIP 12310 Health informatics – Principles and guidelines for the measurement of conformance in the implementation of terminological systems.

    Project Insight No 496 – Vocabulary WG – Leader: Beverly Knight.

The following were among the points raised during questions and discussion:

- Richard Dixon Hughes asked about ongoing delays in progressing the data types standard. Audrey Dickerson (TC215 Secretariat) said they got delayed by ISO Central Secretariat (ISO/CS) in Geneva because they had invalidly edited the coding and were not accepting the corrected version. TC215 is working with ISO/CS on the changes and various delegates made suggestions for resolving the problems – including putting the schemas in as diagrams.

- Lise Stevens asked whether HL7 would formally meet to talk about lessons learned in the joint standardization processes. John Quinn would be interested in the feedback – process harmonization across SDOs remains a concern. Melvin Reynolds agreed that here are past experiences that should be shared; however, even when it is agreed that things should change, it is hard to get the necessary changes propagated across and into the work practices of SDOs.

- Melvin Reynolds indicated that, if possible, JIC members need to consider handing over the lead on a project and allowing the lead SDO to do the work with input from others, where this would be most efficient and then have the others adopt it directly. Charlie McCay asked if this could be considered for next WGM.

- Bob Dolin (HL7 Chair) would like to devote some time to discussion of the efficiency of the relationships with other SDOs.

- Richard Dixon Hughes reminded those present that the "Joint Working Group" ISO/TC215/WG9 will next be meeting in May 2010 in Rio; hopefully, at a convenient time between the ISO/TC215 plenary and the HL7 WGM – possibly on the Sunday in Q4/Q5 – instead of the "HL7 Activities with Other SDOs" (as had happened when WG9 had met at previous HL7 WGMs).

16. TECHNICAL STEERING COMMITTEE (TSC)

The TSC commenced work on the Saturday leading into the WGM, with further meetings on Sunday evening, Monday night, Tuesday lunch and Wednesday afternoon. In total, and excluding reports to other groups, TSC led around 18 hours of face–to–face discussion at the January 2010 meeting, including the Innovations Workshop, HL7 Activities with Other SDOs and the Co–Chairs forum.

As the body within HL7 with overall responsibility for managing the technical work program and product delivery, TSC is extremely active, carrying out most of its work on weekly teleconferences – with its sessions at WGMs being oriented toward coordination and technical governance, interaction with the wider HL7 stakeholder community (particularly Co–Chairs, the Board and others in leadership), product strategy and technology development.

For more details on TSC and its activities, follow the links from:

http://hl7t3f.org/wiki/index.php?title=Main_Page

Topics considered, reviewed or progressed by the TSC at the January 2010 WGM included:

- Continuing development of the HL7 roadmap, fleshing out the details of the many roadmap projects assigned to the TSC and tracking roadmap development.
- With Lynn Laakso (TSC Project Manager) and John Quinn (CTO), reviewing, approving and tracking projects, and following up issues arising from management of the HL7 project portfolio.
- Determining/recommending and progressing tools and technical infrastructure for use across the HL7 organisation (dependent on resources in Electronic Services) and (with the CTO) providing direction and guidance to the HL7 tooling project.
- Oversight and provision of feedback on ArB activities, including: development and application of SAEAF and enterprise architecture implementation plan (EA IF) and reviewing progression and implications of the SAEAF "Alpha" projects.
- Define scope of HL7 Quality Plan and establish project to develop and deliver it.
- DCMs – pursuing concerns and processes relating to consistency of clinical content (also see reporting of discussions on DCMs – section 22 below).
- JIC Project: Harmonised health informatics document registry and glossary – adoption and progression within HL7.
- Work Group Visibility Project (to provide visibility of work group scopes and activities) – moving toward annual maintenance of WG missions charters, work plans.
- Working with ORC (Organizational Relations Committee) on monitoring and managing how projects and work groups manage their relations with other organisations.
- Tracking and convening discussion of HL7 activities and projects being carried out with other SDOs – including SCO (US), JIC members and ISO/TC215 (International) and MOU holders.
- Reviewing IPR, patent, and copyright issues – ensuring reliable advice is obtained and is provided to the HL7 community, assisting with IPR policy development – including possibility of separately managing HL7 IP access rights and decoupling them from HL7 membership rights.
- Fostering development of product strategy – observing v2/v3/CDA task force and providing considered input and feedback on issues arising.
- Progressively consider deliverables and issues coming out of the Working Group Meeting and arrange discussion and resolution of hot topics within the TSC domain (of which there are many).
- Set up and conduct of Innovations Workshops – and deciding which innovations should be pursued and how they should be progressed.

- Impact on quality and progression of HL7 work where Work Groups do not meet at a WGM (particularly an issue at international WGMs) – for International Council. Status: benchmarking US WGMs for effectiveness, seeking to identify relevant metrics with the IC.
- Technical governance – determining and documenting the process of ArB nomination and confirmation (in draft).
- Technical governance – monitoring and reviewing the role of the Steering Divisions.
- Technical governance – review/update and assess progress against: (1) TSC mission and charter; (2) TSC Communications Plan; and (3) TSC Decision Making Practices (up for revision).
- Technical governance – review HL7 Technology Plan 2009 and update topics/milestones.
- Technical governance – review and update TSC SWOT, three year plan, three–year plan detail.
- Reviewing results and outcomes of HSSP Process Project.

17. ARCHITECTURE REVIEW BOARD (ARB)

The ArB and TSC have produced formal membership criteria that define the requirements for ArB membership. These include a combination of influence and competence. The criteria have been unanimously supported by the TSC.

The TSC and ArB have agreed to a formal SAEAF harmonisation process (as was conducted for the RIM). This will formalise the process of contribution and agreement for the SAEAF. A simplified peer review process will be engaged when Behavioural Framework and Governance Framework are published.

Ken Buetow (National Cancer Institute) has emailed HL7 to request continued HL7 custodianship of SAEAF intellectual content while NCI will formerly implement SAEAF for new infrastructure development. Ongoing discussions with the National Institute of Health (NIH) and Federal Health Architecture (FHA) about adoption of SAEAF.

ArB has been using DITA in its publication of the SAEAF book. ArB has decided to adopt Topic Maps as a formal knowledge notation as it works well with DITA.

18. SAEAF DEVELOPMENT AND IMPLEMENTATION

Work on developing and publishing SAEAF documentation is progressing well since the decision was taken to hire a professional technical writer (Karen Smith) and use the DITA publishing platform kindly donated by IBM. The formal documentation process has also facilitated cross checking and validation of the content to improve quality and has incorporated some learnings from early implementation. The status of each part of the SAEAF documentation at the time of this meeting was:

- SAEAF Introduction – released for review/use (comments welcome, edits expected)
- Enterprise Conformance and Compliance Framework (ECCF) – released for review/use (comments welcome, edits expected)
- Behavioral Framework (BF) – ready for public review, expecting release mid–Feb
- Governance Framework (GF) – in development – expected for May 2010 meeting in Brazil
- Information Framework (IF) (including core principles) – in development – expected for May 2010 meeting in Brazil, and
- Implementation Guide (IG) – in development – pending (will impact HDF).

The latest versions of the SAEAF documentation can be found by following links from:

http://wiki.hl7.org/index.php?title=SAEAF_200902_Documenthttp://wiki.hl7.org/index.php?title=SAEAF_200902_Document

Proposed Alpha projects are skewed toward core HL7 infrastructure and are only progressing slowly. The current list of SAEAF Alpha projects is given in the table below indicating the group/s responsible for development.

Project	**Responsible Working Group or Organisation**	**Status**
Privacy, Access and Security Services (PASS)	Security and Service Oriented Architecture (SOA)	passed ballot and follows the SAEAF
Common Terminology Services 2 (CTS2)	Vocabulary and SOA	Passed initial ballot, in review with OMG and has yet to start SAEAF alignment
caEHR – Several NCI projects including cancer ambulatory oncology EHR specification	US NIH/NCI and SOA	Informative stage, with full time staff allocated tothe EHR working group to develop an oncology EHR for NCI
Implementable Technology Specifications (ITS)	InM	Informative stage
V3 Composite Order	OO	Orders and Observations (O–O) is working on a Domain Analysis Model (DAM) for pathology orders that uses the Behavioural Framework.
CDA R3 (with focus on SAEAF compliance)	Structured Documents	
EHR–S Functional Model R2	EHR (just commencing the SAEAF process)	Informative stage
Privacy Access and Security Services – functional model	Security and SOA	
Infoway Blueprint 2015	Canada Health Infoway	Is starting process and will result in a formal alignment of SAEAF and TOGAF

Two projects are underway that are using SAEAF to develop customised enterprise architecture, with experiences being fed back to the ArB and HL7 EA Implementation Project (EA–IP) Advisory Group:

- HL7 ArB with the TSC's direction is moving to creating an Enterprise Architecture for HL7 that will represent an instantiation of SAEAF.
- NCI (National Cancer Institute) will be developing its own Enterprise Architecture for the national cancer information sharing grid – CABIG 2, a further instantiation of SAEAF.

More information on progress on the Alpha projects, EA implementations and other SAEAF implementation issues may be found on the HL7 EA–IP Wiki:

See:

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

During this meeting, it was also noted that:

- SAEAF Alpha projects have been selected to exercise the SAEAF so as to provide implementation feedback and refine existing HL7 artefacts so that they are SAEAF compliant.
- Each Alpha Project has an assigned ArB mentor who is working with the project.
- Availability of SAEAF facilitators to work with HL7 projects continues to be an issue with no easy way of rapidly growing real SAEAF expertise within the HL7 community. To assist in raising awareness, all Co–Chairs were allowed to attend one of the two SAEAF tutorials for free.

- A mutually beneficial collaborative relationship has been forged between HL7 and NIH/NCI that has allowed NCI to provide some support for current SAEAF work (as noted in the CTO's report).
- Tools and other artefacts developed by NCI in applying SAEAF will be readily available and will potentially be of considerable value to HL7.
- The TSC reported many people remain confused about the difference between the SAEAF framework and an Enterprise Architecture (EA). Many expect SAEAF to replace an EA whereas, in reality, SAEAF defines a set of languages to define EA viewpoints and augments the enterprise perspective of an EA with an external interoperability view. A proposal has been made to rename SAEAF to SAIF replacing Enterprise Architecture with Interoperability.
- Many projects have expectations that SAEAF will replace existing HL7 artefacts with new SAEAF compliant artefacts. A transition strategy for this migration needs to be clearly articulated.
- Most projects are still in the embryonic stage with many issues about applying SAEAF. Ongoing sources of confusion include: the service–aware motivation of SAEAF and the difference between SAEAF and an Enterprise Architecture.
- The HL7 SAEAF implementation should result in an HL7 EA that is compliant to the SAEAF. This work will result from the application of SAEAF through the Alpha projects.

Working Group Project gForge web site:

http://gforge.hl7.org/gf/project/saeaf/http://gforge.hl7.org/gf/project/saeaf/

Action:

Promulgate the interoperability agenda of SAEAF within Australia so as to better set up Australian development to align with HL7 strategic direction.

Align SAEAF framework to Australian interoperability requirements. Keys include the governance, compliance/conformance, information, and behaviour frameworks.

Action Owner: NEHTA and Standards Australia IT–014–06 (HL7 Australia) / NEHTA

19. CLINICAL INTEROPERABILITY COUNCIL (CIC)

19.1 TUBERCULOSIS DAM

A ballot on the TB Domain Analysis Model (DAM) is not now likely until 2011 as the process of developing the model is taking longer than expected due to interest from CDC and FDA.

The DAM needs to be certified and validated. The work is relying on volunteer work and so is slow. There is considerable support for the project, however funding is being sought to get the process moving faster.

19.2 EMS DAM

Sarah Ryan and J Lyle have worked on the EMS DAM over past year with the intention of balloting it at the May 2010 WGM. The project needs more from CIC to have a look at it and provide comments and input on the DAM.

19.3 ENDOSCOPY PROCEDURE NOTE IMPLANTATION GUIDE

This project is developing a CDA R2 implementation guide – using of CCD templates in an attempt to try and reduce the time to produce implementation guides. There was some discussion about the purpose definition which says this is a note that excludes incision or excision and there was also discussion around its place in either the Universal realm or the US realm. Work on this project I being primarily progressed in the Structured Documents (SD) Work Group.

There has been a deliberate decision to separate procedure notes from operative notes even though the latter should be a subset of the first and the reasoning behind this was thought to be related to a problem with LOINC structures.

19.4 ACS DAM – CARDIOVASCULAR DAM

The Acute Coronary Syndrome (ACS) DAM project is not yet ready to bring a revised project scope statement to the CIC. They seem to be getting bogged down trying to get consensus on the 'Top 100' data elements.

19.5 DAM FOR PAEDIATRIC PREOPERATIVE ANAESTHESIA ASSESSMENT

Work to date (being led by the GAS WG) has focussed on assembly of requirements/use cases, with the following progress noted:

- A set of actual use cases for the US has been sourced from Duke University.
- Comprehensive merged lists containing some 420 data elements have been sourced from The Netherlands. The clinicians involved think that these are representative of the area, although there has been no outside review.
- Use cases have been looked at by the UK which seems to be reasonably happy.
- The project has been registered (number 542) but the project scope statement has yet to be approved by the TSC. Some minor updates to the project scope statement that was approved during the last WGM were noted.
- It was suggested that the project be presented to the international affiliates meeting so that other countries could give feedback.
- Next steps – expand use cases, add definitions, define definitions and publish docs for comment.
- What is the DAM to be used for? Potentially an implementation guide.

19.6 ROYAL COLLEGE OF PHYSICIANS (UK) – CLINICAL NOTES FOR HOSPITAL ADMISSIONS

It was reported that the Royal College of Physicians (RCP) in the UK have produced a set of headings that have been approved by the Academy of Medical Royal Colleges as a proforma to guide information to be provided for hospital admissions.

Royal College of Physicians is now working on section headings and then detail beneath those; for example: What is a presenting complaint. Then the UK CfH LRA (Logical Record Architecture) group will produce technical models of these.

19.7 HARMONISATION OF DAMS, DCMS AND OTHER CLINICAL MODELS

There was a lot of discussion with the CIC about how to harmonise different DAMs – "grouping" sets of data elements together. This process is rapidly going to get out of hand as more and more DAMs are produced. Ocean Informatics demonstrated an approach to this for DCMs (with *open*EHR archetypes as the example) where grouping data elements into higher level sets of reusable structures made harmonisation much easier.

The CIC was looking closely at tooling to help them manage their processes and one approach looked at was the CDISC tooling. A demonstration of the *open*EHR approach was also given and it was felt that these approaches were probably not mutually exclusive but complementary.

20. CLINICAL STATEMENT

The clinical statement (CS) is a common pattern of HL7 V3 (a DMIM) which is used by the Patient Care, Structured Documents and Orders and Observations Committees to express rich clinical content. It has been developed over 3 years and allows nearly any clinical statement to be encoded in its rich, recursive structure. At present it has passed ballot as a DSTU but did not have a specific "home" or owner within HL7. This led to the formation of the Clinical Statement working group at the January 2009 WGM with representation from the technical and clinical content committees. Its workspace can be found at:

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

This was the fourth WGM at which the CS WG met as a separate entity (prior to that, CS was managed at joint sessions of the Patient Care (PC), Structured Documents (SD) and Orders and Observations (OO) WGs.

The main discussion centred around how to extend the current Clinical Statement to incorporate Change Requests from SD/CDA, OO and Medications.

A key issue was the scope of the CS content anticipated for Clinical Document Architecture Release 3 (CDA R3). Robust debate over two quarters ably led by Grahame Grieve with significant input from the new HL7 Chair (and Co–Chair of Structured Documents) Bob Dolin as well as a cast of "thousands" (standing room only) led to a decision to extend Clinical Statement to include all relevant clinical classes from the HL7 Reference Implementation Model (RIM). As Grahame noted, this will prove a significant challenge for the current toolset development pathway and is likely to be the rate limiting step for roll–out of CDA R3.

21. COMMUNITY BASED COLLABORATIVE CARE (CBCC)

CBCC carried out ballot resolution for the Consent DAM, validated the PASS project ballot resolution and commenced the harmonization of the Privacy DAM and the Security DAM.

The harmonization is a cross committee activity, which, with things like PASS, is becoming much more common in the HL7 world and does not necessarily involve the Service Orientated Architecture group, as was traditionally the case.

The Healthcare, Community Services and Provider Directory services project (also known as HSD) was discussed extensively which resulted in an extensive demonstration and discussion of the Victorian Human Services Directory. With the new initiatives in Healthcare this service and tool now appears to have a lot more relevance to the Americans.

Working Group web site:

http://wiki.hl7.org/index.php?title=Community–Based_Collaborative_Care

22. DETAILED CLINICAL MODELS (DCM) PROJECTS

22.1 CURRENT STATUS OF DCM PROJECTS

As noted in previous reports on HL7 and ISO/TC215 working group meetings, the work on detailed clinical models is being led by Dr William Goossen of The Netherlands involves two main streams of proposed activity

- HL7 project 320 – piloting the complete specification of 10 generalised DCMs, and
- ISO/TC215 project 13972 – preparation of an international standard covering [generic] quality criteria in the four areas of:
  - clinical endorsement
  - DCM metadata
  - DCM modelling and model transforms, and
  - DCM repository services.

A further component of the original HL7 work was aimed at defining the requirements for a DCM registry/repository. The registry aspect of this project is being taken forward by the templates registry pilot project being led by Keith Boone (reported under Templates WG).

HL7 Project 320 on development of DCMs was originally registered in 2008. There does not appear to have been significant progress on DCM work since the September 2009 HL7 meeting at which approval of the detailed project proposal was deferred by the TSC due to concerns about the project scope and unresolved overlaps with other HL7 technical activity (notably Tooling, CDA templates and SAEAF).

Considerable discussions at the previous Working Group Meeting (WGM) on tooling apparently have not produced any decision or roadmap to advance questions surrounding tools and methodologies. Enterprise Architect (EA) is still the favoured modelling tool, although some exploration of use of the Ocean Informatics Archetype Editor has been done. However, the issue/difficulty of transforming the platform independent DCM

to platform dependent artefacts such as HL7 clinical templates is still very much unresolved. and an update on scope statement was initiated in 2009. The updated scope was voted on and accepted in January 2010, and will be processed to TSC voting soon.

ISO project 13972 *Quality criteria and methodology for detailed clinical models* passed ballot a new work item in July 2009 with Australia being the only country to oppose the work item in its current form (15 were in favour and 7 abstained). The proposal was seeking to go to a full international standard (rather than a technical specification – for trial use until the proposed methods are sufficiently established) and recommended that a poorly written outline with many blank sections be adopted as a Committee Draft.

Although Australia has put forward three experts (Heather Leslie, Evelyn Hovenga, Richard Dixon Hughes) to work on preparing the Committee Draft, there continue to be concerns in Australia about the acceptability of the single modelling approach originally proposed, the outlined methodology for DCM development and compatibility with existing archetype–based work (including the Clinical Knowledge Manager tool, the *open*EHR archetype repository and archetypes developed for NHS CfH in the UK.

Work on the Committee Draft is proceeding slowly, with limited engagement of Australian experts to date.

The issue of governance was raised at the January 2010 meeting and was agreed as a critical success factor for DCM development and acceptance. Dr Goossen, the project leader, asked whether Australia (through Stephen Chu) might be able to lead the development of contents for the governance wiki page.

Conference calls will be planned for February 2010 to develop plans for further work on the project and balloting contents.

Working Group web site:

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

Action:

Stephen Chu (NEHTA)to determine if it might be able to join IT–014–09 (EHR Interoperability) and whether it would be possible and appropriate for him to be nominated to ISO project 13972 as a further Australian expert – with a view to leading the development of governance principles and policy governing DCM development.

Seek wider input from others in Australia.

Action Owners: Stephen Chu and Richard Dixon Hughes (Co–Chair IT–014–09)

22.2 REVIEW OF DCM PROJECT PROPOSALS BY TSC AND PC WG

There was a lot of discussion within TSC, Patient Care WG (PC WG), and other work groups about the proposed DCM approach to clinical content development (specifically as proposed in HL7 Project 320). There has been much thought recently within HL7 about the many different approaches that HL7 has to clinical modelling and some concern that the DCM project was introducing yet another approach.

HL7 has a number of approaches used to define clinical content – Domain Analysis Models which are collections of data elements and metadata, Clinical Statements which are small sets of RIM based models that model a particular clinical entity, and Templates, which despite years of work have not been completely defined or standardised. Indeed currently within HL7 there are at least three different template methodologies – the CfH RMIM based templates, CDA rule based templates and another one that Graham Grieve produced a paper about. DCMs are yet another way of defining clinical content and the HL7 TSC was concerned that the approach had not had enough thought and methodological review.

The TSC called a joint meeting with Patient Care WG to discuss its issues and gave PC WG a list of 34 questions. Despite having little time to prepare, William Goossen had attempted to answer some of them prior to the joint meeting. In summary, the concerns boil down to three key issues:

- A new methodology was being introduced into HL7 and ISO without any methodological review.
- Patient Care as a working group were discussing and agreeing on a methodology which is not part of the scope of the WG. All methodology discussions should be dealt with by the MnM WG.
- The project scope statement does not seek to involve relevant interested groups. At least MnM should be mentioned in the scope statement.

The final outcome was that the TSC felt that the DCM approach was not ready to be on the path to becoming a "Draft Standard for Trial Use" and that its branding within HL7 was wrong.

The TSC recommended that the DCM approach become part of the new 'Innovation' program within HL7. This would remove it from the path to ballot as a standard and would enable the HL7 community to work in this area as an experimental approach which would engender less concern.

The TSC Chair, Charlie McCay, noted that it "was slightly shocking" that as an organisation, that there is no agreement within HL7 on a formalism for defining clinical content.

During discussion in PC WG, it was agreed that the definition statement for DCM suggested that these artefacts were computable when in fact they were not. There was general agreement that changes need to be made to clarify the scope and functionality of the DCM process.

There was discussion around the feasibility of the proposal to use UML to formalise DCMs and how this was difficult for clinicians to approach. On this subject, there was no agreement in the room, with some people believing that clinicians could be easily taught to understand UML while others did not believe that it was useful. It was felt that UML that was stripped of any complex notation and did not display cardinality or other attributes was useful for clinicians, however it remains to be seen whether or not this is useful for any other purpose. UML that is stripped down like this is not much different to a mind map approach.

The US Veterans Health Administration presented some work on clinical modelling and clinician engagement using their own 'DCM' approach although they found that in fact it was difficult to get clinicians to understand the models until they started to use mind maps. The project was focussed on a skin assessment.

Dr Hugh Leslie also gave a presentation of the Ocean Informatics approach to using *open*EHR archetypes and templates to produce CDA instances.

22.3 POTENTIAL FOR ARCHETYPES IN HL7 TO SUPPORT DCM

There have been calls from members of the openEHR community as well as members at HL7 who can see the benefit of Archetype methodologies for high level clinical model development to HL7, to look for a path to bring these together. DCM can align one–for–one with an archetype set, and indeed shortly after the DCM project got underway at HL7 it was intended to be done this way.

At the IT–014–06–06 WG, following from earlier Health Connect Discharge Referral work, we have recognized the value of Archetyped data as a solution to the limitation of representing clinical data in our HL7 Version 2 messages, and the consequent potential to communicate maximally rich clinical data on exiting deployed V2 infrastructure. We have two projects at IT–014–06–06 working to a published standard and it will be of value to Australian government deployments if this can be brought into the HL7 International framework.

David Rowed met with Ken Lunn who heads up the new Innovations Group, and Charlie McCay, Chair of the TSC, and argued that we bring Archetypes in HL7 together with the DCM activity as a combined effort in the Innovations Group. Both were supportive. This will be followed up with a formal email request for Charlie to take to TSC.

Recommendation:

Standards Australia should continue to monitor the developments within HL7 regarding clinical content development. As DCM is no longer on the path to ballot as standard at this time, a wait and see approach should be used with regards to this technology.

Recommendation:

Australia should support DCM work and Archetypes in HL7 as activities in the Innovations group at WG meetings, and limit Patient Care group resources being applied to DCM. Issues that arise in IT–014–06–06 Archetyped Data communications specifications and standards should also be worked on within that group. At present Patient Care is still scheduling Teleconferences on DCM.

23. EDUCATION

There is significant overlap and close collaboration between the activities of the Education Work Group and Marketing Council at HL7. Specifically, the University Project which involves the development and piloting of HL7 content for use in university curricula and the Ambassador Program are managed by the Marketing

Council, not the Education WG and are reported under the Marketing Council, despite having a strong educational content.

Education delivery activities within HL7 International comprise tutorials, the E–Learning Course, on–site training and the certification of HL7 experts. Educational Summits are held in the USA about three times per year, but these are essentially clusters of tutorials. Background activities in support of education delivery include ongoing curriculum development, development of a tutorials database, electronic outlets, collaborative education and strengthening capacity to deliver educational products.

23.1 TUTORIALS

HL7 offers a range of standardized training programs in the form of tutorials. The following tutorials were offered at the January 2010 WGM:

- HL7 Organization and Process – Introduction/Orientation for first time attendees (free)
- Introduction to Version 2 (two parts of 1/2 day each)
- HL7 Version 2.5/2.6 Control Specialist Certification Review
- Introduction to Version 3 (Part 1: Fundamentals and Part 2: Messaging)
- Version 3 Messaging Implementation (Part 1: Analysis and Specification and Part 2: Implementation Mechanics)
- Version 3 XML ITS and Data Types
- Version 3 Implementation for Project Managers
- Version 3 RIM Certification Exam Review
- Introduction to Clinical Document Architecture
- Clinical Document Architecture Advanced
- Continuity of Care Document (CCD)
- HL7 CDA Specialist Certification Review
- Version 3 Specification Development Tools: Using HL7s Version 3 Message Development Tools
- Introduction to Vocabulary
- Advanced Application of Vocabulary in HL7
- Domain Analysis Model (DAM)
- Services, Service – Awareness and HL7
- SAEAF Behavioural Framework
- Introduction to Electronic Health Record (Systems Functional Model)
- Electronic Health Record, Advanced – Conformance and Profiles
- Personal Health Record (Systems Functional Model), and
- Insight – Project Management Tool (free tutorial).

HL7 educational materials presented at WGMs that are copyrighted and solely owned by HL7 Inc. are made available Affiliates within two weeks of the close the meeting. Additional tutorials may be made available where the faculty instructor has assigned copyright or joint copyright of the tutorial material to HL7 Inc. to distribute to the Chairs of the Affiliates; or where the faculty instructor provides written permission for HL7 Inc. to distribute to Affiliates without assigning copyright.

The use of these HL7 educational materials is strictly limited to only Affiliate–sponsored educational sessions by agents of HL7 Inc. or its Affiliates.

HL7 Australia is currently designing an education and training program for use in Australia that will draw from such material.

23.2 E–LEARNING COURSE (ELC)

The HL7 e–Learning Course is a web–based workshop, a set of guided exercises that teaches by practice and example. It features HL7 Certified Teachers providing online assistance, reading material, bibliographic material, discussion forums, glossaries and self evaluation quizzes. Tutors evaluate student progress against each module.

The ELC comprises four modules – Introduction, HL7 version 2.x, HL7 version 3 and HL7 CDA r2. It is highly structured, with only specific pathways through the modules being offered, as depicted below. The whole course is provided over 14 weeks, with units released on a week by week basis.

In 2009 (with strong encouragement from Australia), the HL7 E–Learning program was broken into modules to provide four optional pathways (Figure 2)

Course Configuration		Module I Intro	Module V HL7 V2.x	Module T HL7 V3	Module C CDA R2
A	Whole Course	X	X	X	X
B	V2.x Only	X	X		
C	V3 Only	X		X	
D	V3/CDA Only	X		X	X

Figure 1 E–Learning Pathways

The content of each module is as follows. Prior experience in HL7 is not required to undertake the ELC.

- MODULE I – INTRODUCTION (THREE WEEKS)
  UNIT 1.1 INTRODUCTION TO HEALTHCARE INTEROPERABILITY
  UNIT 1.2 INTRODUCTION TO VOCABULARIES IN HEALTHCARE
  UNIT 1.3 INTRODUCTION TO UNIFIED MODELING LANGUAGE (UML)
  UNIT 1.4 INTRODUCTION TO EXTENSIBLE MARKUP LANGUAGE (XML)

- MODULE V – HL7 V2.x (FOUR WEEKS)
  UNIT 2.1 INTRODUCTION TO HL7 VERSION 2.X, DATA TYPES, ACK
  UNIT 2.2 HL7 V2.X: PATIENT ADMINISTRATION, ORDERS AND RESULTS
  UNIT 2.3 HL7 V2.X: Z–SEGMENTS / IMPLEMENTATION / PROFILES
  UNIT 2.4 HL7 V2X.XML: XML IMPLEMENTATION OF V2.X MESSAGING

- MODULE T – HL7 V3 (FOUR WEEKS)
  UNIT 3.1 INTRODUCTION TO HL7 V3
  UNIT 3.2 REFERENCE INFORMATION MODEL RIM / DERIVED MODELS
  UNIT 3.3 HL7 V3 DATA TYPES AND THEIR XML REPRESENTATION
  UNIT 3.4 HL7 V3: FROM THE MODEL TO THE MESSAGE

- MODULE C – HL7 CDA R2 (THREE WEEKS)
  UNIT 4.1 INTRODUCTION TO HL7 CDA R2
  UNIT 4.2 CDA R2 ARCHITECTURE: HEADER, BODY AND ENTRIES
  UNIT 4.3 CDA R2 IMPLEMENTATION GUIDES
  UNIT 4.4 CDA R2 ENTRIES: CLINICAL STATEMENT

The ELC was developed by HL7 Argentina with support from HL7 International. It is subject to strict copyright control. HL7 Australia has the rights to offer the course in Australia and will consider this, although there are currently no Australian certified tutors but Chris Lynton–Moll, Secretary of HL7 Australia has been trained as

a course administrator with the skills and tools needed to set up an Affiliate–based ELC program (Note – as an online course the lack of Australian tutors is not necessarily a blocker, but Australian tutors would be an advantage.) Discussions with HL7 New Zealand representatives during the Phoenix meeting canvassed the option of collaboration to develop local extensions to the course.

The ELC is subject to a prescribed charging regime applicable to all Affiliates with the fee structure being weighted towards encouraging uptake of the whole course. Delivery of the course requires significant supporting infrastructure including:

- A course administrator, tutors/tutors–in–training, and an e–learning platform expert (to make the platform available online).
- A senior tutor/course co–coordinator (required to be someone who has taught >4 courses and appointed by the Affiliate). Volunteer subject matter experts may act as co–tutors/tutors–in–training. Enough tutors are needed to staff each module based on 20 students per virtual classroom.
- IT infrastructure (LINUX platform).

Affiliates are required to notify HL7 when running a course, and to submit student grades and evaluation survey results. HL7 International issues the completion certificates.

The International Council and the Board of HL7 International have approved a scholarship scheme to encourage students from developing countries to participate.

23.3 OTHER HL7 EDUCATION ACTIVITIES:

- **On–site Training** – HL7 International and many Affiliates provide on–site training, generally through contracted agents.
- **Certification of HL7 Professionals** – HL7 also offers certification testing to professionals to demonstrate achievement of industry–recognized levels of proficiency and expertise.
- **Curriculum Development** – The education program to date has largely been organized in terms of provider–driven content – i.e. “supply driven”. However, Education Work Group is keen to move to a more modular approach directed by specific learning objectives for potential student cohorts.
- **Tutorials database** – The Work Group has commenced development of a tutorial database, to capture details of education provided by HL7 and allow systematic intelligence about these offerings to be compiled. Work is continuing on a volunteer basis, populating the database with baseline and historical information.
- **Electronic outlets** – The Work Group is investigating the provision of education and training through a variety of electronic mechanisms such as web and pod–casts.
- **Strengthening capacity** – A key issue (in Australia as well as internationally) is ensuring consistently high standards of education and training provision, including the provision of backup. A tutorial speaker policy is under development.

Another potential educational initiative under discussion is a series of linked books that cover the HL7 environment, which was presented to the HL7 International board meeting but the board referred the matter back for further work on both the policy implications and the business case.

The need was also expressed for stronger leadership within the Education Work Group, specifically in relation to international experience and linkages.

Working Group web site:

www.hl7.org/Special/committees/education/index.cfm

Action: HL7 Australia will be assessing HL7 training needs in collaboration with NEHTA and developing and implementing curricula over the course of 2010.

Action Owner: HL7 Australia and NEHTA

24. ELECTRONIC HEALTH RECORDS (EHR WG)

The cornerstone activities of the EHR WG is progressing the EHR Systems Functional Model (EHR–S FM) and the functional profiles that are derived from it. It also has responsibility for the Personal Health Record Systems Functional Model (PHR–S FM) and associated profiles. These models have particular importance in the USA, where they have provided a basis for systems certification programs that provide users or certified systems with access to Government e–health incentives.

Another line of work has been progressed by a subgroup focussing on what they have defined as "EHR Interoperability" – focussing on the elements required for there to be a train of trust when information is captured in an EHR system and is then communicated and used at various downstream points in the health care process. HL7 took a policy decision to reflect the core requirements of the so–called "interoperability model" in the next generation of the EHR–S FM; however, the chief proponent of this earlier work, Gary Dickenson, has controversially repackaged much of the same material as an ISO new work item on "Standards Convergence to promote EHR Interoperability" (discussed further below).

There were Co–Chair ballots at this WGM with Pat Van Dyke of Delta Healthcare Plans being re–elected and a former Co–Chair, Gary Dickenson, also being elected as a write–in candidate. Some of the other matters considered at meetings of the EHR WG included:

- A well–attended presentation by Heather Grain on the e–health Glossary and Standards Registry – communicating the essentials of this project and the need for engagement to a broad audience including key representatives of EHR WG, PC WG.
- Progress in development of functional profiles and a DAM to support the of the Vital Records function. While the initial goal was unifying various approaches across some 50 US jurisdictions, the project has sought comparative international input from the start, with Victorian Department of Health providing early input. It seems that a truly international VR profile is going to be hard to achieve and that US–CDC are going to have to develop a local US version first – accommodating international requirements wherever possible.
- Presentation by Security WG and discussion of need to adopt ontology–based security architecture.
- Progression of the Ambulatory Oncology functional profile at the US–NCI (Helen Stevens is working on the project) and its progression as part of a SAEAF Alpha project. The EHR–S FM requirements stack is proving to be a significant benefit.
- Discussion of patient safety issues and the need for balance in demands and adoption of risk–managed rather than fault–free approaches if the considerable benefits of e–health are not to be severely inhibited.
- A project being led by the Public Health Data Standards Consortium (PHDSC) ad–hoc Task Force formed to progress a roadmap for health information systems interoperability for public health covering areas such as:
  - Communicable diseases
  - Immunisations
  - Biosurveillance, and
  - Environmental health monitoring part of Public Health function.
- It was found, that to be useful in public health, there was a need for extensions to the EHR–S FM, with the intention of developing a public health functional profile or possibly there was a need for an independent public health FM. The final outcome of this project is intended to be presented at RIO in May. For more information:

  www.phdsc.org/health_info/ehr–task–force.asp
- Tooling for managing versions of the EHR–S FM and functional profile – both during standards/profile development and in implementation. Two different tools were demonstrated.

24.1 EHR SYSTEMS FUNCTIONAL MODEL (EHR–S FM)

The harmonised Release 1.1 (R1.1) of the EHR System Functional Model (EHR–S FM) has now been adopted as ISO standard 10781 with the HL7 EHR Working Group now working on R2, with a view to balloting later this year. The bulk of the update process involves considering each of the 187 functional areas in the EHR–S FM Release 1 and reconciling additions, deletions and changes in light of the following inputs:

- Changes already applied to produce R1.1
- All comments received in producing R1.1 but deferred for later consideration (including international comments from the ISO 10781 DIS and FDIS ballots)
- EHR–S FM R2 – Parking lot for proposed changes and issues
- EHR WG deliberations from August 2009 onwards
- RM–ES(Record Management and Evidentiary Support) FP – content and use
- LTC (Long Term Care) FP – content and use
- BH (Behavioural Health) FP – content and use
- CH (Child Health) FP – content and use
- EDIS (Emergency Department Information System) FP – content and use
- Proposed VR (Vital Reporting) FP
- Other EHR FPs – development issues, content and use
- CCHIT Inpatient FP – content, use (including certification experience)
- HITSP interoperability specifications – including public health applications
- HL7 Interoperability Model – incorporate and consolidate all relevant content
- HL7 Lifecycle Model [for Health Records] – incorporate/consolidate all relevant content
- PHR–S Functional Model and profiles
- ISO/TS 18308 Requirements for an EHR Architecture
- Support for new industry requirements – SOA, security, privacy, clinical quality, genomics, fraud management, certification etc
- US–NIH/NCI Ambulatory Oncology caEHR pilot of SAEAF using EHR–S FM, and
- Institutional Memory.

To fast–track the work, AHIMA has hired staff to work through the existing functional profiles on the NIST website and enter them into comparative tables for review by EHR WG members working on R2. This work is a SAEAF Alpha project and provides an essential viewpoint that is orthogonal to the information–centric work carried out by most other WGs.

In addition, a new ambulatory oncology FM has been developed, as well as a Vital records/Cause of Death Functional Profile, and a Standalone e–prescribing Model. An HL7 Diabetes Use Case is also being developed.

Emergent areas on the EHR WG's outlook include the medical home and personalised medicine.

The EHR WG also spent several sessions in break–out groups to work on reconciliation of inputs for development of EHR–S FM R2, which continues by teleconference every week.

Originally the EHR–S FM R2 work was aiming for completion by late March on the assumption that Canada required the standard for its certification program this year. At this meeting, it was confirmed (through Ron

Parker) that Canada would base its requirements on the existing R1.1 document – allowing more orderly completion of R2.

24.2 PROPOSED ISO "STANDARDS CONVERGENCE" PROJECT

From the HL7 EHR Interoperability Group, a New Work Item Proposal (NWIP) on "Standards Convergence to promote EHR Interoperability" was submitted to the ISO/CEN/etc Joint Initiative Council in October 2009. The aim is to produce an ISO Technical Specification. The NWIP is currently being balloted for inclusion on the ISO work program, with the ballot closing in early April 2010.

This project aims to converge/simplify a range of standards with implications for end–to–end EHR record interoperability into a single profile. Implicated standards include:

- ISO/Technical Report 21089:2004 Health informatics – Trusted end–to–end information flows
- HL7 Electronic Health Record (EHR) Interoperability Model DSTU (EHR–IM)
- HL7 EHR Lifecycle Model DSTU
- ISO 10781:2009 Health Informatics – Electronic Health Record System Functional Model
- HL7 Records Management and Evidentiary Support Functional Profile DSTU
- HL7 CDA Release 2
- HL7 Implementation Guide for CDA Release 2 – Reference Profile for EHR Interoperability DSTU, and
- The ISO 13606 series on EHR communication.

Australia has been closely involved with the development on many of these standards. The project builds on and aims to meet substantial use case development undertaken under the auspices of the U.S. Health Information Standards Panel (HITSP).

Comment:

This is potentially a "big thinking" piece of work but as with all such proposals will need an extremely clear project scope and roadmap if it is to enhance rather than obfuscate the standards landscape. Australia needs to consider and articulate its response to the NWIP very carefully.

24.3 QUALITY REPORTING USING EHRS

Quality Reporting (using EHRs) is a US–centric project proposal based on the US EHR Incentive Program requirements for quality and performance measurement and reporting. The project is in the very early stages, with detailed planning currently underway.

Comment:

While it is US–centric, it would be worth maintaining a close watching brief given current Australian initiatives on performance measurement and in particular national reporting on safety and quality – as indicated in "Towards national indicators of safety and quality in health care" emerging from the ACSQHC/AIHW and the ACSQHC's draft National Safety and Quality Standards.

The garnering of secondary data from clinical/operational workflows is one of the "holy grails" of informatics and a significant potential benefit realization objective from investment in iEHRs.

25. HEALTH DEVICES

The WGM hosted a joint meeting of the ISO/TC215 Work Group 7 (Health Devices), and the HL7 Health Devices Committee and the IEEE 11073 Health Devices Committee. The latter group specifies much of the low level device software behaviour characteristics. Representatives of IEC/62A/JWG7 were also present.

Current Co–Chairs of the joint ISO/HL7 working group are Todd Cooper and Melvin Reynolds with the Secretariat supplied by Patty Krantz of Medtronic (patty.krantz@medtronic.com)

It was noted during the introduction by the Co–Chairs that whilst major Australian companies Resmed and Cochlear were active in the international device manufacturing industry they were not represented on any of

the three international health devices groups at this meeting. In particular, there is considerable preliminary work being undertaken in ventilator control which Resmed would be very welcome to participate in.

25.1 DEVICE COMMUNICATION STANDARDS – IEEE/ISO 11073

The following device ballots are currently active at IEEE:

- P11073–10103 – implantable cardiac device (UL) (Nomenclature) – invitation stage
- P11073–10418 – INR (PHD) analyser – invitation stage
- P11073–10419 – Insulin Pump (PHD) – initial ballot
- P11073–10420 – Body Composition Analyser (PHD) – comment resolution, and
- P11073–10421 – Peak expiratory flow meter (PHD) – comment resolution.

The first batch of 7 ISO/IEEE 11073 personal health device documents have at last been issued for FDIS ballot in ISO and these will be available for vote by Australia shortly through Standards Australia.

The USA Conformance and compliance initiative embodied in HITSP has significant Health Device requirements which have been recently specified in the document "HITSP Device Connectivity Technical Note – TN905" available from:

www.hitsp.org/Handlers/HitspFileServer.aspx?FileGuid=bc0c6307–7ef2–4983–bac7–954cc6ba80c9

This document incorporates a Device Roadmap for the next 3 years and a gap analysis with existing standards and capabilities:

Interoperability Category	2010	2011	2012	2013	Comments
Device Semantic Content	• Data set for initial set of devices (physiological monitor, infusion pump) • Device configuration information	• Data set for ventilator • CDA Template for Rich Device Data • Alarm & Events (generic & infusion pumps)	• Dialysis devices • POCT devices (glucose monitor, blood gas analyzers) • Hemodynamic monitors	• Heart lung bypass machines • Anesthesia monitors	These data components include standardized terminologies and models that preserve the richness and safety envelope of the acquired data (incl. co-constraints between parameters and allowable units of measurement, value ranges and body sites)
Device Enterprise Data Reporting	• Basic reporting to EHRS • Operational settings, monitored parameters	• Wave snippets with annotations (non-real-time) • Device workflow events • Quality of Data (parameter metadata) • Automated device-patient association	• Device discovery & reporting configuration (e.g., filters) • CDSS Data Acquisition Support • Real-time Location Tracking (RTLS)	• Clinical Decision Support System Data Acquisition	"Workflow events" identify non-alarm conditions that should be recorded and may affect workflow automation (e.g., infusion pump switchover from piggyback to primary infusate) RTLS – See 5.3.2.2
POCT Device Reporting			• POCT device communication		This interaction is fundamentally different from that provided for by the Device Enterprise Data Reporting capability
Alarm Communication & Management		• Alarm reporting (incl. evidentiary data) • Evidentiary data support (incl. wave snippets w/annotations)	• Alarm Status Handling • Multi-device "smart" alarm semantics • Alarm history	• Remote alarm limit adjustments • Remote alarm silencing	This function was deferred to 2011 due to a standards gap in the Alarm Manager to Alarm Communicator interface
Closed Loop Medication Administration		• BCMA to Infusion Pump System Programming • Medication delivery status monitoring and alerting	• Infusion Pump Event Communication	• External pump control (limited)	Pump control is limited to pause or limit setting and must be balanced with safety risks and security considerations
Device Point-of-Care Integration		• Discovery & Association • Data Reporting	• Symmetric "bi-directional" communication • External Control (basic) • Safety interlock (basic)	• "Hot swapping" support • Point-of-Care Real-time CDSS Support	This set of capabilities address the "standards-based first communication link" requirement, sometimes called "plug and play" connectivity
Comprehensive Data Archiving			• Service API • Persistent data interchange format	• Services for filtering and summarization	See requirements in section 5.3.5.

Gap	Interface[33]	Description	Coordination	Comments
Mapping from ISO/IEEE 11073 Semantics & HL7 V3 Constructs	SDI #1 – 4 SDI #6	Abstract device semantics are specified using ISO/IEEE 11073 standards; to represent this information in an HL7 CDA document, a normative mapping must be made between ISO/IEEE 11073 constructs and HL7 version 3 Reference Information Model (RIM) elements, and ultimately to CDA templates and other version 3 applications	• IHE PCD • HL7 • ISO/IEEE 11073	• There are currently no active projects addressing this gap
Normative Mapping from ISO/IEEE 11073 Semantics and SNOMED-CT	SDI #1 – 4 SDI #6	Abstract device semantics are specified using ISO/IEEE 11073 standards. When then information is used by some applications, such as in a CDA document, there is a requirement that SNOMED CT terminology be used. This is an issue both with personal health devices, such as those within the scope of the HITSP/IS77 Remote Monitoring, as well as those identified in the CDC Extension/Gap document	• IEEE 11073 • IHT SDO	• A Memorandum of Understanding has been announced between IHT SDO and IEEE to work toward the harmonization and mapping identified by this gap
Mapping from ICE interoperability use cases[34] to Capabilities and Constructs	SDI #4 SDI #7	Multi-organizational gap analysis to indicate where existing standards (ISO/IEEE 11073 and HL7) can be strengthened	• MD PnP Interoperability Program • IHE PCD (incl. ICE-PAC JWG) • SDOs • FDA	• The ICE-PAC Joint Working Group has met weekly since October 2008 to define and apply a process that analyzes ICE use case scenarios down to the detailed interoperability specification requirements level, identifying any "gaps" that need to be addressed, either in base or composite standards
Device Identification and Association Management	All interfaces	The unique identification of devices along with managing their association with patients, clinicians and various systems is crucial for any device data management system. Though there are various standards and regulatory projects underway in this general area, they are mostly not coordinated and there are gaps in the capabilities being developed	• FDA • SDOs • IHE PCD	• Includes Barcode & RFID • Mechanisms for associating and disassociating • FDA's UDI guidance[35] • Supply chain management standardization
Real-time Location Tracking Systems (RTLS) Interface to Enterprise Applications	SDI #1 – 4	Some work has been done in standardizing RTLS integration into the enterprise (e.g., within HL7 version 3); however, there are significant functional gaps that are needed to support, for example, medical alarm processing and equipment management functions	• SDOs • IHE PCD • RTLS System Vendors	• Needed for patient and device location tracking • Also RFID organizations

This document will largely be the focus of activities driven from the USA over the next three years.

One common theme during these meetings was the need for a universal identification scheme for all medical devices to enable robust auditing requirements to be met. This would usefully be combined with a GPS location system so the position of every device could be tracked. This was seen as particularly important for mobile and implanted devices as often location was an important audit requirement.

To meet that need, GS1 (the group that do barcodes for everything from groceries to patients) has proposed a Universal Device Identification (UDI) to be included in the GS1 international catalogue and was actively promoting its benefits at this meeting. No information however was available concerning potential costs. While all agreed that such identification was required, the various Standards bodies needed to do further work in this area.

The three committees are cooperating with the Industry Continua Alliance (a non–profit alliance of more than 1900 companies world– wide) which is defining conformance criteria in conjunction with IHE International for Health Devices.

The IHE Connectathon (Chicago, January 2010) had a large section devoted to conformance testing of IHE and Continua profiles built on the Standards from these groups. The Continua Alliance has selected the IHE XDR profile for secure point–to–point messaging between devices and management stations and HL7 version 2.5 for message content.

Recent research in the USA has shown that use of smart home monitoring devices is associated with a 35–50% decrease in mortality in US Veterans Administration patients with a 19.7% decrease in hospital admissions and 25.3% reduction in bed–days of care (4000 patients followed over 3 years).

The Phase one devices from Continua fall into three categories:

- health and wellness – worried well vital sign monitoring – intelligent weight scale, blood pressure measurement, pedometer
- disease management – oximeter, glucometer, weight t scale => disease management services, health care provider, and
- aging independently – basic life monitoring – bed pressure, bathroom sensor, gas/water sensor, emergency sensor.

Continua companies have now marketed 11 devices with a further 50 to be released before the end of 2010

The current principal area of detail work at this meeting was further definition of the wireless standards and security (Secure Bluetooth, ZIGBEE) to be used in the next generation of Health Devices. This work is to be completed by the middle of this year and will involve two further joint meetings in Germany in February and

the USA in April. It has been divided in to upper and lower protocols and the work assigned to HL7 and break–out technical IEEE sub–committees.

Action:

Standards Australia (with support from IT–014) approach the Australian medical device industry (e.g. ResMed and Cochlear) to assess their interest/capacity in providing input to international standards work in the health devices area.

25.2 IEC/ISO STANDARD 80001–1: APPLICATION OF RISK MANAGEMENT FOR IT–NETWORKS INCORPORATING MEDICAL DEVICES"

80001–1 was recently balloted as a joint IEC/CDV and ISO Draft International Standard (ISO/DIS) with Australia being one of two countries (the other being Holland) to vote negatively on this at ISO with an additional two countries (Germany and Canada) voting negative at IEC (where Australia is apparently not represented on the relevant committee). The basis of the Australian negative vote was the inconsistency between this proposed draft standard and other relevant ISO standards on Risk Management (ISO 13000:2009, ISO/IEC 31010:2009 and ISO Guide 73).

Richard Dixon Hughes presented the Australian viewpoint on behalf of Standards Australia, supported by Stephen Chu of NEHTA. The joint meeting noted that:

- 80001–1 builds directly on the medical device risk management regimes in ISO 14971:2007 (which was acknowledged in the Australian comments).
- The harmonised approach to risk management set out in ISO Guide 73, ISO 13000 etc is intended to "cover the field" of risk management but has only recently been finalised.
- The Australian comments raise major issues that may require ISO 14971:2007 to be revised. This will affect medical device certification schemes – particularly in the EU – and will take some time to resolve.
- The first step is to get more definitive communication and input from the relevant experts in the ISO risk management community.

The meeting was receptive to the Australian arguments and undertook to find out from the ISO Board how Guide 73 should be applied as it was clearly at variance with 80001–1. Further work to resolve the Australian comments will need to be undertaken but it was hoped that these standards could be successfully harmonized over time.

26. IHE

Andy Bond, Stephen Chu, and Vince McCauley met with Charles Parisot (IHE Technical Co–Chair) to discuss the status of the IHE Pharmacy profile and how Australia might become engaged in that endeavour.

The IHE joint meeting did not occur this cycle because of the joint ISO/IEEE Health Devices meeting and the ISO/IEC Joint Working group meeting.

27. IMPLEMENTATION TECHNOLOGY SPECIFICATIONS (ITS)

The ITS WG had somewhat lost its way in the past few meetings, torn between pressures from outside users concerning the direction HL7 had chosen to go, and considerable inertia in that direction. But at this meeting, the interest in exploring alternative approaches met with real energy to develop and test specifications, along with approval for doing so from the committee. A useful summary comment may be found here:

http://motorcycleguy.blogspot.com/2010/01/implementation–technology.html.

The ITS R2 ballot was not reconciled at the meeting. It appears that it will need to be reballoted.

28. INFRASTRUCTURE AND MESSAGING (INM)

The Infrastructure and Messaging WG met only briefly at the January 2010 WGM. Much of the long term work of this committee is in abeyance while ArB deliberations regarding SAEAF and other related

specifications are proceeding. INM has a few v2.8 proposals on the table, but these are not being pursued with any great energy while v2.7 is held up (Frank Oemig of HL7 Germany has raised a formal challenge to the technical integrity of HL7v2.6 in relation to many of the changes in v2.6 and v2.7, including some sought and obtained by Australian interests).

Grahame Grieve noted that Canada is now interested in pushing further v2 messaging wrapper work, and it appears that they are finally allocating resources to this work.

29. MARKETING GROUP AND MARKETING COUNCIL

The three key marketing targets for HL7 are:

- traditional stakeholders/members
- grants and other funding by non–governmental organizations (NGOs), such as private foundations, and
- the so–called "profiler–enforcer community, which comprises the governmental agencies responsible for healthcare in the countries and regions in which HL7 products are incorporated into healthcare IT.

There are also three primary areas of opportunity for HL7 products:

- Firstly, HL7 has begun to develop implementation tools (guides) for its standards products, and this may open a new market for the organization. It also presents an opportunity to move into the other areas beyond messaging and documents.
- Secondly, the renewed emphasis around the world on healthcare and improving healthcare outcomes presents an opportunity to HL7. As more money pours into system development in this area, HL7 has an opportunity to have its products represented in the new systems. HL7 has begun developing profiles for the EHR–S and personal health record system (PHR–S) Functional Models.
- Finally, the change of administration in the USA will bring a new approach to healthcare that will create opportunities both for HL7 products and for increased funding. The impacts of this are likely to ripple into international markets.

HL7 marketing seeks to address the following relevant issues across all of its major markets, including Australia:

- **Key messages**. HL7 must develop clear and concise messages, and not be: 1) vague, in an attempt to please everyone; or 2) over–ridden with technical jargon.
- **Reducing complexity**. HL7's stock–in–trade is technical standards. However, the implementation case is complex.
- **Targeting strategic stakeholder audiences**. While HL7's benefits may be known at technical levels, the pathways for extending HL7's key messages to level strategic HIT decisions are approved and funded is less clear. The value proposition at the strategic level is not clear – HL7 may be necessary to realization of value, but it is not sufficient.

HL7 International has developed a comprehensive marketing strategy. Elements relevant to Australia, especially in light of ensuring the success of the 2011 Sydney WGM, include:

- HL7 branding has already begun to implement a new tag line, namely "Unlocking the Power of Health Information"
- a visible presence at health and health informatics events
- the Product and Services Guide – so potential customers can find products and services needed to implement HL7 effectively
- the Ambassador Program (see below), and
- The Universities Program (see below).

29.1 AMBASSADOR PROGRAM

The Ambassador Program provides standardized short conference/executive presentations that promote awareness of key HL7 products. The program authorises and trains qualified speakers to present on behalf of HL7. Potential speakers must personally participate in an HL7 Work Group or Affiliate. They must apply to the program, and have their participation renewed on an annual basis. Access to the standard presentations and other Ambassador Session materials is restricted to persons participating in the Ambassador Program.

The key concept in the Ambassador Program is having a uniform approach. Ambassador sessions are short (30 minutes) for delivery to audiences who need to know what HL7 has to contribute in specific domains. Ambassador programs currently include the following (noting current/potential Australian involvement):

- EHR System Functional Model
- PHR System Functional Model
- Introduction to CDA/CCD (Klaus Veil trained)
- Introduction to HL7 V3
- SOA (Vince McCauley in training)
- Clinical Genomics
- HL7 Standards for Pharmacies, and
- Introduction to HL7 and HL7 Benefits (Klaus Veil trained).

An ambassador session for HL7 V2 is currently under development, with Max Walker (Department of Health, Victoria) contributing to the content development and being trained as one of the initial ambassadors to present this topic.

The Marketing Council sought new topics for the Ambassador program, which resulted with potentially 17 extra topics (in addition to HL7v2, which is already well advanced) of which the following were given priority:

- HL7 and Healthcare Devices
- HL7 for Quality Reporting
- HL7 for Meaningful Use
- HL7 Public Health and Emergency Response
- HL7 for Bio surveillance
- HL7 Public Health
- HL7 RIMBAA
- HL7 for Conformance and Certification, and
- HL7 for Clinicians (targeting CIC).

Others under consideration include:

- HL7 SAEAF (demand is high but SAEAF and its implications needs to stabilise)
- HL7 V2/V3 Migration
- HL7 Structured Product Label for drugs (and possibility devices)
- HL7 Annotated EKG or other RCRIM
- HL7 Clinical Decision Support
- HL7 for various clinical domains:– Emergency Care; Anesthesia; Anatomic Pathology; Pharmacy

- HL7 International Cooperation (to be incorporated into existing "HL7 101" session), and
- HL7 Patient Safety.

Future topics that may be of particular interest to Australia include Healthcare Devices; SAEAF; patient safety; pharmacy; standards for clinicians; public health and emergency response; quality reporting; migration; and national conformance programs.

Action:

HL7 Australia will be establishing an Ambassador program during 2010 (Vince McCauley is leading this initiative).

More Senior HL7 Australia members to consider becoming Ambassadors for HL7 International.

Action Owner: HL7 Australia

29.2 UNIVERSITY PROJECT

A University Program – focusing initially on the case for interoperability – is being developed for a consortium of universities. Topics include the case for interoperability, the standards environment, adoption and deployment challenges, etc. It is a post–graduate program.

The aim is to increase the number of universities teaching about HL7 standards as part of postgraduate programs globally. A secondary aim is to increase HL7's membership base.

The initial set of course material has been created and more is under development. Five US universities have commenced piloting the program.

The availability of this program should be of interest to the Australian Health Informatics Education Committee. More information on the University Project is on HL7 Listserv under: "university"

Action:

Advise Australasian Health Informatics Education Committee and through them the Australian Health Informatics Education Council of the University Project.

Action Owner: HL7 Australia

30. MODELLING AND METHODOLOGY (MNM)

At this time, MnM primarily functions as a clearing house for cross –committee design issues; there is no significant work on changing the v3 methodology in any fundamental way. Highlights of this meeting:

- Full adoption of datatypes R2 is still held up by ballot issues with regard to ITS r2.
- MnM finally has a working proposal that makes sense of context conduction, and that we believe is workable for both content specifiers, and for implementers of production systems. However the changes are not strictly backwards compatible and MnM must review how such a large change could be introduced.
- The moodCode attribute continues to be controversial. For a start, the definitions of the codes are appalling. MnM passed a proposal to rework the mood code definitions to have much greater clarity. In addition, MnM will work with RIMBAA to publish a white paper describing how mood codes should be understood and used.

31. PATIENT ADMINISTRATION (PA)

The PA Working Group met all week. The main topics were:

- V3 Registries enhancements for social services
- V3 Encounter / scheduling
- V3 CMET needs of Clinical Statement and Patient Safety, and

- V2.8.

A Joint Meeting with the SOA WG to discuss the development of an HSSP registries service. This is just starting with a scope statement but is likely to include a generic as well as specific service instance to support a variety of registry needs. The Registry Service Specification will include both generic registry service as well as a specific instance such as patient registry. This could also form the basis for HPSDS (see SOA).

The "hot issue" was the proposal by Frank Oemig (HL7 Germany) to withdraw or amend V2.6.

Working Group web site:

www.HL7.org/Special/committees/pafm/index.cfm

32. PATIENT CARE

Patient Care WG has a strong membership of IT–competent clinicians including those from nursing, allied and community health. The Patient Care WG have been the focal point for several recent Australian e–health standards development activities, notably:

- PC WG is where HL7 clinical communication standards work from Australia has been brought. This work has been in Referral, Discharge Summaries, Mental Health, Community and Collaborative Care.
- PC, together with its previously sponsored Community Based Health WG, has responsibility for the ongoing maintenance and further development of the HL7 Version 2 Referral and Discharge standards. These form the basis of Standards Australia AS4700.6 specifications.
- The PC WG recognises that it does not have sufficient expertise to maintain and develop these version 2 standards and therefore has assigned this to its Australian members.

Some other key characteristics of the PC WG and its activities at the January 2010 WGM include:

- PC WG mainly works on Version 3 message specifications and has published DSTUs and informative preliminary specifications in the current, as well as previous, HL7 Version 3 ballots.
- The WG does models and specifications for clinical referrals through the *Patient Care Provision* set of Version 3 messages. This is a very large section of the V3 ballot and is frequently updated to accommodate new clinical information requirements.
- PC WG (along with SD WG and OO WG) was a major initial driver of the Clinical Statement Pattern Project and now maintains a message–focussed version of this: The *Care Statement*.
- PC has also been the focal point within HL7 for development of the Detailed Clinical Model project in parallel with the DCM work at ISO under the same lead (Dr William Goossen)

The modelling of clinical concepts at PC has high generic value beyond its implementation in the HL7 V3 RIM environment. Precise modelling aids all manner of communication of concepts including: Referral, Collaborative Care within Patient Care Provision, as well as core concepts such as Problem, Diagnosis, Condition, Concern over Time Care Plan, and Assessment Scales, as well as their supporting dynamic models of care interactions.

PC WG had only one of its three Co–Chairs present at this WGM which limited the amount of business that could be formally discussed and managed and indeed for two of the WGM sessions there was no Co–Chair available so the group then met informally and worked on the Care Plan project, although no voting could take place.

Much of the PC WG time at this WGM was taken up again with discussion about Detailed Clinical Model (DCM) issues and in particular, the questions asked by the Technical Steering Committee. This issue is discussed separately under the heading of Detailed Clinical Models in section 22 above.

Hugh Leslie gave a presentation of the Ocean Informatics approach to using *open*EHR archetypes and templates to produce CDA instances. This approach uses a constant set of archetypes and then creates a template for a particular use case. The Template is then used to create a standard XML schema which can be used to map to some external data such as a V2 message or an application schema. Once a data instance is produced that conforms to the schema, the data can be transformed into a message instance

such as CDA. The interesting thing about this approach is that the transforms are archetype based and therefore can be reused and only need to be built once. The RIM structures produced from the code are therefore always the same, and the process is completely reversible. This approach is being used in real systems around the world.

Some of the other matters discussed in the PC WG included:

- Joint session with EHR TC

  A joint session hosted by the EHR WG (see section 24 above) which looked at the EHR–S Functional Model from a public health perspective; progress with a project to model functional and informational requirements in the diabetes domain; and a well–attended presentation by Heather Grain on the e–health Glossary and Standards Registry.

- Diabetes Data Strategy Project – Diabe–DS

  This project has many sponsors across HL7 including EHR, CIC and PC WG. It aims to look at a common set of data elements that overlap from EHR and secondary uses so that this data can be exchanged for re–use in different settings.

  The process involves looking at sets of data elements and then creating a harmonised set in the overlap between various primary and secondary uses. Once a set of data elements is devised, it is expected that HL7 CDA templates will be built to match data elements.

- It was mentioned that there is a need for heuristics to group data and DCMs were mentioned as a possible solution.

Comment:

The approach within HL7 of trying to harmonise large sets of data elements, seems to be a common approach including the production of Domain Analysis Models for various things (DAMs).

Experience suggests that this approach is unlikely to produce useful models as different elements usually have slightly different meanings in different contexts. The approach of grouping elements together into higher level structures i.e. *open*EHR archetypes or DCMs is much more likely to produce useful models as the higher level structure gives meaning and context to an individual element.

32.1 PATIENT CARE GLOSSARY PROJECT

The clinical concepts which PC WG models, and for which it develops communication specifications, are in many cases not properly defined, and by implication, not necessarily agreed. This has caused significant difficulties in the group at past meetings and delays progress as well as potentially raising questions as to the validity of the process. The HL7 Glossaries are deficient in the Patient Care areas.

At the meeting Heather Grain presented the e–health Glossary and Standards Registry project and PC WG agreed to join this to ensure robust definitions are agreed upon prior to future modelling and message development. It was agreed to do this work as a Patient Care Glossary project which will address key concepts inpatient care. David Rowed is to develop the project scope statement for this work.

32.2 SERVICE SPECIFICATION FOR DYNAMIC MANAGEMENT OF PRIMARY CARE PROCESSES

In September 2009, Dr David Rowed (Australia) and Australian delegates from IT–014–06–06 had secured SOA WG support for a proposal for a new specification of a Primary Care Management Service. This work item will require significant resources and it appears may be able to leverage previous work done by HITSP and interest from the US Department of Defence, US Veterans Affairs and the UK Primary Care group.

It was initially approved as a PC WG project as this is where the use case came from (the Commonwealth–funded GP Computer System Functional Specifications project).

This type of platform and deployment is seen by its proponents as key to high quality interoperability, modularity, and scalability as well as specialised Clinical Decision Support and care management services in the next generation of clinical systems.

Approval is subject a number of conditions, including that a WG be the owner and main sponsor of the project. Discussions have been taking place with Patient Care over its ownership of the project, and at this meeting PC voted to formally take it on as sponsor.

David Rowed is co–coordinating the development of the project through the PC WG and is to lead development of the project scope for Patient Care WG to take to the TSC. Vendor collaborators and key government and professional stakeholders have been identified in Australia as well as internationally.

Action:

The service specification for dynamic management of primary care processes project needs to be reviewed by IT–014 and shared with potential supporters with a view to resource commitment and agreement on a way forward.

Action Owner: IT–014, specifically IT–014–06.

32.3 ARCHETYPES IN HL7

Australia has proposed that work on this be coupled with DCM and work via the new Innovations group. See report on DCM in section 22 above.

32.4 CARE PLAN PROJECT

The Care Plan project is of importance to Australia where the HIC is funding such processes as part of Primary Care initiatives covering GP and Mental Health services which integrate with Allied Health and secondary provision.

As this communication forms part of the required payloads of Referral communications, and the project is being done jointly with Structured Documents, IT–014–06–06 should to be part of this work hopefully within the scope of its joint projects with NEHTA.

Both IHE and HL7 (Patient Care Work Group) have interests and worked on "care plans". IHE has produced a "Patient Plan of Care" trial implementation supplement as one of the "Patient Care Coordination" Technical Framework Supplement. It has a heavy nursing focus.

The Patient Care Work Group has expressed the intention to develop multi–disciplinary "care plan" to support disease management. Earlier work by HL7 Patient Care Work Group on "care plan" resulted in a "care plan" informative R–MIM being developed in 2006. The Work Group intends to re–initiate the care plan work with the aim to progress the care plan R–MIM to DSTU status. It dedicated two quarters of time during the Phoenix meeting to discuss how to move the "care plan" work forward.

It was proposed that a project proposal be developed to fully define the project scope and that the project should be SAEAF compliant. It was agreed that the project should seek to validate existing care delivery approaches and processes in multiple clinical domains to ensure that the care plan structure and contents are generically applicable across all domains. The project work should reference information from the following groups:

- CarePlans.com
- European Pathway Association, and
- CEN ContSys standards.

and should ensure conformance/adequate coverage of HITSP C162 and C83 requirements. The IHE Patient Plan of Care workflow profile should also be evaluated.

The Australian delegates recommended that the storyboards and use cases should cover the following categories:

- Acute care requirement transfer of care
- Chronic disease management, and
- Antenatal and perinatal care.

These storyboards/use cases will ensure that care plans are used in care coordination across multiple care settings and domains.

This will be done jointly with Structured Documents WG and teleconferences will begin in March.

33. PHARMACY

The Pharmacy WG met from Monday through to Thursday. More information on the WG's activities are available from its website:

Working Group web site:

www.HL7.org/Special/committees/medication/index.cfm

33.1 HL7V3 PHARMACY – BALLOT RECONCILIATION

Three full quarter–day sessions were dedicated to reconciliation of ballot comments on HL7v3 Pharmacy Domain specifications in relation to:

- Medication dispense and supply topic (which covers issuing of medication to a patient or representative, as well as bulk supplies of medication).
- Medication statement topic (which deals with recording of statements about medications a patient has received or receiving other than a prescribed medications, e.g. OTC medications; or as patient statements about medication history).

These topics will be balloted again in the May 2010 ballot cycle. It is useful that Australia review these topics against its requirements and provide ballot comments or inputs where appropriate.

33.2 CROSS–DOMAIN HARMONIZATION OF PHARMACY MODEL ARTEFACTS

Pharmacy WG produced a number of constrained models/artefacts for prescription order, dispensing/supply, administrations of medications. Other WGs also produce or use constrained models that are related to medication/pharmacy. An inventory exercise on other WGs which may/have incorporated pharmacy CMETs identified about 12 items.

Detail analysis on the "immunization" model identified a number of differences between this model and the medication order and administration models. It was agreed that there existed strong need to establish processes to harmonize related models from other WGs (especially Structured Document/CDA) and the pharmacy models. Joint sessions with OO, Structured Document, Patient Care, etc should be initiated to discuss harmonization issues with the aim to foster consistency across domains. This is considered especially important as CDA R3 will likely to include modified version of the full RIM (Right Handside) which will result in proliferations of templates to meet different domain requirements.

Australia (NEHTA) presented a number of prescription/medication order modelling/mapping issues to the WG for discussion. These issues arise from the need to model administration and regulatory requirements (such as pertinence to regulation 24, number of repeats, brand substitutes, etc) in V3 pharmacy and/or CDA. All except one can be mapped to the "PolicyAct" class of the "Medication Order" R–MIM. It was determined that there is no satisfactory equivalent for mapping the "minimal interval between repeats" requirement in V3. Pharmacy WG will submit this use case to MnM for RIM review. A short term solution is to model this requirement has an "observation act". The WG requested Australia (NEHTA) to present the modelling outcome for further discussion and inclusion in its suite of artefacts.

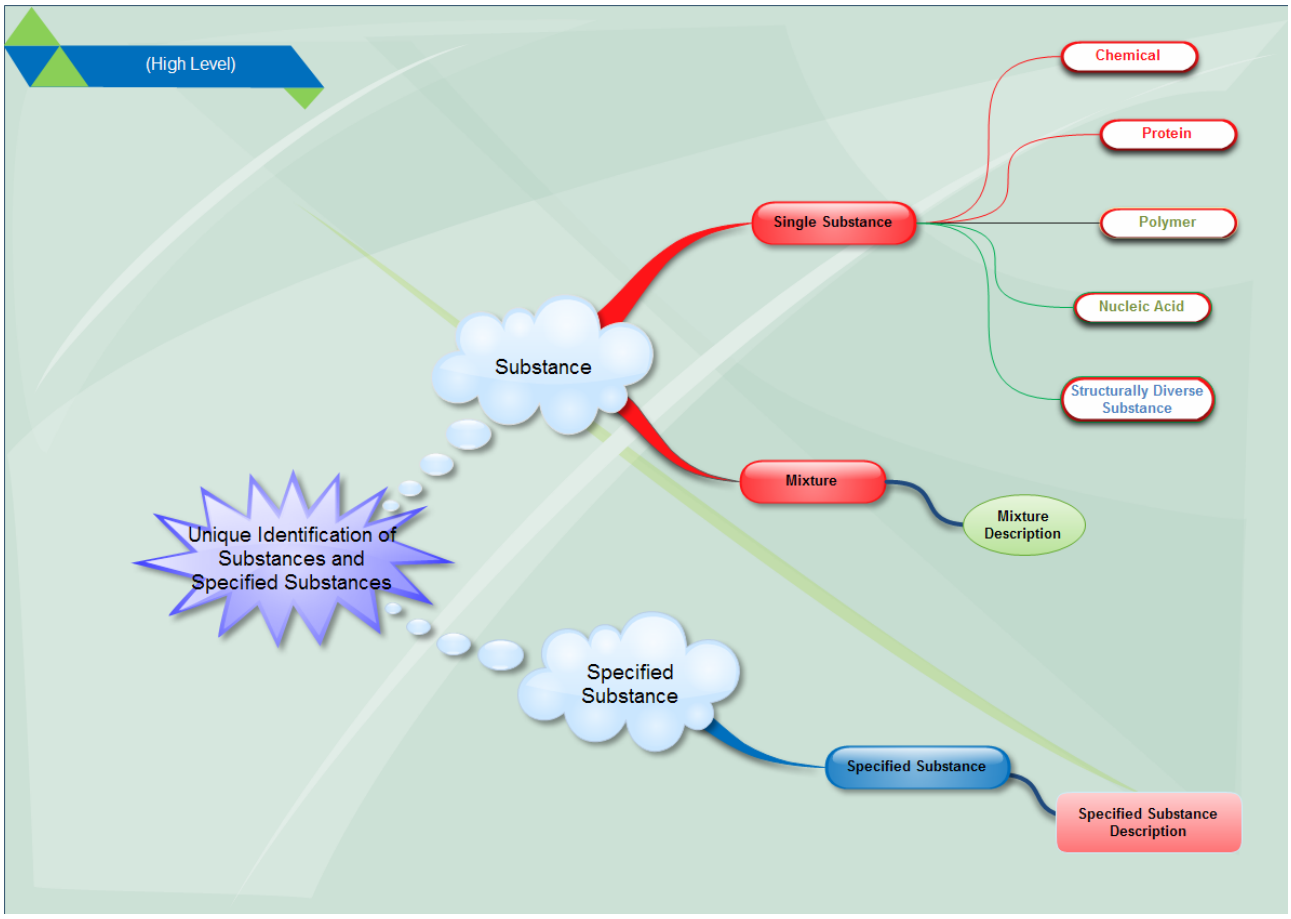
33.3 IDENTIFICATION AND DESCRIPTION OF SUBSTANCES AND SPECIFIED SUBSTANCES

The "Health Informatics – Identification of Medicinal Products – Data elements and structures to uniquely identify and described substances and specified substances" is a work item approved by ISO/TC215 (prEN ISO 11238) and has been submitted to HL7 as a joint project proposal.

The project scope or objective is to develop data elements, structures and relationships between the data elements required to uniquely define and identify substances and specified substances including medicinal

products, dietary supplements, food and feed additives and cosmetics. The deliverables will include a HL7V3 CMET and schema for exchange of information on substances and specified substances. It is intended to complement or extend the pharmacy and medication models developed by the Pharmacy WG.

The following high level model was presented.



It is anticipated that the CMET and schema will be ready in time for May 2010 ballot as DSTU artefacts.

33.4 IDENTIFICATION OF MEDICINAL PRODUCTS (IDMP)

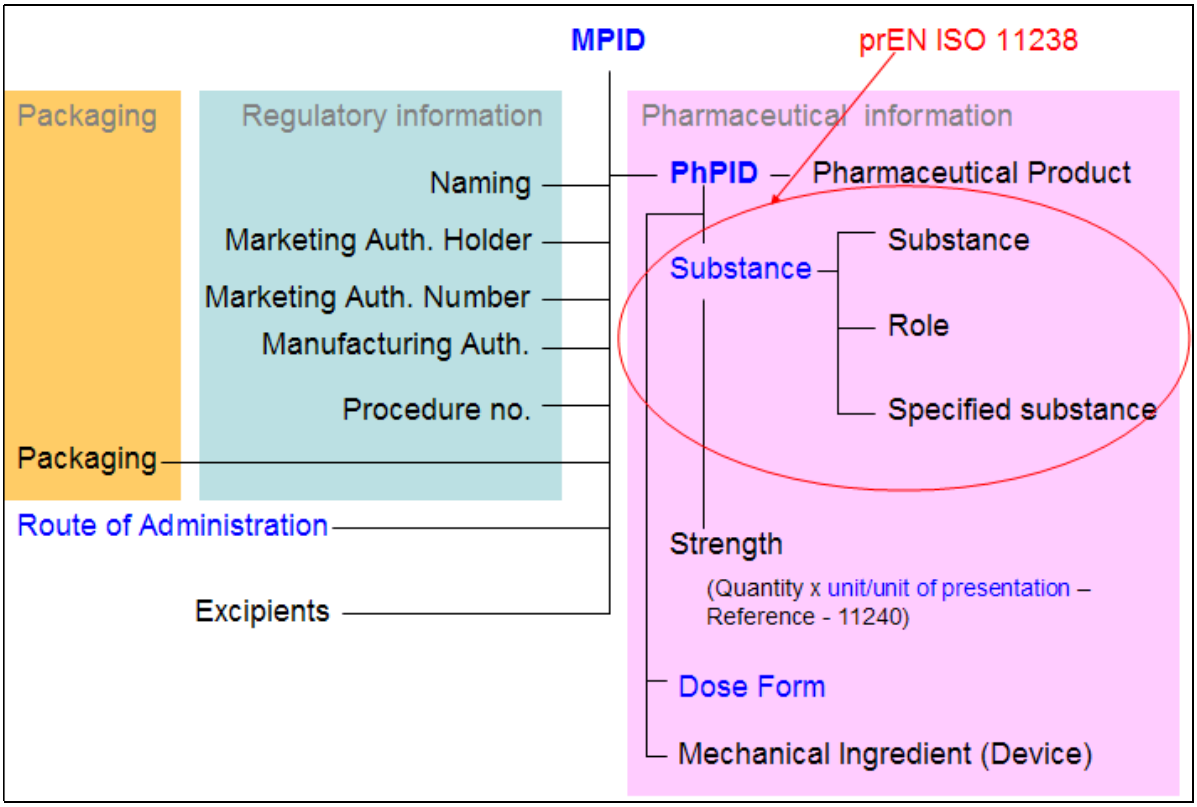
The IDMP project (a joint ISO/TC 215 and HL7 project) was presented to the Pharmacy WG at the September 2009 meeting.

The project is intended to support five component work items that comprise:

- 11238 – Data elements and structures to uniquely identify and describe substances and specified substances (Ingredients/ Substances)
- 11239 – Routes of Administration, Dose Forms and Units of Presentation (Dose/Unit/Route)
- 11240 – Units of Measure (UOM)
- 11615 – Medicinal Product Identifiers (MPIDs), and
- 11616 – Pharmaceutical Product Identifiers (PHPIDS).

It went through the ISO ballot processes in August 2009 and attracted large number of comments from ISO committees, HL7, CEN, and CDISC. The comments have been reconciled and the plan is to progress the documents to enable HL7 informative ballot in May 2010 (Rio meeting).

The Australian delegate asked on how the prEN ISO 11238 (Data elements and structures to uniquely identify and describe substances and specified substances) is related to this project. A high level IDMP model was presented to explain the relationship.



33.5 OID FOR [PROPRIETARY] DRUG FORMULARY CODES

While RxNorm, a standardized nomenclature for clinical drugs and drug delivery devices produced by the National Library of Medicine (NLM) has been available in USA since 2005, proprietary drug formulary codes (for example First Data Bank) have wide penetration throughout USA and Canadian markets.

A request has been submitted to the Pharmacy WG for clarification and advice on the proper processes for submitting proprietary drug code systems to HL7 for OID issue. It was determined that the source organization (e.g. First Data Bank) would request an organization OID from HL7, create separate OIDs for individual code systems under the organization root OID, then register the OIDs with HL7 or publish them on its own website. The individual organization is to be responsible for maintaining OIDs it creates under its root OID. (See OID discussion in Vocabulary WG below.)

33.6 PROPOSED V2.8 ENHANCEMENT FOR MEDICATION

The RXG and RXC segments in v2.x are used to communicate medication administration information but do not contain the quantity of medication to be administered. The RXC segment is used when communicating multi–ingredient medication orders. The RXE segment contains a dispense quantity and quantity unit field but these values may not correspond to quantities need for the ordered dose.

For example, for Warfarin 12 mg order – RXE segment communicates the Warfarin order details (i.e.Warfarin tablet 12mg) and the RXC (treatment component order) segment communicates the Warfarin medications required to satisfy the order but does not inform the number of dose forms needed for each administration. The nurse needs to perform the calculation to determine the number of dose forms needed (e.g. 1 tablet of 2mg + 2 tablets of 5mg).

To improve clinical safety, it was proposed that “quantity” and “quantity unit” fields as calculated by the pharmacist be added to the RXC and RXG segments. The proposal was accepted after short discussions.

34. PUBLIC HEALTH EMERGENCY RESPONSE

The North American Association of Central Cancer Registries (NAACCR) conducted a trial using CDA to update Registries and presented on issues discovered. In some previous experiences difficulty has been

experienced representing some elements in CDA as they cannot be mapped back to the RIM. In this project that was not the case. However, from a technical point of view a couple of observations were made.

- a CDA document is 5 to 20 times larger than a flat file
- CDA is 1 record per document, and
- processing 100,000 records must be done in "batch mode overnight".

Working Group web site:

www.HL7.org/Special/committees/pher/index.cfm

35. PUBLISHING (V2.X)

Neither of the Co–Chairs could attend this WGM and interim co–Chair Tony Julian led the meeting.

Committee web site:

www.HL7.org/Special/committees/publishing/index.cfm

36. SECURITY WG

The Security DAM is complete and is based upon ISO 22600 Privilege Management and Access Control

Discussion about the development of ontology driven policy specifications occurred during this meeting. Current privacy/security artefacts mapped to SAEAF: CIM – Security DAM, Privacy DAM, PASS Access; PIM – CPCD v2; PSM – CD CDA r2 Proposed security work items: CIM – PASS Management, Privacy/Security DAM Harmonisation; PIM – Privacy Policy Templates, PASS Access.

It is proposed to use an ontology–based approach for policy specification allowing for formal computability of policy constructs. This might use a pseudo–code for policies that could then be mapped into XACML.

Working Group web site:

www.HL7.org/Special/committees/secure/index.cfm

37. SERVICES–ORIENTED ARCHITECTURE (SOA)

Don Jorgenson was confirmed as a new Co–Chair and Ann Wright (UK NHS) was elected as the first non–US Co–Chair (interim to be confirmed at next WG meeting).

37.1 HSSP – BACKGROUND

The HSSP (Health Services Specification Project) was established some 3 years ago by HL7 in collaboration with the Object Management Group (OMG) to provide a general framework for Service Architecture specification in the Health arena.

The two specifications used to initiate the project were:

- The Entity Identification Service (EIS), which is a generic specification of a service to manage identity of persons (patients, providers) and organizations within Healthcare.
- The Retrieve, Locate, Update Service (RLUS), which is used to find and update health record information.

Work is also now well advanced on three further services:

- A Human Services Directory Service (HSDS) being led by Max Walker from the Victorian Department of Health.
- A Clinical terminology Service (CTS2) and a Clinical Decision Support Service (CDSS) being led by Prof. Kensaku Kawamoto of Duke University, Division of Clinical Informatics.

The **HSSP process** is as follows:

- A service specification in 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 which prepares a detailed Request for Proposal (RFP) to specify what is required in an implementation.
- From the Responders to the RFP one or more task forces are formed including at least 2 health software companies prepared to implement the specification.
- A platform dependent specification is then completed and implemented by at least 2 vendors. Feedback from the implementation experience informs the specification in a feed back loop which usually has at least 2 iterations.
- The completed specification is then balloted within OMG and goes though a detailed independent analysis similar to a thesis defence. HL7 by its membership of OMG has complete transparency of this process and is able to provide input.
- After passing OMG final ballot the completed specification 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 Standard.

Previous educational efforts by the SOA WG have led to a much greater general understanding of SOA principles and an acceptance of the process. All Committees are now considering SOA initiatives.

Joint meetings were held at this meeting between SOA and Security and SOA and Vocabulary.

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. It is available at:

http://hssp.wikispaces.com

Another resource is *The Practical Guide for SOA in Healthcare (Parts 1 and 2)*, which documents the HSSP process and the Service Development Framework (SDF) used by HSSP. It is a remarkably accessible document and is also recommended reading for those interested in SOA specifications in healthcare. It can be accessed at

http://hssp.wikispaces.com/practicalguide

The guide has been revised to include information learnt from the first full HSSP cycle and incorporates the relationship with HL7's Service Aware Enterprise Architecture Framework (SAEAF).

The revised document contains 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. It has been extended to include analysis of HITSP, HSSP, HL7 SAEAF, US Federal Enterprise Architecture, and other industry reference sources to elaborate a mature healthcare SOA Reference Architecture.

37.2 THE HITSP RELATIONSHIP

Via HITSP, a reference architecture for EHRs is being developed using RIM/CDA data models/specifications, EHR functional model and EHR Interoperability model.

The project's aims are to create an informative mapping/analysis document to implement a step in HL7's roadmap, identify gaps and overlaps in HL7's portfolio and identify gaps in the EHR–S FM; pilot SAEAF; validate HITSP's Multi–Enterprise Architecture of Networked Services Standards (MEANS) framework/methodology; create a Healthcare SOA Reference Architecture (H–SOA–RA) Version 2 and other architectural artefacts; and demonstrate a standards–driven Model Driven Architecture (MDA) approach.

The key end user target is US health domain federal agencies and their non–federal contractors and partners, but the overall results should be more globally applicable. The project also fulfils the federal health architecture mandate to establish a service reference model (e.g., H–SOA–RA V2) for the health domain as a candidate for the Federal Health Architecture (FHA) Service Reference model (SRM). A draft set of health domain services, their definitions, and mapping of V2.5 message content mappings has already been

created and derived from the EHR–S FM by DOHA of Defence in conjunction with the Veterans' Administration. This project will add the V3.0 messages.

The project is taking account of the HITSP re–use paradigm by building CDA documents from groups of standardized data modules. HITSP's CDA Content Modules Component defines the content modules for document based HITSP constructs utilizing clinical information. These Content modules are based on IHE PCC Technical Framework Volume II, Release 4, which contains specifications for document sections that are consistent with all implementation guides for clinical documents currently selected for HITSP constructs.

Discussion with HL7 New Zealand representatives at this meeting suggests a common interest in an information and education event around SAEAF.

Action:

HL7 Australia will further assess the HITSP relationship.

37.3 HSSP PROCESS AND OMG RELATIONSHIP

The HSSP process revision (leading to the process set out above) has been completed and approved by the HL7 Technical Steering Committee (TSC). Under the agreement with OMG, the SOA Work Group is the HL7 International side of the Health Services Specification Project (HSSP) and has cross–domain responsibility for providing input and expertise on services specifications, their development and application to other HL7 Work Groups and Committees.

There continues to be some friction between HL7 and the OMG around the HSSP process. This is not from those involved in the effort but more from those concerned about the governance of HL7 specifications and the artefacts that are generated.

The CEO of OMG Richard Soley again attended the HL7 WGM and met with the HL7 Board and senior executive personnel.

There is good reason to see the building of a strong relationship between HSSP and the SAEAF given they both leverage the OMG MDA approach. Agreement and specificity of the MDA layers is needed between the OMG (HSSP) and HL7 (SAEAF).

The PASS (Privacy Access and Security Services) specification has passed ballot (and is being progressed within the SAEAF Alpha process).

The SOA in Healthcare Conference – run by the HSSP will be held in Washington DC in June. The HSSP web site is:

http://hssp.wikispaces.com/

37.4 PROGRESSION OF CLINICAL TERMINOLOGY SERVICE (CTS2)

Following some refinement of the HL7/OMG process at the last meeting, this has completed DSTU ballot, the OMG RFP was issued in December and formal Responses close on 30 January 2010.

It is anticipated the OMG process will be completed in time for the May HL7 Working Group meeting.

The OMG RFP for CTS2 is available from the HSSP wiki, with the following key features:

- scope: "query, authoring and management of functional terminologies in a distributed environment"
- shall have MDA–capable platform independent model (PIM) – MDA = Model Document architecture. This should be expressed in UML [but it appears that this may not be possible – submitter using Z notation]
- shall include a platform specific model in the form of a Web service endpoint (WSDL with SOAP/HTML binding)
- shall define explicit operations that support all mandatory capabilities (defined .section 6)
- interface specifications shall support complex terminologies e.g. SNOMED CT, RxNORM

- shall support the ISO 11179.3 R2 Clause 10 notion of a conceptual domain and support the following functions: list conceptual domain, return conceptual domain, create conceptual domain, maintain conceptual domain
- conforming implementation must implement at least one CTS2 profile
- shall support vocabulary requirements in the HL7 MIF (Message Implementation Framework)
- must not be limited to Healthcare domain – Boeing and Car manufacturers have expressed interest, and
- preference given to submissions using SoaML to specify the service.

The HSSP processes in OMG have been modified for the CTS2 work item – allowing HL7 individual members to take part as "supporters" (members of the OMG task force without a vote) or "reviewers". Supporters agree to perform timely and regular review of artefacts when requested. Reviewers may review artefacts when requested – all HL7 members are automatically eligible to be reviewers. Normally these roles are limited to OMG members.

37.5 RELATIONSHIP TO REVIEW OF IHTSDO WORKBENCH

The CTS2 process needs more informed feedback from the HL7 community to support "submitters" from within the HL7 (and associated IHTSDO) communities to provide meaningful and timely input to the OMG process. The actions required are:

- Appropriate OMG submitters from HL7 to be identified, and engage with the OMG process.
- Submitters to come back to the HL7 community and discuss and engage with the CTO to facilitate feedback that would preferably include HL7 Vocabulary hosting meetings of the HL7/IHTSDO vocabulary communities to ensure that they are informed of issues, learning and actions planned.
- Incorporation of feedback from the testing of the IHTSDO workbench within HL7 into the OMG process. The intention is not to develop new material but to leverage the learnings of the OMG process and early implementers to inform the development of the normative CTS2 in the most effective manner.

37.6 EXTENSION OF CTS2 SCOPE

A taskforce will be instituted to work on a system functional model to bring forward additional high level service (including provision of concept level reasoning and compositional functionality) that can build upon the functionality defined in CTS2. This will go forward as a SAEAF alpha project.

37.7 PROGRESSION OF OTHER SOA PROJECTS

Identity Cross reference Service (IXS) – formerly the Entity Identity Service – EIS).

IXS Passed final normative ballot last meeting and is in the process of publication. A number of groups in the USA, The UK NHS, The Netherlands and the European Community are considering implementations.

Action:

Australian national identity (Patient/Provider/Organisation) infrastructure access should be based on IXS.

Action Owner: NEHTA

37.8 HEALTH SERVICES DIRECTORY SERVICE (HSDS)

The work on this service is being led by Max Walker from the Victorian Department of Health and continues on schedule. A completed DSTU was submitted to ballot prior to the January 2010 WG meeting and all comments were satisfactorily resolved during the meeting.

Having passed HL7 DSTU ballot, this work will be submitted to OMG for official completion of the RFP though work on this has been occurring in parallel with the work on the HL7 DSTU. This should enable a rapid issuance of the RFP with the aim of having this work completed in time for the January 2011 WG meeting in Sydney.

37.9 CLINICAL DECISION SUPPORT SERVICE (CDSS)

CDSS completed DSTU three ballot cycles back (about 12 months ago) and despite some initial delays in formation of the OMG Task Force, it is now making good progress and may complete the OMG process in time for the May WG meeting. Considerable interest has been expressed in this service by a wide range of HL7 Committees who wish to see application of Decision Support in their Domain. The flexibility of the service design should enable implementation in many Domains including some outside Health.

Action:

Ensure HSSP service specifications are recognised as candidate architecture constructs for system design. Contribute to and leverage designs such as HPSDS and CTS2.

Action Owner: NEHTA

38. STRUCTURED DOCUMENTS (SD)

Work Group web site: http://www.hl7.org/Special/committees/structure/index.cfm

In addition to the major topic of progressing CDA Release 3 (CDA R3), the following activities of the SD WG were particularly noted.

38.1 CONSISTENCY OF CDA IMPLEMENTATION GUIDES

There was discussion on whether CDA Implementation Guides should be realm specific or not. Special markup for realm specific content could to be considered. Realm vocabulary was raised as an issue when creating common CDA implementation guides

There was discussion on CDA Implementation Guide consistency in terms of structure, vocab, modelling, processes, style etc, which lead to a proposal to form task force to define consistent publication guidelines for CDA implementation guides (international context) with the priority being consistency in conformance statements.

Note that this whole discussion ducked the essential issue, of how to get consistency in clinical modelling. This will need to be addressed in the future as a consequence of the CDA R3 decision discussed below.

Action:

Contribute to the task force defining consistent publication guidelines across CDA Implementation Guides.

Action Owner: NEHTA (Sarah Gaunt)

38.2 DEMONSTRATION OF V2/V3/CDA MAPPING TOOL

Robert Worden presented his mapping tool. This tool can be used for bi–directional mappings between V2 and CDA (or V3). Creating the mappings will be set up as a Structured Documents project.

Action:

Evaluate the v2/v3/CDA mapping tool for use in Australia.

Action Owner: NEHTA (Sarah Gaunt)

38.3 CLINICAL PROCEDURE NOTE PROJECT

Ballot reconciliation was carried out for the Implementation Guide for CDA Release 2: Procedure Note project. This project aims to design a basic procedure note in XML as a constraint on CDA r2. The note will be basic enough to be used for all procedures and a sample note for endoscopy will be part of this universal realm implementation guide.

38.4 CDA R3 – REPRESENTATION OF CLINICAL CONTENT

One of the hot topics in the Structured Documents WG was the formal proposals for CDA R3 – namely what the right hand side (RHS) (clinical statement part) of CDA will look like. There were three main formal proposals, as follows:

- Right hand side = RIM normative content, minus some stuff.
- Right hand side = Clinical Statement model, plus some stuff.
- Right hand side = start with CDA R2, and add based on clearly defined requirements and proposals.

For a detailed analysis of the proposals, see:

http://wiki.hl7.org/index.php?title=CDA_R3_Right_Hand_Side_of_Model_Analysis

After a full quarter of discussion around governance, scope, policy and consistency, a motion was passed as follows: CDA R3 will use RIM's Normative context for the right hand side of the model with a dependency on establishing governance and modelling process working with TSC to ensure consistency across or among balloted models.

Note that this does not simply mean, CDA entries will use the unrestrained power of the RIM. Templates will become more important, along with implementation guides. SD WG recognises that while this decision solves some problems, it raises several other risks, particularly for implementers, and the note about governance and modelling is a statement of intent to work in these areas

Also, this is rated as a "dependency" – it's not clear what will happen if this aspect of the work doesn't proceed satisfactorily, but it's clear that the committee would have to re–evaluate this decision.

GreenCDA

GreenCDA is a simplified take on CDA. The theory is to exchange CDA documents using easier to understand XML. This simplification is made possible by the use of profiles that define default and fixed realm or company specific content. The resulting XML will have such content stripped out. 80% of CDA features will be covered by greenCDA. An XSL transform will be used to convert the greenCDA to CDA. The main beneficiaries of greenCDA will be developers due to the simplified XML

There is a close relationship between greenCDA and some of the NEHTA work on CDA implementation strategies, and also in some of the new work coming out of the ITS group, and we should watch these developments closely.

Template Registry Project

Structured Documents met with Templates (and others) during Q1 and Q2 on Friday to discuss the Template Registry Project – see report in Templates below.

39. TEMPLATES

The main activity of the Templates WG is defining requirements for the Template Registry project co–sponsored by Tooling, Structured Documents, Patient Care and Vocabulary. The objective of the project is to develop standard procedures and registry/registries for creation and management of HL7 templates (which are standardised clinical data structures based on the HL7 RIM).

The "Template Registry Project Scope Statement" (Project code 970387) has been approved. A template registry business requirement specification has also been developed and was opened for comment after the September 2009 WGM meeting. This business requirement specification covers the following areas:

- The repository, the different systems and services that may interact with the template registry. These systems and services include client systems such as authoring applications, web browsers, terminology services, metadata management services, indexing and retrieval services, user interface, etc.
- Requirements of stakeholder groups that contribute to development, annotation, review, approval and use of templates.

- Principles of template governance
- Use cases covering review, accept, notification of changes, authentication, audit, access control, review, rejection, revision, deletion, publishing, activation, retiring, freezing, replacement and approval, and version control of templates.

The Template WG met during Q1 and Q2 on Friday at the January 2010 meeting during which each category of the business requirements was discussed in relative detail, with over 50 people being present in the session. All present agreed in principle:

- with the broad categories of business requirements
- that the business requirement specification should be submitted for further peer review, and
- to progress development of technical requirements for design and implementation of HL7 template registry/registries – based on the emerging business requirements

After further discussion and a presentation by Keith Boone, the WG also agreed to support the initiation of a pilot project covering the following task list and/or development activities:

- back end: metadata and registry design
- front end: to support query and viewing
- vocabulary interface
- basic CTS with subsumption testing and terminology lookup capabilities
- separation of structural template from value sets
- concept domain development
- review processes, and
- notification services (active and passive): what templates are available, who is/are using which template(s).

The task list will be finalized via conference calls after the WGM.

Action:

Contribute Australian CDA Templates to Template Registry Project.

Action Owner: NEHTA (Sarah Gaunt)

39.1 HL7 TEMPLATES DSTU

It was noted that the HL7 Templates DSTU has expired, and HL7 must now decide whether to take it to a full normative specification. The extent of trial use has been disappointing. This wasn't really on the table at the WGM, but needs to be resolved.

40. TOOLING

The following are among the matters addressed by the Tooling WG.
Progress with OHT CDA tooling developments

Demonstrations of the Open Health Tool's (OHT) CDA Tools were given over 2 quarters. These tools are a component of the Model Driven Health Tools (MDHT) project, which will develop a UML approach for constraining HL7 Clinical Document Architecture (CDA) to create reusable templates and implementation guides. For more details about this project, see:

https://mdht.projects.openhealthtools.org/cda/index.html

Action:

Evaluate tool for use in creating CDA Implementation Guides. Feed back to the MDHT project to effect any desirable changes.

Action Owner: NEHTA (Sarah Gaunt)

40.1 PRIORITISATION OF TOOLING WORK

Tooling WG has prioritised the work required of tools for HL7 process support. Highest priority has gone to those elements required to give the new development platform.

- Static model designer
  - end user documentation
  - enhancements to support HL7 roll–out
  - development of training material
  - upgrade to XML generator
- XML processing implementation – implement updated XML publication process, and
- XML schema validation enhancement – replacement for the dated Ramsey system validator.

Investment Projects have the lowest priority (not because they are least important but because they require higher priority items to be completed or are expected to take some time to complete. They include:

- IHTSDO Workbench enhancement (as distinct from evaluation). At the end of the priority list because there are so many dependencies – Russ Hamm is the liaison between vocabulary tooling and general tooling activities in HL7.
- Requirements analysis for shared artefact repository. Assemble requirements for a shared artefact repository that includes capabilities identified for OID registry, templates registry and registry of other artefacts produced for HL7 specifications.

40.2 EVALUATION OF IHTSDO TERMINOLOGY WORK BENCH

HL7 has evaluated the IHTSDO terminology work bench product suite and considers that it has the core capabilities to maintain HL7's vocab resources and assist in managing other vocab activities. Ongoing evaluation and experimentation is returning positive responses. Russell Hamm (Apelon) is the project lead and liaison with IHTSDO for the project.

The next step is for the Tooling and Vocab WGs scope and carry out a pilot project using the workbench – potentially crafting shareable subsets/refsets and recommending SNOMED changes using the workbench. More hands–on experience with the software is a key objective for HL7.

A new release of the workbench is expected shortly to this open source product that offers significant functionality extension. A link to CollabNet where the source code repository is maintained can be requested through bje.ihtsdo.org.

From the viewpoint of the Vocab WG, major issues for discussion with Tooling WG include:

- Need to move to a more resilient and suitable platform for our data (as the current system is beyond capacity.
- Need to identify the additional requirements and capacity of the tool to support binding and other modelling associated requirements of HL7.

Vocabulary WG will monitor and action progress on this work, noting that Tooling WG are concerned that HL7 has a well–formed position on key requirements before large investments are made in enhancing and modifying the tools for use in HL7.

41. VOCABULARY

Vocabulary WG met from Sunday to Friday at this meeting. 59 people attended the Vocabulary meeting.

41.1 HL7 CONTENT VS RECOGNISED INTERNATIONAL CONTENT (EG SNOMED–CT)

There are cases where HL7 content overlaps with the content in SNOMED–CT. Today the policy is that a code is only created in HL7 where it doesn't exist in any other area, therefore we should not be creating content that is in SNOMED–CT. It was recognized that not all countries have access to SNOMED and some may also need to indicate local realm content.

Having determined this policy it is necessary to identify when the process should occur to remove and replace those concepts that have previously been defined in HL7 and also exist in SNOMED–CT.

This requires HL7 to have a process to support the implementation of relevant international terminology sub–sets – appropriate links are required. There is a proposal around this issue later in the week on Tuesday Q1. Identification of a subset of the standard terminology to be used with this model is needed and this becomes part of the definition of the model. E.g.: for these kinds of things you should always use SNOMED–CT to represent them.

It would be advantageous to develop a transition plan to move from HL7 terminology management to the integration of internationally governed terminologies into HL7 processes. This should be done for all vocabulary domains, and V2/V3 have different levels of quality in the data representations. As of V2.7 all terminological concepts have been removed from the published component. Design reference sets in a similar domain in V3 and say that it could be used also in V2. Is it possible in the context of the movement towards standard vocabularies to take into consideration the broader need and be consistent?

There is a need to identify and establish a policy statement that makes clear the value sets HL7 required to actively maintain such as:

- structural HL7 message value sets
- where there is no publicly available international code system HL7 may maintain the value set, and
- we could consider development of a union of local codes to produce the super–set and allow constraint to manage locally.

Policy items identified in discussion:

- When publicly available we will not maintain within HL7 we will deprecate our value sets and indicate the 'new' code source.
- Where there is more than one purpose / use case of a value set, each use represents a different value set.
- The prose documentation that comes with the value set must include the intended use of the value set. Without this it is not possible to identify whether the change being made may break the utility of the value set.
- We only add a value set if it needs to be bound.
- Only add value sets when their usage is known and defined.

A proposal is to be developed that identifies the issues and preferred solution for consideration of the International Council.

It is important to recognise that this problem will need to be addressed at some point and the feeling was that we have reached a time when this change of policy is appropriate.

Action:

IT–014–02, in conjunction with IT–014–06, to consider the Australian position on the HL7 / SNOWMED–CT policy.

Action Owner: IT–014–02 and NEHTA Clinical Terminology

41.2 OIDS

In HL7 the OID registry has over 4000 entries on www.hl7.org. Approximately 600 of these are pending and require review, several hundred have been rejected or retired. A request has been received to host OIDs for various countries' healthcare systems in the HL7 repository, this was not supported.

Germany decided to build an OID registry for healthcare. This is a high priority in DOHA of Health in Germany. This work was based upon HL7 principles with the objective of being interoperable with HL7 and with France Telecom which holds a large repository, not only healthcare. Germany decided to use HL7 OIDS when they are international, otherwise local German OIDs are registered and used in Germany. The problem is that there are missing OIDs and it is not clear where the appropriate OIDs are held.

European initiatives require an internationally quality assured OID registry and there is a need for this to be funded. This has raised issues that relate to the processes and responsibilities for maintenance of registries and to exchange formats.

The need to clarify processes and requirements for OID maintenance and stability of the metadata set is now generally accepted.

This meeting had representation from ISO/CEN and HL7 representatives and considered the use case development agreed by the stakeholder community for OID management at the ISO meeting. The resulting outline of requirements is as follows (with comments):

- Process
  - the process must be as simple to use and manage as possible
  - search – there is a requirement to be able to search for: (1) Search criteria, and (2) Search target, and
  - exchange – what do we mean, what is to be exchanged?
- Process and policy to support the OID life cycle
  - request for an OID
    - When a request is made a temporary OID ID may be provided immediately upon request to support testing.
    - This is an temporary OID.
    - Where temporary OIDs are used they will be deprecated after the initial temporary time period has elapsed.
    - If questions are sent to the responsible body related to missing or unclear information in the request for an OID.
    - The OID will be considered Pending for XX days (30 days suggested).
    - If no response is received the OID will not be registered.
  - OID Creation
    - When to create a new OID?
    - How to decide when a new OID is/is not required?
  - rejection
  - update
    - When it can be changed?
    - What do you do when an object exists but the responsible organization no longer exists?
    - What to do when an OID is created in the past is not the correct OID to use and it is wrong.
    - What is the process for retirement of OIDs.
    - What do you do when you have an error and the error has been used?
    - What is a substantive enough change to require a new OID?
    - Eg: if the name changes or the description changes these are a new OID, whereas, if the organization responsible changes it is not.
    - There is a need to develop clear rules for this, but also a need to recognise that manual review and assessment is essential.
  - retirement
    - When should an OID be retired?

- maintenance of history of each OID entry

- Attributes of an OID
  - we need to identify required extensions to the metadata and a process to handle unforseen extension requirements
    - immutable vs. mutable
    - OID ID
    - OID registration date
    - OID status date
    - OID type (requires different validation processes)

    Note: The classification hierarchy in HL7 is driven by management requirements within HL7. It has nothing to do with the actual meaning of the items being registered. Should there be such a classification and what structure is best suited to the process requirements. An ISO standard for universal OID categories is required while sub–categories are required to meet other purposes. This would handle additional categories to support local needs. E.g. code system or value set. Orange OIDS (used in the Netherlands) – categories that are required, existing categories, and local country categories.
  - status indicators
    - entering is when an OID is being created (status indicator)
    - pending – need to make sure that the content is complete and robust (status indicator). When insufficient information is provided to support registration this will be communicated to the responsible body. If the body does not respond within XX (30 suggested) days the request will be rejected.
    - rejected (request rejected)
    - approved complete (ready to use)
    - deprecated (do not use) it is not appropriate to delete.
    - deprecation requires the ability to indicate the approved OID that should be used in place of the deprecated OID (though it is recognised that there will be occasions where a replaced by will not be available)
  - replaced by identifying the OID which has replaced a previously approved OID
  - responsible Body (Organization responsible) eg the person or organization responsible for publication

    Note: In the past the email address was an individual. Organisational email addresses which are automated cause difficulties in communication. More comprehensive registrant information is now sought to aid on–going maintenance of OID registers. This presently includes:

    (1) registrant name;

    (2) mailing address;

    (3) URL;

    (4) telephone number;

    (5) email address;

    (6) contact individual [person to contact regarding questions about the OID registration information – the technical people responsible for the use of the OID information];

    (7) submitter [the person who actually submits the request – may be clerical or associated person who may not be a member of the responsible body]

Ted Klein (US, HL7) and Sylvia Thun (EU) will work together to compare the HL7 metamodel with the proposed ISO metamodel and prepare a proposed joint metamodel.

41.3 POST–COORDINATION CONFORMANCE

What does it mean to be conformant when you are dealing with post–coordination? Conformance means that the coded concept carried in a model instance is tested whether or not it is an expansion of the value set. What if it is the same concept but it is expressed differently? There are a number of systems that support post coordination and thereby have more than one way of expressing the same concept. The only current mechanism for dealing with post–coordination in value set definitions is when value sets are defined

explicitly with expansions. There is no process for dealing with intentional definitions for post–coordination. What needs to be done to define the value set.

A new project has been established to identify appropriate resolution of the process for applying the rules required for representation of compositional grammar in the value set machinery of HL7 (V2 and V3). HL7 need to have a position on conformance where value set constraints are intended to be populated by post–coordinated expressions. This project will consider an approach for SNOMED–CT to inform the later development of a generic solution.

Issues such as this one must be coordinated with the Implementation/Conformance Work Group.

Resolution of this issue will be based upon use cases and straw man proposals will be developed to support improved understanding both of the problem and the recommended solution.

A wiki will be established to collect real world use cases to define the usage requirements prior to identification of the solution. This work will be harmonised with IHTSDO initiatives. Heather Grain is responsible for development of the scope statement.

41.4 VALUE SET CONSTRAINT CONFORMANCE

The original objective of HL7 was to be agnostic to code systems in order to not 'offend' any of the players. This has proven to be a poor process, as there is a need to for consistent representation of content of information.

Internationally there will be cases where countries legislate for a specific code set which may not be the preferred set. The proposed change does not restrict the ability to do this. A country may choose to not use the preferred code system –this could be considered not compliant, but these countries may have their own realm standards to which they are compliant.

This is particularly relevant in the clinical environment. There is a need to understand the border between the clinical domains and other domains. IN the context of harmonisation there is the issue that the modelling process must understand some of the technical requirements to support the right use of terminology in the context of an HL7 model. Taking the knowledge of how this should occur out of those few who know and understand harmonisation, but to extend to those who do the models.

We need a way to make clear what the modeller had in mind. There is a need for a reference value set (as a proposed requirement of the modelling elements) so that the model in ballot includes a full and complete example value set that could be used to implement the solution.

Example: the need to differentiate between the service and the delivery of the service.

It was decided that for a coded element in an internationally balloted static model the vocab declaration requires a concept domain and an optional part that states the preferred code system that establishes the semantics of the coded element. There would also be an optional binding to a preferred realm value set that is consistent with the vocabulary declaration. The second step is the real definition of the concept domain because it is the thing that can be tested for conformance.

This will require the creation of a new generic special realm to support this process and Identification of the cases where a preferred code system is required.

41.5 E–HEALTH GLOSSARY AND STANDARDS REGISTRY

The e–health Glossary and Standards Registry developed and being deployed by ISO/TC215 has been approved for use by all member bodies of the Joint Initiative Council (the current members of which are ISO/TC215, CEN/TC251, CDISC, HL7, IHTSDO and GS1). The leads for this development were: Australia (glossary); and Canada (document register and SKMT systems development).

The SKMT tool and current glossary content was demonstrated to various groups at the January 2010 WGM and can be accessed at www.cred.ca/skmt_glossary. Access requires registration but this is free and open to all.

Discussions with the HL7 Publishing WG (which maintains the HL7 Glossary) have occurred and it is intended that the V3 glossary content will be extracted and automatically put into the SKMT. The recommended process within HL7 is:

When a definition is required, check and see if there is a definition already in the SKMT:

1. *If there is and it is acceptable – use the SKMT definition;*
2. *If there is and it is not acceptable – then either*

2.1 *Enter the required definition and declare context (eg: HL7 messaging)*

or

2.2 *Where the existing definition is considered wrong/out of date or inadequate in some other way, enter the suggested improved definition with a pending status and request harmonization (the consideration of the other standards bodies to agree on the suggested change);*

or

3. *If there is not – add the definition with a status of pending. When balloting is complete the status can be changed to candidate. The SKMT review process will update the status to standard if there are no conflicts in the definition (duplications etc).*

Heather Grain was requested to present and explain the SKMT to Patient Care and EHR at this meeting. Each of these working groups wanted to trial the tool to assist in their standards development activities.

Action:

Activity on the V3 glossary content be extracted and automatically put into the SKMT requires ongoing support from Australia for it to progress.

41.6 OTHER MATTERS CONSIDERED AT VOCAB WG

The following are among the other matters addressed by the Vocab WG:

Evaluation of IHTSDO Work Bench

The Vocab WG is working with the Tooling WG on evaluation of the IHTSDO Work Bench for maintaining consistent clinical vocabulary and code sets for use with HL7 – as reported in section 40.2 above.

Vocabulary Facilitation

Vocabulary facilitators are responsible for providing cross–domain advice and guidance on vocabulary issues to other WGs, including helping their committees to formulate and submit appropriately coordinated vocabulary submission as part of HL7 harmonisation processes. The process of facilitation has been reviewed and will be more effectively communicated.

Syntax for Vocabulary Binding in Implementation Guides

This work will provide guidance on the use/role of interface and reference characteristics and properties within terminologies

Update of TermInfo

The TermInfo specifications provide guidance for co–implementing SNOMED in HL7 V3 standards.

As a collaborative project, IHTSDO wants to reduce representational gaps in TermInfo and will be working with the HL7 Vocab WG to extend the TermInfo ballot to get input from the IHTSO community and produce the next generation of TermInfo as a joint offering.

The work from this project has been brought back into the Vocabulary WG and is seen as fundamental to the core principles document and decision making for terminology binding and process within HL7 messages.

A process for feedback of ballot comments and HL7 issues to IHTSDO is to be established.

Advice to IDMP project

A specific issue has been raised by the IDMP project in the Pharmacy WG: What are capsules/tablets? ‘Tablets’ are units, they are units of counting rather than units of measure. UCUM does not deal with this concept. The concept may be represented in the form of the measurement, whether a dose form or an observation (count). Guidance will be provided to the IDMP project on this point.

Requirements for modification of ISO 11179

HL7 requirements and requirements identified through the SKMT glossary and document registry process are beyond the capacity of the current specifications in ISO 11179 – metadata registry (part 3).

Liaison has been established between ISO WG3 and HL7 Vocab (H. Grain) and ISO/IEC JTC1/SC 32, the owners of ISO 11179. A consolidated list of functional requirements for consideration in the review of ISO 11179 will be developed.

42. GOVERNANCE AND OPERATIONS COMMITTEE

This Board–appointed committee has oversight of the processes that HL7 International uses to create standards. It documents these processes in the HL7 International "Governance and Operations Manual" (GOM).

Leading up to the January 2010 WGM, Klaus Veil pursued an issue regarding the qualifications of the US representative to the International Council. The proposed wording was "... US citizens living and working in the United States ..." As a result of Klaus' input this has now been amended to " ... US citizens or permanent residents living and working in the United States ...".

Working Group web site:

www.HL7.org/Special/committees/gno/

43. PROCESS IMPROVEMENT COMMITTEE

Helen Stevens–Love has been appointed Co–Chair of this Board–appointed committee that collects member input, concerns and complaints on the HL7 International processes. It feeds into various areas, including the committee "Decision Making Practices" (DMP) documents and the "Governance and Operations Manual" (GOM).

Committee web site:

www.HL7.org/Special/committees/pi/

Committee wiki:

http://wiki.HL7.org/index.php?title=PIC

44. ORGANIZATIONAL RELATIONS COMMITTEE

This Board–appointed committee has oversight of the various formalised relationships that HL7 International has with International and US organisations. The committee met Monday lunchtime with the following agenda:

- review the Mission and Charter
- develop preliminary framework for levels of relationships
- develop preliminary framework for criteria/requirements for MOUs
- review the Mohawk College MOU (following the Board meeting on Tuesday – the need for HL7 to have a different form of agreement for prototyping/conformance organisations was recognised – the normal HL7 MOU does not address the needs of either party), and
- review the X12 Data Determination Coordination Project.

Working Group web site:

www.HL7.org/Special/committees/orgrelations/

List of formal agreements:

www.HL7.org/about/agreements.cfm

ANNEXURE A – REPORTS BY HL7 AFFILIATES

As normal, most of the Affiliates present gave a short presentation on developments in their own countries and/or anything that they wished to bring to the attention of the International Council.

HL7 ARGENTINA

HL7 Argentina aims to promote the use of interoperable healthcare software to improve quality and effectiveness of healthcare providers by: publishing/adapting /developing standards; enabling knowledge of these standards through organization of courses; participating in congresses and conferences about healthcare interoperability related issues; and contributing to linkage and exchange of information and experiences between HL7 Argentina membership and other Affiliates through the world.

HL7 Argentina has 30 members – 3 individuals, 1 government agency, 12 healthcare providers and 14 software developers/consultants.

HL7 Argentina has placed special emphasis on the development and use of e–learning. The HL7 e–Learning Course (available internationally in English and Spanish) has trained almost 1000 students since 2005. A contract is in place with HL7 International for maintenance of the e–Learning Course to 2011.

2010 priorities include: trying to interest regional governments to adopt healthcare information standards; trying to adopt a coordinated regional approach from South American HL7 Affiliates; increased participation in conferences and hosting the Rio HL7 International WGM and 2010 IHIC.

HL7 AUSTRALIA

A new management committee was elected in November 2009. Thanks were noted to Klaus Veil, HL7 Australia's inaugural but now immediate past–President, whose contributions have been substantial not only in Australia but internationally.

HL7 Australia's strategic plan has been updated but is yet to be ratified by the membership. Key initiatives include more systematic education and training; an "ambassador" program; continued support for standardization; support for certification; a review of online capabilities; greater collaboration with Affiliates in NZ and the Asia–Pacific; building the membership base and visibility of the organisation; and improving governance.

HL7 AUSTRIA

HL7 Austria was not represented at this meeting

HL7 BRAZIL

HL7 Brazil is preparing to host the May 2010 HL7 International WGM, which will be preceded by the International HL7 Interoperability Conference (IHIC) – see:

www.ihic2010.hl7.org.ar.

IHIC will feature:

- HL7 v2.x and 3.0 messages
- Clinical Document Architecture (CDA)
- Imaging Diagnostics and DICOM Standard
- Use of HL7 in IHE profiles
- Terminologies, Ontologies and Coding Systems : use of local and international standards
- Use of other standards in combination with HL7 standards: ASTM, ISO, CEN
- Business Models, regional and large scale deployment:
- Electronic Healthcare Record: from strategy to implementation
- Legal and regulatory issues.

- Epidemiology, disease surveillance and control
- Geographical information systems for population health
- Disaster medicine, emergency management and public health

IHIC will again incorporate the "Send me your CDA!" HL7 CDA Interoperability Showcase to display basic interoperability of applications using a HL7 V3 and HL7 CDA R2 standards.

Other Brazilian initiatives heavily focus on education, training and regional partnerships.

HL7 CANADA

The Infoway Standards Collaborative (SC) continues to develop, maintain and integrate pan–Canadian message and terminology specifications. It is currently conducting a Public Review (similar to a ballot) for a delta–release of various pan–Canadian specifications (based on HL7 v3).

The SC recently held its Fall Partnership meetings. These semi–annual meetings of HL7 Canada also include ISO and IHTSDO Constituencies. Nine domain–based SC Working Groups meet in–person over 3 days, deliberating messaging, terminology and related health informatics standards. A new (10th) group on Public Health Surveillance was established. The meetings attracted 200+ stakeholders. See:

www.infoway–inforoute.ca/lang–en/standards–collaborative/partnership

HL7 CHILE

A new HL7 Chile Strategy will be supported by a Roadmap that clearly defines both standards and technologies to be developed and used, and those that will not, in the **National Healthcare Information Project (SIDRA).**

Other HL7 Chile priorities focus on ensuring the organization is organized and positioned to collaborate effectively with national initiatives such as SIDRA.

HL7 CHINA

Background to the current positioning of HL7 China includes:

- China began to computerize its hospitals in the early 90's. Progress was slow, with initial focus on financial systems.
- About 5 years ago Chinese hospitals began to move more aggressively toward clinical systems.
- Many software solutions were developed, with several hundred small software companies emerging in China.
- In 2005, china spent less than 1% of total healthcare costs on IT, or about $US600 million. In 2007, China spent over $US1 billion HIT, and Dorenfest predicted a rise to between $US2 and 3 billion by 2010.

HL7 China was founded in 2006. There 15 chapter members – 2 from government, 2 from hospitals, 4 from universities/research institutes and 7 from HIT vendors. It operates in partnership with national standardization agencies, the Ministry of Health, DICOM China and IHE China. It is supported by the Ministry of Health in developing 44 EHR Data Element Sets and a Regional Health Information Network Platform Construction Guide.

HL7 COLUMBIA

The main membership of HL7 Colombia is IT Companies interested in using HL7. Other members include Universities working on interoperability in Health IT. There are important opportunities to work with Universities in Colombia.

HL7 Columbia's activities to date have included national and international Web conferences, support for IHE, localizations for laboratory orders, and participation in the Government's telehealth agenda.

HL7 CROATIA

HL7 Croatia was not represented at the meeting.

HL7 CZECH REPUBLIC

HL7 Czech Republic was not represented at the meeting.

HL7 DENMARK

HL7 Denmark was not represented at the meeting.

HL7 FINLAND

HL7 Finland has 80 organizational members, very active technical committees developing implementation guides, provides active support for the National EMR project, and is more recently supporting IHE.

Responsibilities between National Insurance Institution (Kela) and HL7 Finland have been re–aligned as follows:

- Kela is in charge of specification work for national services, support services and implementation
- HL7 Finland is in charge of QA and approval of HL7 related specifications.

A new strategy will be elaborated for HL7 Finland for 2011 onwards, reflecting these arrangements.

National projects have included a national e–prescription centre and national e–archive.

HL7 FRANCE

A new overarching organization – InteropSanté – has been created. It is a vehicle for collaboration between HPRIM–HL7 France and IHE France. Almost all relevant French organizations are members.

Substantial effort is being directed towards terminologies, including French translation(s) of display names for LOINC, HL7 vocabularies, etc; sets of French keywords as “properties” of international codes; mappings between French terminologies and classifications; and consideration of SNOMED CT.

HL7 France is considering proposing a WGM in Paris in May 2012, contiguous with a major health IT conference.

HL7 GERMANY

In terms of standards development, HL7 Germany has a new joint working group on medical devices (with IHE, HL7, DIN, VDE); there are new Government approaches concerning Drug safety (taking HL7 into consideration), is participating in the epSOS project (a large scale European Open e–health initiative) and is working on new Implementation Guides re – eNursing Summary, Diagnosis.

HL7 Germany also places substantial emphasis on visibility at and contributions to conferences, seminars, etc.

HL7 GREECE

HL7 Greece’s 2009 agenda comprised:

- participation in national conferences
- a call for membership (~90 expressions of interest received)
- invitations to key organizations as honorary members
- exploration of Web 2.0 technologies, establishment of Google groups for technical committees, an HL7–Hellas ad–hoc Linked–in group and HL7 Hellas on Facebook
- updating bylaws, and

- support for CALLIOPE EU (Creating a European coordination network for e–health interoperability implementation).

These priorities will continue in 2010.

HL7 HONG KONG

HL7 Hong Kong was inaugurated in October 2009. (Note – there was some concern raised about the validity of having a separate organization for Hong Kong, when China is already an Affiliate.)

The Hong Kong Government intends to support HL7 Hong Kong as a non–profit organization. The Memorandum and Articles of the Organization are being finalized, and the inaugural Annual General Meeting will be held in March/April 2010.

Early priorities will include training courses (HL7 Basic, Version 2/3), construction of a website and collaboration with the eHR Information Standards Office of Hong Kong.

HL7 INDIA

HL7 India was not represented at the meeting.

HL7 IRELAND

HL7 Ireland was not represented at the meeting. Ireland's Affiliate status is being monitored.

HL7 ITALY

HL7 Italy's core activities are localization, promotion and education. It has active groups on v2 and v3 (messages and documents), and is establishing a project team to develop a CDA R2 Implementation Guide for Patient Summaries. Its last publication was a CDA R2 Implementation Guide for Prescriptions.

Some HL7 Italy members are deeply involved in the architectural design of European Union epSOS Pilot.

Future activities will include a public OID registry, with lifecycle management; a public registry for code systems and value sets; and a public repository for Italian conformance statements. A SOA in healthcare project team and formal agreements re national e–health activity are being discussed.

HL7 JAPAN

HL7 Japan's recent priorities have included education (participation in conferences, running seminars), translation of the HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD); development of a Standardized Structured Medical Information Exchange (SS–MIX) – a trial project concerning pharmaceuticals and medical devices.

HL7 MEXICO

HL7 Mexico's plans for 2010 comprise increasing membership (by up to 50%); re–activating some working groups; a focus on training in V 3.0 and vocabularies; and improving the website. Areas of Interest based on healthcare system national projects include:

- ambulatory services
- hospital services
- orders
- epidemiology
- interoperability
- design and developer tools, and
- EHR functional model.

HL7 THE NETHERLANDS

HL7 Netherlands has 215 organizational members, over 500 registered individuals and around 45 active volunteers. 2009 activities included a thematic conference on Clinical Information and Detailed Clinical Models, 6 TC and TSC meetings and many electronic exchanges, and V2, V3, EHR and V3 implementation courses.

2010 activities will include publication of the 9th HL7 Magazine, a Health Information Architecture Working Conference (jointly with IHE The Netherlands and the Dutch Architecture Forum), a national HL7 Conference (December) and HL7 University program.

HL7 NEW ZEALAND

New Zealand is undertaking its first CDA Project – re dispensing, for a District Health Board representing around 1M people. The Ministry of Health appears to be showing interest in strategies to migrate the health sector from V2.0 to V3.0 and the role and use of SAEAF.

HL7 New Zealand is interested to hear from people/Affiliates with experience in these areas. It is also interested in related training, education and information sharing. It will consider online training (tailored for the region) and visiting speakers. It is very interested in collaborating with Australia and in working towards the January 2011 meeting in Sydney.

HL7 NORWAY

The national ICT program has initiated a process for establishing HL7 Norway. HL7v3 has been selected as the primary standard for information exchange in the health sector.

HL7 Norway's priorities will be to train decision makers, architects and developers; develop national implementation guides; and contribute to international standardization work.

An expert group has been convened to coordinate ongoing HL7 activities in Norway, provide resources for national, regional and local projects and drive the establishment of HL7 Norway.

A v3 Implementation Guide has been published for patient administrative services; and future activities will include:

- CDA for exchange of clinical record documents in XDS schemes
- critical information interfaces (allergies), and
- National E–health Projects– the National Health Record, E–prescribing and National Medication Service.

HL7 PAKISTAN

A proposal to form an HL7 Pakistan Affiliate is being developed. Key HL7 activities in Pakistan include:

- the Health Life Horizon Project – to interconnect healthcare organizations sharing data in a standard way through HL7 V3 (funded by National ICT RandD Funds Pakistan)
- HL7 System Deployment at CITILab – a renowned clinical laboratory
- collaboration with the SKM Cancer Hospital and Research Centre
- a workshop on HL7 Standards, Secure Electronic Medical Record Exchange and Patient Identification Solutions (June 2009), and
- a comprehensive tutorial at the Frontier of Information Technology Conference (December 2009).

Future activities include a Semantic Electronic Health Record, Telemedicine and Healthcare Devices.

HL7 Pakistan is also looking for research collaborations at PhD level.

HL7 ROMANIA

HL7 Romania is relatively new (established 2006) and still expanding. Recently the National College of Romanian Doctors (a national organization that encompasses all doctors in Romania) joined the association. Most of the important players in medical IT are members. Unfortunately there is little buy–in from Government as yet.

There are a few HL7 pilot projects underway, but in general interoperability between medical IT applications remains a low priority as yet in Romania. Companies are still developing their own solutions that do not work together.

HL7 RUSSIA

HL7 Russia was not represented at this meeting.

HL7 SINGAPORE

HL7 Singapore was not represented at this meeting.

HL7 SPAIN

HL7 Spain's 2009 activities included:

- establishing a Technical Committee on Electronic Prescription; publication of a on "practical interoperability", and building technology platform for services to interoperability
- training and certification, and
- collaborations with industry and educational partners.

Coming events will include:

- hosting a conference in Barcelona in March 2010 – European Health Interoperability Meeting (E–HIM) – in association with E–Health Week
- increasing visible of the role of HL7 standards in European health care interoperability, and
- alliance with IHE Europe.

HL7 SWEDEN

HL7 Sweden was not represented at this meeting.

HL7 SWITZERLAND

Current activities include development of CDA–CH schematron rules, to be balloted in Q1 2010 and planned to be published as a Swiss–Standard by Q3/Q4 2010; and support for the formation of IHE Switzerland.

A coming event is presentation at Info Society Days 2010 (Berne March 8th –12th), which will feature eEducation, eGovernment and e–health Forums.

HL7 TAIWAN

There were well over 350 participants at the 8th Asia–Pacific HL7 Conference, held jointly with the Conference on Medical Informatics, in Taiwan in October 2009. **Australia should look to promote the Sydney meeting at this event.**

The EMR promotion project, funded by DOHA of Health, has now published 108 EMR templates using CDA R2 and hosted 8 workshops on EMR template standards. 2010 priorities will include HL7 v3/CDA R2 training and certification testing, other promotional and educational events, LOINC workshops, and establishment of certification criteria for EMR template standards.

The Taiwan government has approved a budget for accelerating adoption of EMRs (US$ 200 million over the period 2010–2012). A national EMR Committee and an EMR Program Office to plan, coordinate and audit EMR projects are being established. TNIA and HL7 Taiwan will work together on the EMR Program Office Project. By 2012 it is expected that 80% of hospitals (400) and 70% of primary care clinics (14,000) will be using the EMR, and 300 hospitals will be using standardized EMR exchange.

HL7 TURKEY

HL7 V3 has been implemented by Ministry of Health "Health–Net" to collect healthcare information from healthcare providers.

HL7 Turkey's mission is to create awareness of the concepts of interoperability; provide required training at any level from undergraduates to professionals; and coordinate and influence players and deciders. Current challenges include the economic crisis, few organizational members, a sectoral preference for and promotion of complete IS solutions and a lack of understanding of integration concepts.

2010 activities will include establishment of IHE Turkey, vendor meetings, seminars and training, a video campaign and volunteer support for Health–Net (national health infrastructure).

HL7 UK

HL7 U.K. has around 210 members – 110 organisational, 100 personal – and the trend continues to be gradual increase. Activities include:

- universities engagement – teaching has been ongoing since October 2009; further course material is being developed and plans for the future are being discussed
- training for v2 and v3
- NHS Interoperability Toolkit – updating the UK v2 profile to reflect new requirements; and discussion concerning an 'Enterprise Wide Agreement' for access to standards, and
- Three or four Technical Committee meetings per year.

There is increasing use of sponsorship to fund these activities. The HL7 UK 2010 Conference will be held on 3 – 4 March in London. **Australia should look to promote the Sydney meeting at this event.**

HL7 URUGUAY

A Regional South American Conference was held in Uruguay in October 2009, with strong Government support. Topics included interoperability, connectivity, LIS/RIS/PACS and health vocabularies.

HL7 USA

The American Recovery and Reinvestment Act will provide $30 billion for incentives to encourage EHRs. Features include requirements for certified systems (meeting agreed sets of requirements) and meaningful use (the systems are used in meaningful ways). HL7 standards play a prominent role in certification. HL7 has submitted a funding proposal to the Office of the National Co–coordinator.