

IT-014 Health Informatics Committee

Australian Delegation Final Report – HL7 International Working Group Meeting – Cambridge, USA, October 2010



Final Version: 1.2

Date Issued: 8th December 2010

Resubmitted: 28th February 2011

Head Author: Heather Grain, IT-014 Health Informatics Committee Chair

Collated by: Standards Australia

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

- Andy Bond (NEHTA)
- Stephen Chu (NEHTA)
- Sarah Gaunt (NEHTA)
- David O'Driscoll (NEHTA)
- Tina Connell-Clark (NEHTA)
- Richard Dixon-Hughes (Delegate)
- David Rowed (Delegate)
- Heather Grain (Delegate)
- Grahame Grieve (Delegate)
- Hugh Leslie (Delegate)
- Michael Stein (Delegate)
- Klaus Veil (Delegate)

Table of Contents

	<i>Page</i>
Table of Contents	2
1 Recommendations arising from the meeting	5
2 Introduction	9
3 Objectives of the HL7 Meeting	10
4 The Working Group Meeting International Attendance	11
4.1 Australian Leadership Positions at HL7 International	13
Positions held by Australians in the HL7 International Community are identified in the table below.	13
5 Meeting Logistics	14
6 Preparing for January 2011 HL7 Working Group Meeting in Sydney	16
6.1 Background	16
6.2 Actions to Progress the Sydney WGM	17
6.3 Education Program for Sydney 2011 WGM	19
6.4 Required actions	20
7 HL7 International	21
7.1 HL7 International 2009-10 Annual Report	21
7.2 HL7 Election Results and Awards	22
8 HL7 Board, Chair and CEO Reports	23
8.1 Business Model Task Force	23
9 CTO Report	25
9.1 Release of HL7 v3 Normative Edition 2010	25
9.2 Tooling Project	25
9.3 SAIF & SAIF Implementation Projects	28
9.4 General discussion - CTO report	28
10 International Council and Affiliates	28
10.1 Update of Affiliate Agreements	30
10.2 IHIC 2011	31
11 24th HL7 Annual Plenary	32
12 Strategic Board-Level Issues	33
12.1 Management of HL7 Intellectual Property (IP)	33
12.2 Internationalization Task Force (ITF)	34
12.3 Working Group Meetings outside North America – France 2012	35
12.4 HL7 Strategic Initiatives and Roadmap	36
12.4.1 Update of Strategic Initiative documents	36
12.4.2 New process for annual review/approval of Strategic Initiative documents	37
13 HL7 V2/V3/CDA Strategy Taskforce	38
14 Architecture review Board (ArB)	40
15 Clinical Interoperability Council (CIC)	42

16	Decision Support	43
17	Detailed Clinical Models	44
18	Education Committee	46
19	Electronic Health Record WG (EHR)	49
	19.1 EHR Systems Functional Model – Release 2	49
	19.2 NIST Test Procedure for Meaningful Use	51
	19.3 EHR System Design Reference Model (EHR-SD RM)	52
	19.4 hData Specification Overview.....	56
	19.5 HL7 Diabetes Data Analysis Project.....	56
	19.6 Other EHR WG activities.....	57
20	Health Care Provider and Services Directory	59
	20.1 Entity Identification Service	59
	20.2 Privacy, Access and Security Services.....	60
	20.3 SOA Services Ontology.....	60
	20.4 UML and MIF	60
21	Implementation and Conformance (I&C)	61
22	ITS	61
23	Marketing	62
	23.1 Marketing General.....	62
	23.2 EU office	62
	23.3 WHO Membership.....	64
	23.4 Other International outreach.....	64
	23.5 US Outreach - Office of the National Coordinator (ONC).....	64
	23.6 US Outreach - Other agencies and groups.....	67
24	Modeling and Methodology (MNM)	69
25	Orders and Observations (OO) and Laboratory	69
26	PHARMACY	69
	26.1 HL7 V3 Topics	69
	26.1.1 Behavioral model.....	69
	26.1.2 Issue on Supply Quantity.....	70
	26.2 Diet Orders.....	70
	26.3 IDMP	72
	26.4 HL7 V2.x Topic	73
	26.5 Security Ontology Project.....	74
27	Organisational Relations Committee (ORC)	74
28	Patient Care Working Group	75
	28.1 Care Plan.....	76
29	SECURITY	77
	29.1 US Initiatives	77
	29.1.1 National Health Information Network (NHIN)	77
	29.1.2 Federal Identity Credentialing and Access Management (FICAM).....	78
	29.1.3 National Strategy for Trusted Identities in Cyberspace	78
30	SERVICE ORIENTED ARCHITECTURE (SOA) & Health Services Specification Project (HSSP)	78

30.1	Clinical Terminologies	79
31	Structured Documents (SD).....	80
31.1	Implementation Guides	80
31.2	CDA R3.....	80
32	Vocabulary.....	80
32.1	Display name	80
32.2	Core Principles.....	81
32.3	Anatomic Pathology Vocabulary Content Project	81
32.4	Vocabulary Binding – Anatomic Pathology	81
32.5	Vocabulary Authority Reference Anatomic Pathology	82
32.6	Issues discussed with MnM.....	82
32.7	Glossary Project.....	83
32.8	Implementation guidelines for conformance of terminological systems.....	83
32.9	Object IDentifiers (OID) project	83
32.10	Maintenance Process for HL7 Vocabulary	83
32.11	Vocabulary Tooling	84
32.12	Binding Syntax (discussion with Implementation Conformance).....	85
32.13	E-Rules for compositional grammar / Post-coordination	86
32.14	Vocabulary Declaration Issues	86

1 RECOMMENDATIONS ARISING FROM THE MEETING

All actions and recommendations identified by the Australian delegation at the October 2010, HL7 Meeting in Cambridge are summarised in this section.

Issue	Action/Recommendations	Alignment to IT-014 Structure
Delegation	Review the areas of interest to Australia prior to the next meeting	IT-014 and Delegate Selection Committee
Education	Identify Australia's priority on education-related topics being considered by HL7's Education Committee and Marketing Council. Priority will relate to our commitments to education teleconferences over the next few months, and at future HL7 international meetings. Australian guidance from the qualified educators in our recent 'delegations' (Heather Grain and Tina Connell-Clark) have been requested by the HL7 Education Committee in the strategic development and in improvement of educational offerings.	IT-014 especially Heather Grain and Tina Connell-Clark in conjunction with Australian Health Informatics Education Council.
National Priorities	Review the areas of interest to Australia prior to the next meeting.	IT-014, DoHA, NeHTA, SA and Delegation Selection Committee
Sydney HL7 Meeting	<p>We are fast approaching the critical period for people in both Australia/NZ and from around the world to seek approvals and commit to be present in Sydney, therefore the following actions need to be progressed with some urgency, so that the registration website and brochures can be finalised.</p> <p>Action: HL7 Australia (Dixon Hughes & Veil) to research payment options and GST implications and arrange with HL7 HQ on set up and wording of payment collection and receipt/invoicing processes (for implementation in last week of October)</p> <p>Action: HL7 Australia Board to confirm final fees schedule for core registration fees, tutorials, reception and, also, applicable discounts</p> <p>Action: HL7 Australia (Veil & Dixon Hughes) to confirm availability of Standards Australia meeting space for ISEM/WGM activities and, if acceptable, have the space booked and confirm the terms/inclusions/exclusions.</p> <p>Action: HL7 Australia (ISEM Education Team) to finalise details and any additional costs of running the OMG SOA in Healthcare Down Under program as part of the ISEM/WGM to include agreeing pricing, drawcard speakers and publicity by final week of October 2010 for inclusion in both the conference brochure, ISEM/WGM website and online registration.</p>	HL7 Australia, SA and NeHTA

	<p>Action: HL7 Australia (ISEM Education Team) to finalise details and any additional costs of running a CDISC/Clinical Trials tutorial program as part of the ISEM/WGM to include agreeing pricing, drawcard speakers and publicity by final week of October 2010 for inclusion in the conference brochure, ISEM/WGM website and online registration.</p> <p>Action: HL7 Australia (ISEM Education Team) to finalise details and any additional costs of running a seminar program on "Health Information Exchange in Multinational Military and Humanitarian Operations: Issues and Imperatives for Success" as part of the ISEM/WGM to include agreeing pricing, drawcard speakers and publicity by final week of October 2010 for inclusion in the conference brochure, ISEM/WGM website and online registration.</p> <p>Action: HL7 Australia (ISEM Education Team) to finalise details and any additional costs of running any other additional education activities (<i>openEHR</i> tutorials, regulatory forum, IHE forum) as part of the ISEM/WGM to include agreeing pricing, drawcard speakers and publicity by final week of October 2010 for inclusion in the conference brochure, ISEM/WGM website and online registration.</p> <p>Action: HL7 Australia (Dixon Hughes) to finalise Cliftons contract and pay deposit.</p> <p>Action: HL7 Australia to engage in significant local Australia and Asia/Pacific marketing campaign to sell uptake of ISEM/WGM activities as soon as online registration becomes available.</p>	
<p>V2/V3/CDA strategic taskforce</p>	<p>This Task Force (TF) is looking at issues surrounding HL7 product uptake and strategy using a widespread consultation process. Several key Australian representatives have been interviewed. The Task Force is now formulating recommendations for presentation to the Board of HL7 International. Richard Dixon Hughes and Grahame Grieve are members of 10-member TF and arranged for a range of key Australian experts to have input to the process. At one point, it looked as if the Task Force leadership was focussing on promoting a particular approach without addressing the diversity of views from the consultation process; however, it has now been agreed that the TF will make findings on each area within its scope.</p> <p>Action: Australians on the HL7 v2/v3/CDA TF to continue encouraging outcomes that address the diversity of opinions and views offered through the consultation processed.</p>	<p>IT-014, all subcommittees and HL7 Australia</p>
<p>CDA alignment with Structured Documents</p>	<p>It was proposed that Canada Health Infoway should list and discuss extension requirements and CDA alignment with Structured Documents WG, Australia should consider our requirements also.</p>	<p>IT-014, subcommittees, IT-014-06, IT-014-06-05, IT-014-09 and NeHTA (Sarah Gaunt)</p>
<p>Glossary</p>	<p>IT-014, IT-014-02 and IT-014-06 need to be aware of any requirement to active contribution and consideration of resource requirements.</p>	<p>IT-014, IT-014-02 and IT-014-06</p>

Detailed Clinical Models	DCM activity at HL7 PC WG is now being monitored closely in light of potential incompatibilities with requirements being supported by Australian experts in ISO. This needs to continue with a view to ensuring that the HL7 DCM projects meet Australian needs and don't divert excessive resources from other work. Monitoring should consider archetypes as one useful and pragmatic approach to DCM development in Australia. Action: IT-014 (IT-014-09 lead – in collaboration with IT-014-02 and IT-14-06-06) and NEHTA to continue focussing on ISO DCM standards and to seek to ensure that development of DCMs under aegis of HL7 PC WG conforms to emerging ISO requirements.	IT-014, IT-014-09, IT-014-06, SA and NEHTA
Security and privacy ontology	IT-014-04, IT-014-09, NEHTA and relevant Australian experts to review and provide further Australian input to ensure that the Security and Privacy Ontology is correct and that any local requirements can be covered in the model.	IT-014-04, IT-014-09, NeHTA and invite relevant experts from IT-012 (IT Security)
SOA and Clinical terminologies	IT-014 and NEHTA and relevant Australian experts to monitor activity in the space to ensure harmonisation with Australia initiatives and the outcomes of the OMG CTS2 RFP process in February 2011. Advice to be provided to the Australian Vocabulary WG co-chair to assist in strong representation of our requirements and views.	IT-014, NeHTA and relevant experts from other SA committees
Clinical Decision Support	IT-014 need to determine the working groups to have oversight of the clinical decision support work at ISO and the priority for HL7 involvement. It began in IT-014-02 as a mechanism for representation of safety and quality concepts, but also fits and is relevant to IT-014-06, and IT-014-09.	IT-014, IT-014-02, IT-014-06 and IT-014-09
Patient Provider Directory	IT-014 and NEHTA to monitor progress of a Patient and Provider Directory SFM and identify national priorities for this work and ensure harmonisation with existing ISO and national initiatives.	IT-014 and NeHTA
SOA services ontology	IT-014 and NEHTA to monitor the development of the SOA Services Ontology and provide input into the development based on local experience and requirements.	IT-014 and NeHTA
SAIF	That IT-014/HL7 seek advice from suitable health informatics educators on material and structure be sought to improve structure and delivery of SAIF tutorials for next meeting.	IT-014 and HL7 Australia
Clinical Terminology Core Principles	This document is one that needs to be carefully reviewed by NEHTA, and IT-014-06 in particular as it relates to the incorporation of vocabulary in CDA content, IT-014-02 should also give input.	IT-014-06, IT-014-02 and NeHTA
Maintenance processes for HL7 vocabulary	HL7 Australia, IT-014-06 and Nehta need to be aware of safety issues related to the terminology releases by some SDOs and to consider Australia's required action/s.	IT-014-06, HL7 Australia and NeHTA
Vocabulary tooling	NEHTA, HL7 Australia and IHTSDO governance members to be made aware of current issues (e.g. use of external code systems and lack of representation of multiple code systems) to inform IHTSDO and HL7.	IT-014-02, IT-014-06, HL7 Australia. NeHTA and IHTSDO
e-rules for Compositional Grammar in Clinical Terminology	Consider the impact upon Australian implementation guides and standards. IT-014-06	IT-014-02, IT-014-06, NeHTA(NCTIS)
Vocabulary Declaration Including Core	Vocabulary declaration will be a major item for discussion at the Sydney meeting. IT-014 should circulate information on the intent and utility of core principles and these issues to the community to support attendance.	IT-014

Principles		
HL7 Business Model Task Force	<p>Given the potential strategic impact of this work on international engagement with HL7 and the cost of using HL7 products, it is important that HL7 Australia track and report developments as they emerge.</p> <p>Action: HL7 Australia to track developments of the new HL7 Business plan, reporting to Australian stakeholders as details are released and organising timely feedback as and when required.</p>	
Board of HL7 International – review of IP management strategies	<p>The Board of HL7 International has engaged attorneys to give advice and has many significant issues still to consider in developing its IP management strategies and new business model. As a qualified lawyer with an Australian/ international perspective, Richard Dixon Hughes has been assisting HL7 executives in this endeavour.</p> <p>Action: Richard Dixon Hughes to continue assisting HL7 International resolve legal issues surrounding the licensing of its intellectual property in HL7 standards.</p>	
Annual update of HL7 vision, mission, strategic initiatives and strategic initiative criteria	<p>Since the HL7 Board approved Version 1.0 of the Strategic Initiatives in December 2009, criteria for measuring their adoption have been under development with input from the Board, the Roadmap Committee, the Advisory Council and the TSC with the aim of making them more relevant and directly useful in the operational management of HL7 International.</p> <p>The Board has implemented a new process to keep the HL7 vision, mission and strategic initiatives fresh on a yearly basis and facilitate operationalisation of the strategic vision through strategic criteria. This involves seeking democratic input by submitting them to ballot for comment at the end of each calendar years.</p> <p>Action. HL7 Australia and IT-014 to review HL7 vision, mission, strategic initiatives, and strategic initiative criteria each year and consider commenting for January ballot cycle.</p>	
Review of proposed "Statement of Understanding" to replace MOUs.	<p>HL7 International is introducing a new statement of understanding (SOU) to replace the different types of memorandum of understanding and other agreements currently being used to document ongoing relationships between HL7 and other organisations.</p> <p>Action. When requested, HL7 Australia to review the proposed SOU template and make appropriate comments.</p>	HL7 Australia
Review and use of materials from HL7 Martopia consultancy	<p>HL7 Australia should review outputs of the work of the Martopia marketing consultants, with a view to giving timely input on international needs and to considering local use of the resulting materials.</p> <p>Action: HL7 Australia to follow progress of the Martopia work, with a view to ensuring that the resulting outputs are relevant to HL7's international context and how the resulting materials can be used in the Australian to assist in publicising HL7 capabilities in Australia.</p>	HL7 Australia
International Council and	<p>The current Affiliate agreements expire on 31 December 2010 and are being reviewed by HL7 International. A draft of the new</p>	HL7 Australia

<p>Affiliates: 1. Review & renewal of Affiliate Agreements</p>	<p>common-form agreement has now been circulated and needs to be reviewed and agreed. Action: HL7 Australia to consider proposed changes to the Affiliate agreement.</p>	
<p>International Council and Affiliates: 2. US\$5,000 for WGM assistance</p>	<p>The Affiliate Chairs agreed to go to email ballot on a proposal to allocate US\$5,000 from their 2010 budget allocation –for HL7 Australia to use in assisting affiliates from developing and emerging economies to be represented at the Sydney WGM.. Action: HL7 Australia to confirm availability of funding to support the developing and emerging countries at the Sydney WGM and, if approved, design and conduct a process to allocate these funds in a fair and transparent way.</p>	HL7 Australia
<p>International Council and Affiliates: 3. Assist HL7 growth in the Philippines</p>	<p>International Mentoring Committee (IMC) are engaging with parties in the Philippines keen to facilitate implementation of HL7 protocols to support the Government's new priority for e-health. Action: HL7 Australia to communicate with the IMC with a view to facilitating some involvement of Philippines interests in the Sydney ISEM/WGM</p>	HL7 Australia
<p>International Council and Affiliates: 4. Australian requirements for IP</p>	<p>Discussions about the obligations of Affiliates in relation to intellectual property (IP) rights raised questions about current Australian practices, our requirements and ensuring that our needs are met (carried forward from May 2010 report) Action: HL7 Australia Board to review Australian requirements for use of HL7 IP, including discussion with Standards Australia as appropriate.</p>	HL7 Australia and Standards Australia
<p>Marketing Council University program</p>	<p>An active campaign is underway to increase the number of universities teaching HL7 standards as part of postgraduate Health Informatics programs. HL7 International are developing an education strategy and it would be appropriate to have Australian input both university, professional and vocational into that process. Action: HL7 Australian and the Australian Health Informatics Education Council (AHIEC) advise members of these developments to encourage participation.</p>	HL7 Australia, AHIEC

2 INTRODUCTION

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

The Australian delegation at the HL7 meeting in October 2010 included representatives from NEHTA as well as members attending on behalf of their employer organisations. The contributions of delegates and other representatives in the Australian team were invaluable. The team approach is collaborative with all members working in partnership to ensure Australia's requirements at the meeting are achieved in the most effective way in the national and public interest. This also allows

the achievements of the delegation to be enhanced through mutual backup, support and input.

This report identifies priority areas for strategic engagement from all relevant parties who have an interest in the national eHealth agenda and quality/safe health information management in Australia. The report also provides an update on areas identified in previous reports as requiring ongoing input.

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

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

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

For details of IT-014 subcommittees and working groups contact Naomi Ryan of Standards Australia (naomi.ryan@standards.org.au). References provided in the text to wikis can be accessed with the user name *wiki* and password *wikiwiki*. Access to references at HL7.com can be obtained via the members only web page of HL7 Australia.

3 OBJECTIVES OF THE HL7 MEETING

The event is a true working meeting, not a conference, with many individual groups meeting to develop, discuss and improve HL7 standards, processes and implementation guides and to determine the most effective way to meet the needs of the stakeholders over 6.5 days

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 (e.g. vocabulary submission requirements).

The number of concurrent sessions makes it difficult 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 assisted in our capacity to cover the most important Australian requirements at the Cambridge meeting.

4 THE WORKING GROUP MEETING INTERNATIONAL ATTENDANCE

Analysis of pre-registration documentation showed that this meeting had more than 550 participants from 24 countries.

There were 12 Australians representatives at this HL7 meeting most of whom have contributed to this report. The funding source for these delegates is indicated in Table 1 below.

Table 1 Delegation by funding source

Funding Source	Number	Change from Previous meeting
Full funding by employer: Private	0	0
Full funding by employer: States/Territories or National Initiatives (NeHTA)	5	0
Full funding – DOHA through Standards Australia contract	7	+1
Total:	12	0

The DOHA funded delegates were selected through an independent panel process jointly with NEHTA, DOHA and Standards Australia.

Figure 1, below 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 and previous meetings. The number of countries attending (24) and was slightly higher than the average of 22 countries. Attendance from major supporting countries such as Canada and Japan were consistent, while the UK's policy on international travel significantly reduced their attendance. Attendances from other European nations including the Netherlands, Italy, and Spain were higher than in previous occasions.

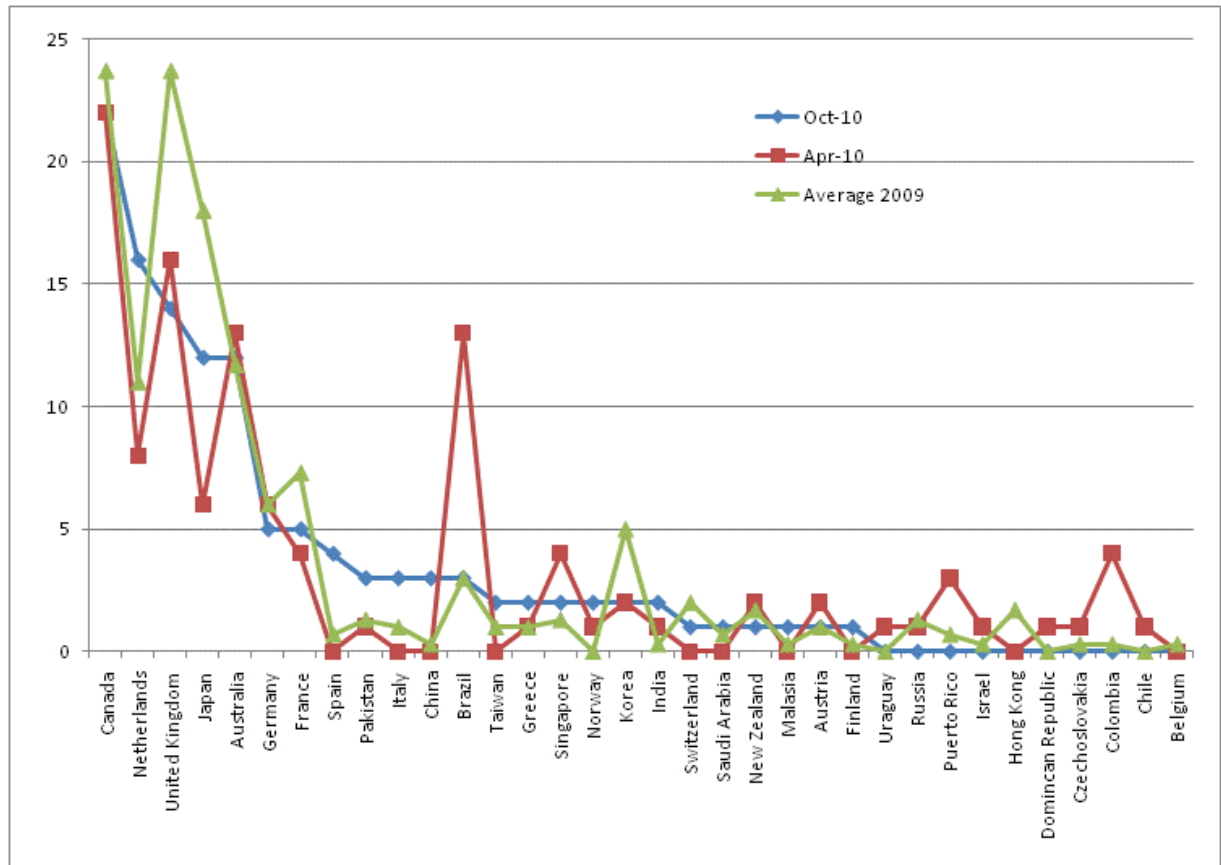


Figure 1 International Attendees

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

The USA traditionally has the largest number of attendees which is around 70% of all attendees at meetings in the USA and 43% for meetings outside the USA. This meeting had a particularly strong US contingent, with 78% of attendees from the USA. This was the first time in recent years that HL7 has held a working group meeting in the North East of the USA and was rewarded with 550 registrants (including HL7 staff).

Following previous recommendations, support for the Australian delegation has continued and the opportunity will exist to extend and improve knowledge and expertise in this area through Australia holding an HL7 international meeting in Sydney in 2011.

Ongoing delegation support is appreciated and required to continue progress in this area. Improvements in the delegate selection process and transparency have occurred and will continue to be monitored for ongoing improvement.

4.1 AUSTRALIAN LEADERSHIP POSITIONS AT HL7 INTERNATIONAL

POSITIONS HELD BY AUSTRALIANS IN THE HL7 INTERNATIONAL COMMUNITY ARE IDENTIFIED IN THE TABLE BELOW.

Work Group or Committee	Position	Status	Person
Advisory Council to the Board of HL7 International	Chair (and ex-officio, non-voting member of Board of HL7 International)	Current	Richard Dixon Hughes
Architectural Review Board	Member	Current	Andy Bond
	Member	Current	Grahame Grieve
Community Based Collaborative Care Work Group	Co-Chair	Current	Max Walker
Conformance Work Group	Co-Chair	Current (re-elected for 2 years)	Jane Gilbert
International Organizing Committee for Jan 2011 WGM in Sydney	Co-Chair	Current	Richard Dixon Hughes
	Member	Current	Vince McCauley
	Member	Current	Chris Lynton-Moll
	Invited Member	Education Committee Liaison & International promotion	Klaus Veil
	Invited Member	NEHTA Liaison, sponsorship and promotion	Tina Connell-Clark
Internationalization Task Force	Member and Chair of Governance Sub-group	Current	Richard Dixon Hughes
Modeling and Methodology Work Group	Co-Chair	Current	Grahame Grieve
Organisational Relations Board Committee	Member	Current	Klaus Veil
Patient Care Work Group	Co-Chair	Current	Klaus Veil
	Co-Chair	Current	Stephen Chu
Structured	Co-Chair	Current –	Grahame Grieve

Documents (Developers of CDA)		elected to 2 year term at this meeting	
V2.x Publishing Work Group	Co-Chair	Current	Klaus Veil
V2/V3/CDA Product Strategy Task Force	Member	Current	Richard Dixon Hughes
	Member	Current	Grahame Grieve
Vocabulary	Co-Chair	Current	Heather Grain

Funding for Individuals

Richard Dixon Hughes - Standards Australia via the DoHA Funding Agreement

Heather Grain - Standards Australia via the DoHA Funding Agreement

Grahame Grieve - Standards Australia via the DoHA Funding Agreement

Klaus Veil - Standards Australia via the DoHA Funding Agreement

David Rowed (Delegate) – Standards Australia via the DoHA Funding Agreement

Hugh Leslie (Delegate) – Standards Australia via the DoHA Funding Agreement

Michael Steine (Delegate) – Standards Australia via the DoHA Funding Agreement

5 MEETING LOGISTICS

HL7 International Working Group Meetings cover 7 days (though this meeting was shorter due in part to overlap with ISO meeting dates and concluded in 6.5 days), with formal meetings occurring from 8am start to 5pm and 10pm (and sometimes later) finishes daily. There are additional executive meetings on the Saturday which are not shown here. The meeting is truly a working meeting as each of the groups identified in Table 3 meet to develop, discuss and improve HL7 standards, processes, implementation guides and to determine the most effective way to meet the needs of the stakeholders at the meeting and in the community. Though community engagement outside the meetings is strong (through regular, often weekly teleconferences) the ability to influence outcomes requires physical presence at the meeting.

	Sun	Mon	Tue	Wed	Thur	Fri
HL7 International Council	X				X	
Anatomic Pathology		X	X			
Architectural Review Board (ArB)	X		X	X	X	
Board of Directors		X				
Affiliates' Council	X					
Architectural review Board (ArB)	X		X		X	
Clinical Decision Support		X		X	X	
Clinical Interoperability Council			X	X		
Clinical Statement					X	
Community Based Collaborative Care		X	X	X		
Education		X	X		X	
Electronic Health Records		X	X	X	X	
HL7 activities with other SDOs	X					
HL7 meeting for nurses			X			
Imaging Integration			X	X		
Implementation conformance		X	X	X	X	
Implementation Technology Specification		X	X	X	X	
Infrastructure and Messaging			X			
Marketing Council			X		X	
Modeling and Methodology	X	X	X	X	X	X
Orders and Observations		X	X	X	X	X
Patient Administration		X	X	X	X	
Patient Care		X	X	X	X	X
Patient Safety		X	X	X		
Pharmacy		X	X	X	X	X
Process Improvement			X			
Public Health Emergency Response		X	X	X	X	X
Regulated Clinical Research Information Management			X	X	X	
Security		X	X	X	X	
Services Oriented Architecture			X	X	X	X
Structured Documents		X	X	X	X	X
Templates					X	X
Tooling			X		X	
Vocabulary	X	X	X	X	X	

Table 2 Meeting Schedule highlighting areas of major Australian interest

Table 2 shows the meeting schedule for some of the larger meeting groups. There were 61 separate working groups and committees, Board and Council meetings at this meeting compared to 50 in Rio.

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 found it sometimes difficult to cover all areas of interest to Australia at this meeting.

Action: Review the areas of interest to Australia prior to the next meeting – Action for delegation selection committee.

6 PREPARING FOR JANUARY 2011 HL7 WORKING GROUP MEETING IN SYDNEY

6.1 BACKGROUND

After preparatory discussions and presentations to HL7 meetings throughout 2009, HL7 Australia submitted a proposal to the Board of HL7 International to hold the international WGM for 2011 in Sydney in January 2011.

This proposal was developed with assistance from an Advisory Group comprising representatives from HL7 Australia, Standards Australia, IT-014 and NEHTA, and two observers from the Department of Health and Ageing (DoHA). At its December meeting, the Board of HL7 International tentatively accepted the proposal from Australia, subject to

- (a) HL7 Australia providing at least \$A100,000 in local sponsorship, to assure financial viability;
- (b) HL7 International being able to make a satisfactory exit from pre-existing arrangements to hold the January 2011 WGM in Florida; and
- (c) being able to enter into suitable contracts with potential meeting venues in Sydney.

An HL7 International staff member undertook a site visit in February 2010, partly funded by HL7 Australia and Business Events Sydney and was shown a range of potentially suitable options for meeting venues and accommodation.

At the May 2010 WGM in Rio de Janeiro, the Board of HL7 International noted that the three pre-conditions had been met with the assistance of sponsorship commitments of \$50,000 from DoHA and \$30,000 from NEHTA, successful deferral of venue bookings for the Florida meeting and the availability of suitable premises at Cliftons training centre and the Amora Hotel.

However, faced with a significant shortfall of around \$150,000 from the Rio meeting, the Board of HL7 International subsequently resolved that continuing with the January 2011 WGM in Sydney would also be conditional on HL7 Australia accepting responsibility for the financial outcome (profit/loss).

Following discussion with NEHTA and DoHA as cornerstone sponsors and a review of the potential costs and its financial position, the Board of HL7 Australia resolved to accept the revised conditions subject to terms that included HL7 Australia having ultimate control over expenditure. This was formalised by exchange of letters between HL7 Australia and HL7 International.

The significant benefits for Australia in securing the WGM include:- widening the opportunities for Australian participation; understanding and influencing the work of HL7 in e-health standards; and in leveraging the attendance of international experts for local education, training and other purposes. HL7 capacity building is a critical success factor in increasing Australia's capabilities to undertake e-health implementation on a national scale.

An International Organizing Committee (IOC) meets most weeks to coordinate management of the event with Richard Dixon Hughes (Treasurer of HL7 Australia) and Mark McDougall (Executive Director of HL7 International) as co-chairs. Regular attendees from Australia include Klaus Veil and Tina Connell-Clark. Others regularly attending these meetings include the HL7 Events Manager – Lillian Bigham, the two International members of the Board of directors of HL7 International – Michael van Campen and Catherine Chronaki, the HL7 International Treasurer – Hans Buitendijk, and the Secretary of the HL7 Technical Steering Committee – Helen Stevens-Love.

HL7 has identified critical success factors for a successful HL7 International WGM that include: -

- financial viability (to date, all WGMs held outside North America have made a substantial loss, which is now impacting on HL7 International's other activities);
- sufficient participation of appropriate technical experts to ensure that standards development work can be successfully progressed at the WGM; and
- advancing perceptions of HL7 International as a global organisation.

HL7 Australia's priorities have been to work with HL7 International (who will continue to provide their WGM management expertise) to finalise cost effective venue and accommodation arrangements, see that HL7 Australia's interests are protected and to increase efforts to secure further funding opportunities to complement existing sponsorships.

Publicising and progressing arrangements for the Sydney 2011 Working Group Meeting (locally co-branded International Standards & Education Meeting in Australia/NZ – ISEM/WGM) was a major focus for all Australian delegates at the Cambridge meeting and most of the delegates were involved and are likely be reporting on their part in these activities.

Our work in these areas has been greatly strengthened by an active collaboration with HL7 New Zealand and their involvement in organising the event.

HL7 Australia is particularly grateful for the staff support that it has received from NEHTA in organising for promotion of the Sydney 2011 ISEM/WGM in Cambridge.

6.2 ACTIONS TO PROGRESS THE SYDNEY WGM

The following are among the key issues addressed and the many activities undertaken in Cambridge with the aim of ensuring the success of the Sydney 2011 ISEM/WGM:

- Participation. Obtaining sufficient participation in the Sydney ISEM/WGM that includes a most of those in leadership positions across HL7 has been identified as essential if the event is to meet the critical success factors of: financial viability, progression of the HL7 work program and enhancing the image of HL7 International, HL7 Australia and the sponsors of the event.

14 work groups did not meet at the previous international meeting in Rio de Janeiro, and some others struggled for quorum and/or sufficient knowledge and expertise to enable effective meeting outcomes.

HL7 Australia has adopted an ambitious target of trying to ensure that no more than 6 work groups do not meet in Sydney and, of those that meet, over 90% achieve quorum and have effective technical leadership.

- All members of the Australian delegation participated in significant marketing of the Sydney 2011 ISEM/WGM at the Cambridge meeting in order to encourage attendance in Sydney. Specific initiatives included:

- Promotional presentation to the International Council at its meeting on Sunday, 3 October
- Promotional presentation to the General Session on the morning of Tuesday, 5 October
- Promotional presentation including Australiana quiz and give away at the main reception event on the General Session on the evening of Wednesday, 6 October
- Use of distinctive baseball caps and T-shirts to identify the Australian delegation and others who were actively promoting attendance in Sydney.

The 30 baseball caps were particularly sought after and were gifted on to others most active in promoting attendance in Sydney.

The T-shirts were put on sale at US\$20 with sufficient being sold to almost cover the supply cost with a substantial residue being bought back for sale and promotion of the Sydney ISEM/WGM at HL7/NEHTA events in Australia. It is considered that active selling of the T-shirts also had the effect of publicising the event, even when a T-Shirt was not bought.

- HL7 registration staff brought the Sydney event to the attention of each registrant as they collected their registration packs – offering them a clip-on Koala and a booklet promoting Sydney (both courtesy of Business Events Sydney (BES) and shipped to Boston by the Australian delegates). Those planning or thinking of attending were encouraged to leave their email addressed for inclusion on the email list for Sydney 2011 information – with over 100 additional names understood to have been added to the contact list for Sydney 2011.
- The clip-on Koalas were very popular and HL7 registration staff received many requests for more than one. Excess Koalas were used as further collateral to help promote the event and to sell the remaining Sydney 2011 T-shirts.
- Work groups and key individuals that were wavering in their commitment to attend were individually targeted with strategies crafted to try and ensure that they would come to Sydney or take other steps to ensure that the Sydney 2011 ISEM/WGM would be well attended and productive.
- With assistance from HL7 HQ staff who were tracking the intended attendance of WG co-chairs in Sydney, likely gaps in co-chair participation were identified in time to enable appointment of interim co-chairs to be organised during face-to-face meetings in Cambridge, ensuring that the work of some committees could be continued in Sydney.
- Specific discussions were held with key individuals to explore what could be done to ensure their attendance, including considering whether paid roles might

be available to participate in the delivery of HL7 tutorials and other incidental education events

- Discussions were held with key groups able to mount events to attract additional participation in Sydney in particular, the Object Management Group (OMG), the US military, CDISC, the RCRIM WG, the Pharmacy WG and Ocean Informatics (in relation to *openEHR*).
- Richard Dixon Hughes and Klaus Veil were asked to give an update to the Affiliate Chairs on the current status and progress of the arrangements for the Sydney 2011 ISEM/WGM and report on lessons learnt.

In a significant gesture, the Affiliate Chairs put forward a proposal to allocate US\$5,000 from their 2010 budget allocation (around 25% of International Council's 2010 funds) for HL7 Australia to use in assisting affiliates from developing and emerging economies to be represented in Sydney. Confirmation of the allocation is subject to a 21-day email ballot, with confirmation yet to be received at the time of writing this report.

Once the funds are confirmed HL7 Australia will need to arrange a process for delegate selection.

These marketing activities were jointly pursued by the members of the Australian delegation, the HL7 HQ leadership team and HL7 event management staff - with a high degree of collaboration and teamwork being achieved.

MOH Holdings Pte Ltd in Singapore – the e-health implementation arm of the Singaporean national health system was well represented at the Cambridge meeting and their personnel were very interested in participating in Sydney. Given their proximity and interest, it is important that HL7 Australia offer a particular welcome to potential delegates from Singapore and MOH holdings in particular. Dr Linda Bird, formerly with DSTC and NEHTA now works for MOH Holdings from Brisbane and agreed to advise on promoting the Sydney 2011 ISEM/WGM with Singaporean interests.

6.3 EDUCATION PROGRAM FOR SYDNEY 2011 WGM

Under the leadership of Klaus Veil and Max Walker, considerable work has taken place developing a progressive educational program to be run as part of the 2011 ISEM/WGM in Sydney – with strong input from HL7 New Zealand, NEHTA, the Education Committee of HL7 International and also from Richard Dixon Hughes and other members of the HL7 Australia Board.

In Cambridge, the ISEM/WGM education component was advanced by follow-up with influential members of HL7 and the potential wider stakeholder community at every opportunity, including:

- Identifying potential ways in which participation in educational activities (as guest speakers etc) might help ensure that a critical mass of significant experts is able to justify the cost and time of coming to Sydney to participate in the ISEM/WGM.

In particular, efforts on this front appear to have helped secure commitments to attend from the Pharmacy WG, PC WG, RCRIM WG and from some US Government representatives.

- Klaus Veil attended meetings of the HL7 International Education Committee and secured their agreement to a modified and extended tutorial program, including new content specifically tailored to current needs in Australia/NZ.

Arrangements for associated education and training were progressed and will take two forms – (a) that delivered routinely in WGMs (i.e. tutorials); and (b) satellite events arranged by HL7 Australia.

Tutorial requirements for the meeting in Sydney in January, 2011 have been reviewed to determine which tutorials will be required for the Australian audience, and which tutors are best equipped to deliver these. While there was an initial preference to focus on having many more Australian tutors, this trend has been moderated by realisation been

- Richard Dixon Hughes, Tina Connell-Clark, Klaus Veil and Andy Bond met with Richard Soley, Chairman & CEO of the Object Management Group (OMG), Ken Rubin and another
- Klaus Veil had discussions with Bron Kisler about CDISC involvement – which is likely to provide a series of 4 tutorials of interest to those involved in clinical trials, clinical research and the regulation of these activities – and broadening the appeal of WGM attendance to a broader base.
- Klaus Veil and Richard Dixon Hughes had a series of meetings with active HL7 members from the US military health services and engaged with Nancy Orvis, Peter Park, Caterina Lasome, David Parramore and Nhan Do on the potential to run a full-day seminar on "Health data exchange in humanitarian and military operations: Experiences, issues, and future directions" or similar. The title was modified from an earlier emphasis on "coalition military operations".

6.4 RECOMMENDED ACTIONS

We are fast approaching the critical period for people in both Australia/NZ and from around the world to seek approvals and commit to be present in Sydney, therefore the following actions need to be progressed with some urgency, so that the registration website and brochures can be finalised.

Action: HL7 Australia (Dixon Hughes & Veil) to research payment options and GST implications and arrange with HL7 HQ on set up and wording of payment collection and receipt/invoicing processes (for implementation in last week of October)

Action: HL7 Australia Board to confirm final fees schedule for core registration fees, tutorials, reception and, also, applicable discounts

Action: HL7 Australia (Veil & Dixon Hughes) to confirm availability of Standards Australia meeting space for ISEM/WGM activities and, if acceptable, have the space booked and confirm the terms/inclusions/exclusions.

Action: HL7 Australia (ISEM Education Team) to finalise details and any additional costs of running the OMG SOA in Healthcare Down Under program as part of the ISEM/WGM to include agreeing pricing, drawcard speakers and publicity by final week of October 2010 for inclusion in both the conference brochure, ISEM/WGM website and online registration.

Action: HL7 Australia (ISEM Education Team) to finalise details and any additional costs of running a CDISC/Clinical Trials tutorial program as part of the ISEM/WGM to include agreeing pricing, drawcard speakers and publicity by final week of October 2010 for inclusion in the conference brochure, ISEM/WGM website and online registration.

Action: HL7 Australia (ISEM Education Team) to finalise details and any additional costs of running a seminar program on "Health Information Exchange in Multinational Military and Humanitarian Operations: Issues and Imperatives for Success" as part of the ISEM/WGM to include agreeing pricing, drawcard speakers and publicity by final week of October 2010 for inclusion in the conference brochure, ISEM/WGM website and online registration.

Action: HL7 Australia (ISEM Education Team) to finalise details and any additional costs of running any other additional education activities (*openEHR* tutorials, regulatory forum, IHE forum) as part of the ISEM/WGM to include agreeing pricing, drawcard speakers and publicity by final week of October 2010 for inclusion in the conference brochure, ISEM/WGM website and online registration.

Action: HL7 Australia (Dixon Hughes) to finalise Cliftons contract and pay deposit.

Action: HL7 Australia to engage in significant local Australia and Asia/Pacific marketing campaign to sell uptake of ISEM/WGM activities as soon as online registration becomes available.

7 HL7 INTERNATIONAL

There was one new affiliate announced which was Pakistan and two others that were moving towards affiliation – Bosnia-Herzegovina and Puerto Rico.

HL7 Ireland has lapsed and the affiliation has been terminated. HL7 Denmark and HL7 Mexico are both in danger of being terminated if there is no activity.

HL7 International are looking closely at a new business model to take the organisation forward. The plan is to introduce the new business model and have new revenue streams by 2012. HL7 are introducing a new strategic initiatives process which will set the overall agenda for the organisation from year to year. This process is still being worked out but is likely to work through a ballot process from year to year in November with draft ballots in January and final board approval by the following November. It remains to be seen whether this is going to be flexible enough to take HL7 forward.

7.1 HL7 INTERNATIONAL 2009-10 ANNUAL REPORT

HL7 International published a formal annual report for the first time in June 2010 with printed copies being available at the Cambridge meeting. It contains the following sections:

- Mission and Vision
- CEO Report
- 2010 Chair Report
- 2009 Chair Report
- Work Groups
- CTO Report

- 2009 Standards Snapshot
- TSC Chair Report
- Executive Director Report
- International Council Report
- HL7 Affiliates & Board of Directors
- Treasurer Report

Copies may be downloaded from:

http://www.hl7.org/documentcenter/public/twitter/HL7_TWITTER_20100603.pdf

7.2 HL7 ELECTION RESULTS AND AWARDS

The following are the results of elections to various HL7 offices announced at the Cambridge meeting.

Office	Elected	Comment
HL7 International – Board of Directors		
Chair-elect of HL7 International	Dr Don Mon	Don becomes Vice-Chair for 2011, replacing Dr Ed Hammond, as Immediate Past Chair in 2010. He then becomes Chair in 2012-13.
Secretary of HL7 International	Dr Jill Kaufman	Re-elected for further 2-year term.
Board member 2011-12	Keith Boone	Keith has a strong technical background and works as a software engineer for GE Medical and is the HL7 technical liaison to IHE.
Board member 2011-12	Dr Ed Hammond	Ed returns as an elected Board member on conclusion of his term as Vice Chair in Dec.
Affiliate director	Catherine Chronaki	Re-elected for further 2-year term.
HL7 International – Technical Steering Committee (for 2011-12)		
Domain Experts Steering Division	Ed Tripp	
Foundation and Technology Steering Division	Tony Julian	
Structure and Semantic Design Steering Division	Gregg Seppala	
Technical and Support Services Steering Division	Patrick Loyd	
Affiliate Representative	Jay Zimmerman	

Office	Elected	Comment
HL7 International – Work Group Co-Chairs (to Sep/Oct 2012)		
Anatomic Pathology	David Booker	
Attachments	Jim McKinley	
Clinical Decision Support	Howard Strasberg	
Clinical Interoperability Council	Sam Brandt	
Education	Abdul Malik Shakir	
Electronic Services	Bill Braithwaite	
Emergency Care	Peter Park	
Financial Management	Beat Heggli	
Health Care Devices	Patty Krantz	
Implementation/Conformance	Jane Gilbert	AHML Pty Ltd, Ballarat, Australia
InM	Dave Shaver,	
	Sandy Stuart	
MnM (Modelling & Methodology)	Woody Beeler	
Orders and Observations	Ken McCaslin	
Patient Safety	Nick Halsey	
PHER (Public Health Emergency Response)	Joginder Madra	
	John Roberts	
RIMBAA - RIM Based Application Architecture	Amnon Shabo	
Tooling	Tim Ireland	
Vocabulary	Jim Case	

14th Annual W. Edward Hammond, PhD Volunteers of the Year Award

- Stan Huff, MD
- Julie James/Hugh Glover
- Charlie Mead, MD
- Mark Shafarman
- Pat Van Dyke
- Mead Walker

8 HL7 BOARD, CHAIR AND CEO REPORTS

The following are among the more significant matters raised at the HL7 International Board or in the reports of the HL7 Chair (Dr Bob Dolin) and the CEO (Dr Charles Jaffe).

8.1 BUSINESS MODEL TASK FORCE

After the Rio meeting, the Chair of HL7, Bob Dolin, asked Dr Don Mon to chair a Business Model Task Force to flesh out the details of key business reforms being considered by the HL7 board, which include many suggestions raised by the Advisory Council and the Board members at the Board retreat held in July this year.

At the Board retreat, broad consensus was reached on principles around a new business model under which HL7 is looking to receiving more of its revenue from stronger commercial exploitation of the IP rights in its standards products from the start of the 2012 year – ideally through licensing at national level around the globe, but if that is not possible, by tapping a broader revenue base among users of HL7 IP without relying so heavily on those who have traditionally chosen to do the right thing and become members of HL7 and its affiliates.

In August 2010, HL7 HQ issued an RFP for a person to take on the role of "HL7 Business Plan Manager/Developer" and undertake a project expected to last approximately a year to operationalize HL7's new business model, including:

- constructing a detailed work plan, including tasks and timelines, that lead to new revenue accruing to the organization by Q1 2012;
- formulating options and evaluating the many details of the model, and
- developing a formal business plan document for adoption and implementation by January 2012.

Having evaluated the various proposals that were received, the Business Model Task Force recommended that HL7 contract with Ms Virginia Riehl to undertake the work through to December 2011. The proposed approach embodies four phases of development:

- (1) Develop business model framework,
- (2) Develop detailed business model,
- (3) Specify implementation plan, and
- (4) Track and coordinate implementation.

Virginia has considerable background in current HL7 issues, having provided consultancy support to the HL7 v2/v3/CDA Task Force and also having facilitated strategic planning sessions for both the Advisory Council and the Board at this year's annual retreat.

It has been recognized that the business model will be tightly coupled to the development of appropriate solutions for management of HL7 International's intellectual property (IP).

Specific areas expected to be addressed by the HL7 business plan include standard business plan components, such as:

- Products/Services being offered
- Public relations plan (e.g. how will we gauge the public reaction before executing the plan)
- Image marketing and customer outreach plan
- Customer analysis and segmentation (e.g. who are the intended customers for this plan)
- Value proposition (e.g. what is the value of this offering to our intended customers)
- Legal/IP analysis (e.g. what legal or IP issues are relevant, and how the plan addresses them)
- Financial analysis (e.g. how will we price the products/services being offered)

- Execution plan (e.g. how will we roll out this plan) – in the form of a "Business model work plan" identifying tasks, timelines, responsible parties and objective milestones.

Given the potential strategic impact of this work on international engagement with HL7 and the cost of using HL7 products, it is important that HL7 Australia track and report developments as they emerge.

Action: HL7 Australia to track developments of the new HL7 Business plan, reporting to Australian stakeholders as details are released and organising timely feedback as and when required.

9 CTO REPORT

In various forums, including the International Council, the TSC, the Co-chairs dinner meeting, the general session on Wednesday and at the Board meeting, the HL7 Chief Technical Officer (CTO), John Quinn, reported on the following.

9.1 RELEASE OF HL7 V3 NORMATIVE EDITION 2010

In July, HL7 published the Normative Edition of HL7v3 for 2010 - many months earlier than had been achieved in previous years.

This success can be almost entirely attributed to recent investments in improved tooling to assist in achieving the task. The reason for the delays in previous years was due to the process having become very manual and the improvements partly justify recent investments in tooling, with the following points being noted:

- Each year there are more artefacts to manage
- There are interdependencies between methodology and tooling.
- HL7 can now better manage changes to the meta-model and the MIF
- Terminology bindings in the MIF will present a challenge next year.
- HL7 still needs a shared artefact repository that is integrated with the other tooling components – this remains the elusive holy grail - a persistent place to store the RIM and other model-derived artefacts.
- While HL7 has created better tools that better support its processes, they require increased coordination, communication and training to use.

9.2 TOOLING PROJECT

In his report the Board of HL7 International, the CTO addressed the following aspects of HL7's current tooling project.

Evolution of Tooling Processes

HL7's original approach to tooling supported a 4-stage process with significant manual intervention at each of the 4 stages:–

- (a) Identifying specification requirements;
- (b) Designing new artefacts;
- (c) Publishing specifications; and
- (d) Implementing specifications (which occurs in the user environment)

With publication of the 2010 normative edition HL7v3, the previous 4-stage process has been surrounded by three transformational activities aimed at introducing new tooling to streamline workflow, which has involved:

- Changing the HL7 meta-model (currently implied through the Model Interchange Format – MIF)
- Changing the design and publication tooling
- Converting and updating previously designed artefacts.

As HL7 moves into the future, there will be a need for both tooling and artefact representation to be capable of improvement and development to improve their quality continually and to support:

- Alignment of HL7 methodology with other SDOs
- Balloting of changed methodology and core reference artefacts
- Evaluating specifications and artefacts against evolving requirements to ensure that they continue to be fit for purpose - which may lead to further changes in methodology, core reference artefacts and/or tooling platforms.

One of the core learnings for HL7 as it moves forward is the recognition that core artefacts (including reference specifications), the meta-models used to define their representation, the tooling and changing business and technical requirements cannot be addressed independently of each other but, rather, these different aspects have many interdependencies.

Feedback from implementers suggests significant changes are proposed in relation to:

- Core Artefacts – RIM, datatypes and vocabulary
- Methodology, and
- Alignment with other SDOs.

All of these changes will potentially impact tooling, with the following implications for managing tooling, processes and artefacts:

- Increased formality for change control – recognising all interdependencies
- Recognition that updates may be needed to previously balloted content to remain current
- Synchronisation of changes into formal releases – both developmental and production
- Increased coordination and communication.

State of Current Tooling Projects

2009 Projects focused on improved stability and quality measures of current tools and core reference artefacts.

The 2010 Tooling Project includes:

- V3 publishing update to enable MIF 2.0 and streamline implementation
- Updates to the Static Model Designer (SMD) initially developed by the NHS as an Open Health Tools (OHT) project. These updates will include changes needed to support the full development cycle of Universal artefacts as well as realm-specific artefacts

2011 tooling will be impacted by balloting of methodology and the Model Interchange Format (MIF)

- The current SMD version implements MIF 2.1.6
- The current MIF reconciliation process will become MIF 2.2
- Our tooling will need to be modified to support MIF 2.2

The suggestion (raised in the v2/v3/CDA task force) that HL7 should move away from the MIF to a more industry-standard way of exchanging model information would clearly need to be reflected by significant changes to HL7 tooling.

Opportunities for collaboration

The following opportunities involving collaborative work are being considered and/or progressed:

- The current project to implement the NHS Static Model Designer. The first increment of this project involving testing with HL7 Tooling and meeting v3 publishing requirements has been completed.
- Canada Health Infoway is sponsoring a project to update and stabilize the v3 generator. This will include incorporation of Canadian enhancements and licensing as an EPL.
- Shared Artefact Repository (SAR) A new project to develop requirements for the SAR was proposed at the October board meeting of the OHT consortium (held directly before the Cambridge meeting). The project will be an OHT charter project led by HL7 and co-sponsored by IHTSDO and OMG and will:
 - assemble SAR requirements from OHT members
 - identify existing technology capabilities to support requirements
 - preferably, be based on an extensible open source architecture with a significant community of HL7 and others able to continue the work and evolve the SAR

HL7 alone has at least 8 types of artefacts that are managed through separate review processes, many with significant interdependencies. Pooling of requirements across participating SDOs and acquiring or developing robust registration and artefact management capabilities will better support a collaborative ecosystem and help demonstrate necessary component accountability - which is increasingly being demanded by key stakeholders, such as the ONC S&I initiative.

- Model Driven Health Tools (MDHT). This is a successful OHT project, sponsored by IBM and VA, to design CDA templates and generate implementation guides. This will require HL7 support if it is to become widely available as an HL7 tool.
- Other projects supporting vocabulary management, conformance testing, etc at OHT.

Implications for ongoing support

Maintaining and enhancing HL7 Tooling requires:

- Help desk support for technical support for installation and configuration and user support for appropriate use
- Both commercially acquired tools and developed tools require ongoing maintenance support
- Formal change management with release schedules and integration testing to ensure tools work together

- Development of new tools requires collaboration with both other SDOs and potential tool users to align methodologies and increase interoperability
- Coordination with other HL7 WGs to align methodology and tools, train and support users and support conversion of existing artefacts

Unfortunately, the benefits of increased tooling cannot be realised within the proposed 2011 budget with the result that HL7 is likely to enter a period of “maintenance” at best during which some of the required improvements will not be achieved due to a lack of resources.

9.3 SAIF & SAIF IMPLEMENTATION PROJECTS

It was noted that a peer-reviewed set of updated SAIF documentation was produced in mid-September and are available on the HL7 GForge website. These are much larger than those produced in May.

NCI (National Cancer Institute) is developing a SAIF-based Enterprise Architecture for caBIG2 and will be releasing an RFP for that work later this year. Their latest design documents are available on the NCI website for comment.

9.4 GENERAL DISCUSSION - CTO REPORT

It was observed that HL7's approaches and architectures are still very healthcare centric and in many places unique to HL7. Moving to industry standard approaches for core ICT specification and development work and being able to collaborate more closely with other SDOs like OMG, W3C, NCPDP, CDISC and IHTSDO and with IHE are recognised as key priorities, some of which should be addressed by the proposed V2/V3/CDA task force recommendations. These changes will need to be the subject of proposals for new products and new product management processes that address and model the conceptual environment in which systems are used and manage the move from current products and new products.

The proposed changes in tooling, methodology and products emphasise the need for clear communication between the various groups within HL7 and particularly between the board and the HL7 technical community.

10 INTERNATIONAL COUNCIL AND AFFILIATES

Meetings of the International Council and the Affiliate Chairs in Cambridge occupied over a day and a half of Affiliate Chair time.

One of the more significant topics related to discussions led by the Chair, Bob Dolin, and CEO, Chuck Jaffe, considering implications of possible new operating models relevant to a truly international organisation driven by the activities of the Board's Internationalization Task Force (discussed further at section 12.2 below) - and the implications of these changes for the existing Affiliates.

Between 80 people and 90 people were present for the main reporting sessions during the plenary meeting of the International Council on the Sunday and 19 Affiliates were formally represented. Brief update reports were given by 25 Affiliates outlining activities in their respective countries.

As usual, the Chair, the CEO and CTO gave reports which summarised aspects of their activities of particular interest to international Affiliates. For more detailed coverage of these matters, refer to the commentaries in sections 6 and 7 above.

The following were among the other points noted from the Affiliates Council (not covered elsewhere)

Update on changes in the Affiliate community

- Since the previous WGM, HL7 Pakistan was admitted as a new affiliate and the chair of HL7 Pakistan was present at the Cambridge meeting.
- Luxembourg – currently has a call for membership out to enable application to proceed to finalisation.
- Since being established earlier in the year, HL7 Norway has been active and is receiving good support for its activities.
- The petition to form a new affiliate from Puerto Rico was still in the process of being finalised and was expected to be approved by the Board of HL7 International in the near future.
- Continued support and encouragement is also being given to the raising of a petition from Bosnia Herzegovina.
- There has been no response from HL7 Ireland despite several attempts to make contact by HL7 personnel operating at various levels.
- The "Due Diligence Committee" is monitoring status of several Affiliates who have not submitted full materials, including: - Chile, Mexico, Denmark

International Mentoring Committee

This committee has the role of supporting new and fledging affiliates. It was noted that:

- The IMC had supported delegates from the Dominican Republic, Pakistan, Puerto Rico, and Singapore attending the previous WGM in Rio de Janeiro in May 2010.
- Initial discussions are underway with potential local leaders of HL7 activities in the Philippines, where there is a New Secretary of Health and "interoperable computer technology" has recently been added as an additional pillar in the Department of Health's national program. There are plans for "Standards in Health Informatics" workshop in early 2011 by UP Manila National Telehealth Center (promoting HL7, and other, health informatics standards).
- Diego Kaminker (Argentina) is working with Peru, Puerto Rico, and Venezuela.
- Gora Datta and John Ritter are working with the Philippines.

Action: HL7 Australia to communicate with the IMC with a view to facilitating some involvement of Philippines interests in the Sydney ISEM/WGM

Other pertinent highlights included:

- **Update of Affiliate Agreements.** These agreements specify the rights and responsibilities of national Affiliates in relation to HL7 International. See section 10.1 below for further information and proposed changes.
- **Use of Intellectual Property (IP).** The substantial discussions about IP issues continued at this WGM. As previously reported, HL7 Australia needs to be clear on its rights and the limitations on its usage of HL7 IP under the Affiliate Agreement and its requirements in respect of IP.

Action: HL7 Australia Board to review Australian requirements for use of HL7 IP, including discussion with Standards Australia as appropriate.

Proposed allocation of US\$5,000 toward involvement of emerging Affiliates from the Global South at the January 2011 HL7 WGM in Sydney. The Affiliate Chairs agreed to go to email ballot on a proposal to allocate US\$5,000 from their 2010 budget allocation – understood to be for HL7 Australia to use in assisting affiliates from developing and emerging economies to be represented in Sydney. Once the funds are confirmed HL7 Australia will need to arrange a process for delegate selection.

Action: HL7 Australia to confirm availability of funding to support the developing and emerging countries at the Sydney WGM and, if approved, design and conduct a process to allocate these funds in a fair and transparent way.

- **Marketing Council – Ambassador Program.** On behalf of the marketing Council, Jill Kaufmann outlined progress in expanding the Ambassador program and the success of the Ambassador online webinars which would make Ambassador content more readily available to Affiliates such as Australia. Some countries are looking to schedule their own webinars to raise HL7 awareness and were invited to publicise them through the HL7 website (Andrea Ribick).

Action: HL7 Australia to publicise availability of online HL7 Ambassador webinars via its electronic newsletter.

Action: HL7 Australia to consider commissioning particular speakers to provide webinars on key topics at appropriate times.

- **Marketing Council - University program.** An active campaign is under way to increase the number of universities teaching HL7 standards as part of postgraduate Healthcare Informatics programs. High-level content is also being provided for insertion into university curricula. The objectives are:
 - Primarily: to increase the number of Universities teaching about HL7 Standards as part of MS/ PHD Healthcare Informatics programs, globally
 - Secondly: to define (and potentially increase) HL7 benefits for Universities as members
 - Thirdly: to increase HL7 membership, participation (and technical contribution) on the part of universities/colleges, faculty and students

Australian delegates share the concerns of some others that the material being developed for the University program is too "lightweight" and not part of the broader education strategy being developed by HL7 Australia and that it would be appropriate to have Australian input from university, professional and vocational interests engaged in that process.

Action: HL7 Australian and the Australian Health Informatics Education Council (AHIEC) advise members of these developments to encourage participation.

10.1 UPDATE OF AFFILIATE AGREEMENTS

The affiliate charter agreements specify the rights and responsibilities of national Affiliates, and are being progressively reconsidered in light of HL7 International moving to a more uniform global business model – becoming less of a US organisation with international partnering arrangements.

While the new business model will probably take two to three years to finalise and implement, the current Affiliate agreements expire on 31 December 2010 and are

being reviewed and updated by HL7 and the Affiliates in light of recent and proposed organisational changes and the need to be clearer in their treatment of issues such as the use of intellectual property. It is proposed that all Affiliate agreements will be in a common form – with a new version being circulated for comment.

The following key changes were noted by the International Council:

- “Academics” added as a core stakeholder group of HL7 International and Affiliates – aligning the Affiliate agreements with activities such as the universities program.
- New concept of a “membership year” introduced to make reporting requirements more attainable

A membership year is defined as a fixed period of twelve (12) months which is used for the calculation and invoicing of membership fees, as well as membership renewal, which may be different from the fiscal year.

- Status reports once a year (through the International Council Around the World)
- Translations not to be made as a “work for hire”, but still to respect copyright laws and rights of HL7 International
- Clarification of how changes in Affiliate status are managed in terms of “HL7 International executive action” should an affiliate not meet the conditions of the Affiliate agreement
- The obligation to physically return standards material upon termination of the agreement has been dropped; however, the rights to copy and distribute the material would still lapse – and there would be no right to continuing updates.

Other topics still being debated and/or progressed included:

- Antiquated notion of “Protocol Specifications”: Bylaws
- Global membership: Internationalization Taskforce and its likely impact on the Affiliate agreement into the future
- Meeting schedules: do the Affiliates want an integrated schedule?
- Updating the Appendices (to be handled by the author/owner of each appendix).
- There have been several informative questions – these are to be captured and presented as an FAQ for Affiliate Agreement Charter.

Action: HL7 Australia to consider proposed changes to the Affiliate agreement.

10.2 IHIC 2011

The United States has put forward a preliminary bid to run the International HL7 Implementation Conference 2011 (IHIC 2011).

11 24TH HL7 ANNUAL PLENARY

In September/October each year HL7 holds its annual plenary meeting. The 2010 annual plenary focused on "Future of health care using genomics as a key tool" with presentation and discussion of the following papers:

Keynote Session 1: Genetics and Genomics in Clinical Medicine

Raju Kucherlapati, PhD,
Paul C. Cabot Professor of Genetics and Professor of Medicine, Harvard
Medical School

Keynote Session 2: Personal Genome Project

George Church, PhD,
Professor of Genetics at Harvard Medical School,
Director of the Center for Computational Genetics,
Founder of Personal Genome Project

Panel Presentation: How HL7 addresses Clinical Services, Commercial Products, & Data Intensive Research, including

Panel presentation 1: Clinical Assessment through Family Health History

Kevin Hughes, MD, FACS, Co-Director, Avon Comprehensive Breast
Evaluation Center, Massachusetts General Hospital;
Associate Professor of Surgery, Harvard Medical School

Panel presentation 2: Touch-points for incorporating genetic data and knowledge into clinical processes

Sandy Aronson, Executive Director of IT, Partners HealthCare
Center for Personalized Genetic Medicine (PCPGM)

Panel presentation 3: NCBI and 20 Years of Standards in Biomedical Research

Jim Ostell, PhD, Chief of the Information Engineering Branch (IEB) of the
National Center for Biotechnology Information (NCBI)

The annual plenary was extremely stimulating and provided valuable insights from leaders in the field, most of whom are based nearby in the Boston/Cambridge area. Key messages included:

- Great strides are being made through the application of molecular genetics to the delivery of personalised medicine and the identification of individuals at risk from genetic disposition to particular disease phenotypes.
- The social and ethical issues associated with protection of privacy, the use of genotype information in clinical and other applications are complex. There is potentially a growing disadvantage to those in communities where family history and genetic information cannot be collected and shared for diseased prevention and the delivery of clinical care because of strict information privacy regimes.
- The part played by de facto proprietary standards in recording and communicating of genetic material and genetic test results and the difficulty of identifying and recording reliable genetic information across populations.
- Practical issues in assembling and maintaining reliable genetic databases given the random nature of genetic material built up by various mutations over time and their impact on the sequencing of genetic material between individuals and across populations.

- The contribution of HL7 through its development of standards used for pedigree and family history.
- The emerging need for new processes supported by close integration of clinical/genetic taxonomy, clinical knowledge management, smart longitudinal EHR systems, clinical decision support, new genetic testing, reporting and follow-up protocols.
- New discoveries about the relationships between genetic information (in both humans and pathogens) and diseases are emerging daily and will continue for the foreseeable future. Genetic information that may not be significant today, could emerge as being important tomorrow – with the prospect that those known to be affected can be identified and offered assistance when new connections between their genetic makeup and particular diseases and/or therapies emerge.
- The huge volumes of information to be communicated and maintained as part of moving to genetically-based clinical care.

Copies of all the presentations may be downloaded from the HL7 website via the following link:

http://www.hl7.org/documentcenter/public/calendarofevents/wgm/boston102010/General_Session_Presentations.zip

12 STRATEGIC BOARD-LEVEL ISSUES

12.1 MANAGEMENT OF HL7 INTELLECTUAL PROPERTY (IP)

Following on from discussions at several meetings of the IP sub-group of the Board's Internationalization Task Force and at the annual Board retreat, the HL7 leadership resolved to obtain legal advice on the more effective management of its intellectual property (IP) and potential licensing measures for exploitation of the IP in its standards products.

Mr Andy Updegrave (of Boston-based attorneys Gesmer Updegrave, LLP – an expert in intellectual property law and former member of the Advisory Council to the HL7 Board) was asked to comment on his understanding of the current situation and measures to better manage intellectual property.

His remit is to review existing IP policy and with the goal of establishing new enforceable IP guidelines for implementation by January 2012.

Mr Updegrave provided a brief commentary analysing the current situation for mainstream licensing of HL7 standards, suggesting a general strategy outlining where further legal input and assistance might best be applied. Unfortunately his planned presentation to the Board of HL7 International had to be cancelled.

He favours simple approaches that are properly documented, whose applicability is easy to understand and that encourage stronger compliance with HL7 licensing conditions into the future (progressively rectifying breaches that may have occurred in the past).

As a lawyer, Richard Dixon Hughes has been assisting by participating in the IP sub-group of the ITF and preparing briefing materials for the HL7 International

leadership to use in seeking legal advice from US-based attorneys on its IP issues and options. This included his participating in telephone discussions between Mr Updegrave and HL7 executives during his time in Cambridge.

The Board of HL7 International has many significant issues still to consider in developing its IP management strategies and new business model.

Action: Richard Dixon Hughes to continue assisting HL7 International resolve legal issues surrounding the licensing of its intellectual property in HL7 standards.

12.2 INTERNATIONALIZATION TASK FORCE (ITF)

The ITF is examining long-term strategic issues associated with HL7 International becoming an organisation that within 1½ - 4 years has a single membership model, a single governance model and a single IP model around the globe. The work includes consideration of residual issues thrown up by: the former "One-member-One-vote" (OMOV) Task Force and new questions arising from the establishment of an HL7 office in Europe, proposals for national licensing of HL7 IP and "country membership" in some countries and a closer relationship with IHTSDO.

The focus is on how HL7 can realise "internationalization" – a strategic direction that is seeking the following benefits to HL7 and its international community:

- Multiplying influence
- Achieving economies of scale
- Greater influence in defining the interoperability agenda, and
- Decreasing the need for realm localisation

This involves some real challenges – in the membership model; in the management of intellectual property (IP) rights, in the relationship with affiliates and in product development.

The core ITF membership is drawn from the members of the HL7 Board and comprises: Chuck Jaffe (CEO) (ITF Lead), Bob Dolin (HL7 Chair), Hans Buitendijk (HL7 Treasurer), Catherine Chronaki, Michael van Campen, Ed Hammond, Richard Dixon-Hughes, Mark McDougall and Karen Van Hentenryck.

Up until the Cambridge meeting, the work was being progressed by five sub-groups:

- **Vision:** Bob Dolin (Lead), Chuck Jaffe, Mark McDougall, Richard Dixon-Hughes, Catherine Chronaki – defining the overall vision and scenarios for its implementation
- **Intellectual Property:** Woody Beeler (Lead), Chuck Jaffe, Richard Dixon-Hughes, Karen Van Hentenryck, Lloyd McKenzie, Hans Buitendijk, Ken Lunn – issues associated with the creation, licensing and use of HL7 Intellectual Property
- **Membership:** Ed Hammond (Lead), Chuck Jaffe, Mark McDougall, Catherine Chronaki, Hans Buitendijk, Michael van Campen - membership models and the proposed rights and privileges of various membership classes.
- **Governance:** Richard Dixon-Hughes (Lead), Hans Buitendijk, Danna Dobson (HL7 Canada), Karen Van Hentenryck, Catherine Chronaki, Michael van Campen – identifying rights, obligations and relationships applicable to various

entities within the HL7 political and business community – including HL7 International itself and its affiliates.

- **Financial Structure:** Hans Buitendijk (Lead), Bill Braithwaite, Mark McDougall, Ed Hammond – revenue and cost modelling supporting new business relationships.

The ITF subgroups have been meeting by teleconference, with an update on progress at the annual retreat in July. They have progressed to various stages of development from defining their scope, objectives, to outlining issues and problems, through to the preparation of options papers and financial models. Overall, progress with the ITF has been slower than anticipated, partly due to its competing for time with other strategic priorities emerging from the Business Model Task Force and the annual retreat of the HL7 International Board and the Advisory Council.

At a plenary meeting of the ITF and all of its sub-groups in Cambridge, it was agreed that the Membership and Financial sub-groups would merge.

As HL7 moves toward being a truly international organisation of the type being considered, it will have a major impact on the role, nature and business models of the existing HL7 Affiliates.

Richard Dixon Hughes is the only Australian on the ITF and is leading the Governance subgroup, which is considering relationships with Affiliates (among other things). His main contribution to date has been through the IP subgroup and the subsequent preparation of briefing materials for consideration by HL7's legal advisors in the US.

12.3 WORKING GROUP MEETINGS OUTSIDE NORTH AMERICA – FRANCE 2012

As reported at some length following the Rio meeting, the Board of HL7 International has been struggling with the appropriate formula for holding successful working group meetings outside North America, with the aim of balancing three key priorities with respect to WGMs:

- (1) being financially viable
- (2) being productive, and
- (3) engaging the international community

The recommendations of a Board Task Force formed to assess International WGMs were received and considered at some length by the HL7 Board at its meeting in Rio and have already had a significant impact on planning for the January 2011 WGM in Sydney – particularly the controversial Board decision that an international Affiliate seeking to run an international WGM would have full responsibility for the financial outcome. This was influenced by the IMIA business model where any profit/loss is borne by the local committee.

The formation of the International Organizing Committee (IOC) to oversee preparations for the January 2011 WGM in Sydney also resulted from the task force recommendation that an organising committee be established for every meeting outside North America, to include the CEO, HL7 Chair, Vice Chair, TSC representative, Executive Director, Treasurer and a group of representatives from the host country.

Australia reported on its experience that the IOC is a proving a valuable forum for collaboration and cooperation.

There was little further consideration of general policy surrounding international Working Group Meetings in Cambridge, as most of the HL7 community is now awaiting the outcomes of the Sydney 2011 meeting to better understand the practical impact of recent policy changes.

During the Cambridge meeting, Nicholas Canu, elaborated on proposals from HL7 France for the May 2012 HL7 international Working Group meeting be held in Paris (from 19 to 25 May) in collaboration with the major annual Health IT expo that is being held in the city at that time. This proposal is in active development and was discussed at both the International Council and the Affiliate Chairs meeting.

With an initial cost estimate of around €400,000 for the proposed venue utilising rooms from the Pullman Hotel and Porte de Versailles centre, Paris is looking potentially too expensive (venues alone almost double the total cost of Sydney). A fallback position is being developed for holding the WGM in Bordeaux in a different week.

It was noted that the HL7 Board needs a firm proposal from HL7 France in time for a decision to be taken no later than at the January 2011 WGM in Sydney. The core of a high-level international organising committee (similar to the Sydney 2011 IOC) has started meeting fortnightly by teleconference to progress the French proposal.

12.4 HL7 STRATEGIC INITIATIVES AND ROADMAP

12.4.1 Update of Strategic Initiative documents

Since becoming Chair of HL7 International, Bob Dolin has been particularly focussed on making the HL7 Strategic Initiatives more directly applicable as a yardstick for assessing the relevance of current and proposed HL7 activities, prioritising activities and resources, and measuring organisational progress.

In order to meet these needs, the Strategic Initiatives need to be unambiguous, with measurable criteria. An initial activity was assigning SMART (Specific, Measurable, Actionable, Relevant, and Timely).

Since the HL7 Board approved Version 1.0 of the Strategic Initiatives in December 2009, criteria for measuring their adoption have been under development with input from the Board, the Roadmap Committee, the Advisory Council and the TSC with the aim of making them more relevant and directly useful in the operational management of HL7 International. This review process has included:

May 2010	Summarized output of Roadmap Committee has been incorporated into draft v1.5 of criteria document
July 2010	Document (v1.6) renamed from "Roadmap" to "Strategic Initiative - Criteria" to reflect that content has been restructured to focus on SI criteria and not roadmap projects. Incorporation of final subgroup review.
August 2010	Feedback from Roadmap Committee, Board and Advisory Council incorporated into v1.7.
September 2010	Revised (to v1.8) based on feedback from TSC and Board. Primarily minor changes to wording of criteria and criteria

descriptions and clarification of examples.

October 2010 Board meeting in Cambridge approves revised strategic initiative documents – incorporating updated SI criteria.

The objective of the SI-criteria document is to further clarify the HL7 Strategic Initiatives by providing concrete criteria upon which progress against each of the initiatives can be assessed.

The journey from HL7's Vision, to HL7's Mission, to HL7's Strategic Initiatives seeks to move from an abstract ideal to an operational and measureable set of objectives, which are then realised through HL7 Roadmap projects as illustrated in the following representation:

- HL7 Vision
 - HL7 Mission
 - HL7 Strategic Initiatives (SIs)
 - HL7 Strategic Initiative criteria (the focus of recent work)
 - Roadmap projects (which may address one or more SIs)

12.4.2 New process for annual review/approval of Strategic Initiative documents

The responsibility of the Board and process for maintaining the HL7 Strategic Initiatives as part of the Strategic Roadmap is set out in section 06.02.01 of the HL7 Governance & Operations Manual (GOM)

The Board received a report outlining a new process that aims to keep the HL7 vision, mission and strategic initiatives fresh on a yearly basis and facilitates operationalisation of the strategic vision through the strategic criteria. It will continue the process of seeking democratic input to the process of updating and maintaining the strategic initiatives by submitting them to ballot for comment at critical points. The main steps in the proposed new process are as follows:

- January ballot cycle – Comments only membership ballot on vision, mission, strategic initiatives, and strategic initiative criteria. Comments are resolved by the SI Committee.
- May 1 – Publish draft revision.
- May – July – TSC and Board input (including discussions at Spring WGM and Board Retreat).
- September 1 – Publish draft revision.
- September-October – Review draft with Board (including discussions at Plenary & WGM in Sep/Oct). Strategic Initiatives committee is used ad hoc.
- November-December – Board approval of Strategic Initiatives and Strategic Initiatives Criteria for the following year.

To more accurately reflect its true role, the Roadmap Committee was renamed the Strategic Initiative Committee (retaining current membership composition).

Action. HL7 Australia and IT-014 to review HL7 vision, mission, strategic initiatives, and strategic initiative criteria each year and consider commenting for January ballot cycle.

13 HL7 V2/V3/CDA STRATEGY TASKFORCE

At the September Working Group Meeting (WGM) in 2009, a strategic task force was convened to identify the challenges within the current HL7 V2/V3 approach, identify options for addressing these challenges, and develop a plan for moving forward. The Task force, is charged with:

- Assessing the current situation with respect to the use of: V2 messaging, V3 messaging, CDA and SOA Interoperability
- Identifying options for moving forward
- Recommending actions and a plan

The work is now nearing completion following a process which has included:

- Production of a problem statement refined through discussions with TF members, senior HL7 office bearers and key experts
- Development of an interview protocol and list of interviewees for widespread consultation with over 50 people being interviewed

Australians included in the interview process have included Andy Bond (NEHTA), Max Walker (Victoria Health), Michael Legg (HISA/ pathology messaging) and Klaus Veil

Issues such as lack of a common vocabulary and datatypes between V2 and V3, the place of messages and documents in a service based interoperability paradigm and the relationship of V2 and V3 to the SAIF initiative have been discussed at some length.

Since the Rio meeting a considerable amount of consideration had been given to the possibility of using a standard intermediate format for clinical information models and terminology binding to/from which other types of related artefacts may be compiled or translated (including HL7v2 and v3 messages). This concept was particularly promoted by Denis Giokas (Canada Health Infoway) and Stan Huff (IMHC) – noting that Infoway has already funded the development of pilot APIs that are being used to provide this type of functionality for some clinical information interchanges between applications in Canada. For a while, the Task Force was considering whether this should be proposed as a potentially ubiquitous solution; however, such an approach lacks the technical integrity to provide general interoperability of clinical information, as highlighted by Grahame Grieve and others.

As time approached for the Cambridge meeting, the Task Force re-focused on its main role and the need for clarity and resolution of the relative positioning of HL7 V2, V3 and CDA. This has been underlined by the omission of V3 messaging from the “Meaningful Use” documents which set the agenda for the USA eHealth initiatives.

The taskforce has focused on conducting extensive consultations with HL7 stakeholders. The consultations have not thrown up any new issues that are not generally well known or widely discussed amongst the HL7 community, but have served to assist the taskforce to properly understand the gravity of issues.

Prior to the meeting Richard Dixon Hughes held a meeting with Dr Andy Bond (NEHTA) and Klaus Veil (HL7v2 expert) to review the draft points which had been put up for discussion to better inform his position at the meeting. The discussion points had been put up as a starting point noting that they were contradictory, ambiguous and inadequately explicit in places.

It remains for the Task Force to complete its work and report in confidence to the Board, who will make any decisions about HL7's product strategy and how this is communicated to the wider stakeholder community; however, without breaking confidences, the meeting was considered significant in that the Task Force:

- Recognises the ubiquity of HL7v2 as the most commonly used means of communicating healthcare information. While v2 is limited by considerable shortcomings, it is accepted that it will be in use for many years and needs to be maintained (the critical question is to what level?). Nevertheless, there would be concern if work on v2 were to divert significant HL7 resources from progressing more rigorous approaches to semantic interoperability.

Richard Dixon Hughes has also raised the need for HL7 leadership to resolve the entrenched differences inhibiting ready adoption of more recent versions of v2 (from v2.6 onward) and effective ongoing maintenance of v2.

- Is differentiating between the use of HDF and HL7v3 RIM-based technologies as a modelling environment and their use in the production of v3 messages and service-oriented payloads.
- Recognises that HL7 needs more efficient and effective methods for representing, organising, and communicating health information and associated business processes – preferably using industry-standard approaches
- Recognises that HL7 needs to progress in stages compatible with being able to support modelling, implementation and publication activities with appropriate tooling (with potential changes in tooling to support new approaches being potentially both costly and time-consuming in an era of fewer resources).
- Discussed strategies for v2, v3, CDA, representation of health information models (both static/information modelling and dynamic/behavioural modelling) and their relation to SAIF, developments in tooling and implementation of HL7 in services-oriented environments.
- Acknowledges the growing role and use of CDA (and variants thereof) as the health-sector's preferred means of representing static clinical content being communicated between health information systems.
- Sees a potential future situation emerging that includes approaches to information and process modelling that better support terminology and behavioural aspects for implementation in services-based paradigms.

At the meeting, the point was strongly made that the work of the Task Force is on the critical path toward HL7 achieving a better integrated approach to its standards work that is more comprehensive, better integrated and more widely understood and accepted. Each month that passes without firm recommendations and decisions on direction is a further month delay in HL7 achieving this end goal.

The Task Force is planning to complete its work over the next few months – in time for the Board to receive and consider its findings by the January 2011 ISEM/WGM in Sydney.

Action: Australians on the TF to continue encouraging outcomes that address the diversity of opinions and views offered through the consultation process.

It is clear that the HL7 community and strategy faces many challenges, and the taskforce believes that a genuine and meaningful change in direction is required. On the other hand, it is not at all clear what action should be taken. In many ways, the existing HL7 strategy is a compromise that makes all parties equally unhappy. Many of the proposed changes will bring comfort to some of the stakeholders while making things more difficult for others.

The taskforce also recognises that there is a number of significant projects within HL7 itself, especially in the ITS work group, that are developing and prototyping potential solutions to the problems that have been identified. Some of these projects are:

- μ ITS
- GreenCDA
- Alternative ITS Projects + hData
- OMG/HL7 MIF/UML project
- Behavioural Framework Project
- DCM
- Etc (about 15 projects)

Taken together, some or all of these projects may come together to deliver genuine and meaningful change. The taskforce is now preparing a final report. At the time of the meeting, the general nature of this report is to recommend that the organisation ensures works to ensure that these projects do not face any organisation or resource roadblocks, and that the board continues to work – either through the taskforce or otherwise – to understand the implications the projects have for the future of HL7's strategy, once their success has been assessed. In the meantime, there are a number of marketing type actions that should be taken. The report should advance in status at the Sydney meeting.

Action: IT-014 and HL7 Australia should keep a close watch on the outcome of the V2/V3/CDA Strategic Task Force and its publications so as to make sensible decisions about adopted standards going forward.

14 ARCHITECTURE REVIEW BOARD (ARB)

A SAIF tutorial day combined an introduction to SAIF (Charlie Mead) along with implementation experiences using SAIF (Ron Parker, Steve Hufnagel and Andy Bond). The two tutorials in one day were well attended but feedback suggested that this was too much material to process in a single day. Similar but refined tutorials will be run in Sydney but delivered over two days allowing attendees to digest introductory material overnight. The combination of tutorials provided a unique combination of introductory evangelism along with the pragmatics of three different implementation stories.

Action: That IT-014/HL7 seek advice from suitable health informatics educators on material and structure be sought to improve structure and delivery of SAIF tutorials for next meeting.

Following on from the May meeting where significant formal feedback was given on SAIF, this meeting provided an opportunity to talk about where the next version of the SAIF documents should be heading. In particular the SAIF Behavioural Framework (BF) generated significant feedback on its role within SAIF and HL7. HL7 has been down the path of defining dynamic behaviour before but the BF takes this to a new

level based around ODP viewpoints and MDA layers. The reaction to the BF was either that it was too complicated or that it didn't provide enough detail to define workable implementations of behaviour.

There have been issues with completeness and coordination across SAIF. While the BF has probably seen the most concerted effort, it has also ended up being representative of a standalone approach across many aspects of SAIF where the individual frameworks don't work as a cohesive set. The BF not only deals with the computation viewpoint of ODP but also covers substantial pieces of the enterprise viewpoint in order to cover the behavioural contracts as they relate to business agreements. This creates problems for other frameworks, such as the governance and conformity assessment (ECCF) frameworks, since they too will need to link to an enterprise language describing business behaviour.

There was plenty of SAIF discussion during shared project meetings with the architecture board. While many are putting extraordinary efforts into aligning to SAIF, there continues to be an apprehension and confusion around latching on to SAIF.

Some of this seems to come from a lack of an overarching entry point, described as the 5 or 10 page document that positioned the pieces of SAIF and gave an overview of how they could be used. At the moment ECCF has become the default single-view of SAIF through the ECCF Specification Stack matrix. Unfortunately this has resulted in some treating the viewpoints of ODP and layers of MDA as an orthogonal set of issues where all combinations of matrix features must be populated to complete an interoperability specification. More correctly, the matrix should be used to position specification artefacts relative to a common architectural position.

In response to these issues, the ARB (Steve Hufnagel and Andy Bond) has undertaken to produce a "10 pager" that provides the SAIF entry point. A first cut at this was produced during the Boston WGM and it continues to evolve through feedback and contributions via the HL7 mailing list. Steve Hufnagel has also been added to the ARB.

The SAIF Alpha projects have reached a point of evaluation whereby some have managed to make good inroads into understanding and in some cases, building upon the framework. Others have opted to continue to dabble without significantly changing their existing approach. In light of this, the Enterprise Architecture work in HL7 has been shifted to become a programme rather than a project whereby individual projects will be treated as a set of activities contributing to a consistent whole. The challenge for HL7 will be injecting sufficient governance and programme management efforts into achieving significant outcomes.

The National Cancer Institute (NCI) continues to be the powerhouse behind the SAIF through their piloting of the framework within NCI. In particular, the expected versions of the Information (IF) and Governance Framework (GF) will emerge from this process as will a version of an implementation guide specifically aimed at NCI. The challenge for HL7 is to ensure that there is a clear distinction between the implementation guide material and the abstracted material that is applicable to all implementations of SAIF. Previous experience has shown it is very easy to default to including implementation-specific material when SAIF will be applied beyond HL7 and NCI.

The Architecture Board will meet in Sydney with most members attending. It is anticipated that a full program of work will be undertaken equivalent to that done at any US-based meeting.

ARB teleconference calls have switched from alternating European and Australian calls to a common weekly call timed for 6am AST.

15 CLINICAL INTEROPERABILITY COUNCIL (CIC)

A joint meeting between Patient Care, EHR and CIC discussed progress on the Diabetes DS project. This project has many sponsors across HL7 including EHR, CIC and Patient Care.

The premise is to look at a common set of data elements that overlap EHR and secondary uses so that this data can be exchanged. The data elements need to be harmonised for re-use in different settings. This process involves looking at sets of data elements and then creating a harmonised set in the overlap between secondary use. 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 to have heuristics for grouping data and DCMs were mentioned as a possible solution. The project is continuing.

CIC DAM development guide is in the process of update. Mead Walker is assisting in development of this work. The purpose of a DAM is to represent information generated in the process of healthcare that can be used in multiple ways despite, or assisted by, a single way of representing information. The hope is to get a common foundation across Healthcare, reimbursement and research through data element standardisation.

Goals for the Guide include:

- Provide guide to development
- Promote reuse
- Provide similar designs to facilitate common usage
- Use in CDA, templates etc.

A DAM is a Domain Analysis Model to improve communication between stakeholders. Requirements used to formally define and structure data and/or process. This is used to develop specifications within HL7 (i.e. Messages, EHR functional models and DCMs).

Educational resources available include:

- HDF – HL7 development framework
- UML – recommended modelling tool for DAMs

HL7 Process:

- Project statement
- Determine who is involved – WG, International communities
- Follow HDF/SAIF process
- Ballot as informative document

The DAM is not just as an information model as it includes multiple components and diagram types and their relationships.

Components include:

- Data Elements, Classes and Attributes, State Model, Activities, Story Boards, and Use Cases. A list of data elements is the most common starting point. Often groups bring lists of data elements and a DAM is the right way to bring them together. Though a storyboard is a common starting point, any of the components can be the starting point.
- ECCF – Enterprise Conformance and Compliance Framework. (Part of SAIF and ISO standard)
- Story Board/Scenario (Case Reports)
- Rationale – provide a story of some relevant occurrence – sequence of events. Informal way of defining what the DAM is about.
- Use Cases – more formal treatment of requirements. These describe a sequence of actions that provide a measurable value to an actor. Use cases involve identifying actors, showing how actors participate in use cases and defining association between use cases.
- Data Elements
 - Represent the data in a way that is more intuitive to clinicians (non modelers) than a class model
 - Allows easy pulling from forms or existing list
 - Easy to consider the unit of data exchange
 - Each data element has a name, description, type of data element and possible a codeset

Example given is “History of peripheral vascular disease” (Modelers will use “Vascular disease history indicator”) May end up with 2 names – one for end users and one for implementers.

Discussion without agreement occurred on whether an element is a concept or a structure – output of the DAM needs to include this or it becomes useless.

- Class and attribute structures including the form of a data model – UML Information model – which is organised into clumps and the relationships between them. Both data elements and class model represents data – difficult to keep synchronised.
- Activity component
- Flow of action and control between activities
- State Machine component – show the behaviour of an individual class within the class diagram - used for critical classes
- Class components are deposited in the CaDSR repository.

Next steps – complete modelling guide for each component and get comments.

16 DECISION SUPPORT

DSS is a DSTU however as it is over 3 years in this status this has lapsed an OMG beta specification was released in December 2009. SEBASTIAN tool set (on the openclinical.org) is the first implementation and is available. The current status is uncertain in the likely road to becoming a normative standard.

A presentation was given by Heather Grain on the ISO initiatives in clinical decision support and the HL7 Decision Support WG are keen to provide input to the technical part of this work and there was interest in the general and specific use parts of the ISO work.

Action: IT-014 needs to determine the working groups to have oversight of the clinical decision support work at ISO and the priority for HL7 involvement. It began in IT-014-02 as a mechanism for representation of safety and quality concepts but also fits and is relevant to IT-014-06 and IT-014-09.

17 DETAILED CLINICAL MODELS

Much of the Patient Care WGM was taken up with discussion about Detailed Clinical Model (DCM) issues and in particular, the balloting of 5 detailed clinical models. These ballots attracted over 260 negative comments. It did not receive the minimal required number of affirmative votes and hence failed the September 2010 ballot.

There were very serious debates during the ballot reconciliation sessions on matter related to the absence of approved standard methodology and quality criteria. WG members expressed strong sentiment that in the absence of those, it was improper to ballot the DCMs and impossible to adequately evaluate and address the negative comments.

It was explained that the methodology and quality criteria specification was in development and under the ballot processes before ISO/TC215. The draft could not be made available to HL7 before an agreement with ISO had been reached. This situation attracted very severe criticism. Many members expressed very serious concerns about the “back-to-front” or “out-of-synch” processes.

The issues raised were predominantly about why there were instances being balloted before a methodology for representing DCMs had actually been agreed. William Goosens initially said that the methodology was being developed in the ISO environment, however then retracted that statement at a later time. There was a lot of disagreement about how models could be assessed or balloted before HL7 had agreed on a methodology. Modelling and Methodology (MnM) were apparently also discussing this issue. There was also concern, that HL7 was relying on a methodology that another organisation had developed (if this was indeed the case). There was also discussion about whether or not an HL7 ballot process was the appropriate environment for developing these models as clinical models need to be flexible and can change rapidly.

The ballot reconciliation process was begun on the 5 DCMs that have been brought to ballot. However due to the very large number of items certain groups of ballot comments were left until another time. This includes content issues. Many of the other issues were around methodology questions and until a methodology is decided these cannot easily be answered. Only a small amount of progress was made on the ballot issues due to concerns about the process from members of patient care. One outcome of the ballot is that the DCM project will work with MnM to clarify the methodology and find a formal basis for it prior to further balloting of the clinical models themselves.

There was some work done on how to progress Evaluation of Care Provision Draft Standard for Trial Use (DTSU) which if not progressed may lapse. Some of the issues discussed were whether to take into account the new versions of the RIM which are not backward compatible especially in regard to Context Conduction. Data type changes were also thought to be an issue and the required changes to the DSTU to bring these up to date would make it impossible to get to ballot in time to stop the DSTU from lapsing. It was decided via motion that in order to enable the DSTU to become fully normative in time there would be no changes to data types, RIM versions or clinical statement patterns as these would take too long to change and get through the ballot process. Future changes would need a new Domain Message Information Model (DMIM).

A discussion was had about an issue within HL7 itself where the same concept was modelled in many different places and ways without a simple way of harmonising the process. For instance, allergies have been modelled in templates, clinical statements, Common Message Element Types (CMETs), Domain Analysis Models (DAM) and Detailed Clinical Models (DCM) over the years.

A joint Vienna Agreement (VA) and Kaiser Permanente project was presented called “A collaborative model to promote data sharing and quality reporting.” The collaboration between the two organisations was to capture outcomes on standardising methods for reducing pressure ulcers. The process followed, was to:

- do a literature review,
- engage clinical experts,
- develop optimum data sets,
- information harmonisation,
- map to reference terminologies,
- develop practice driven information models in UML and
- validate models beyond the organisations.

There was a request for a discussion about the next steps and a number of different options within the HL7 organisation were discussed including turning this into a DAM. It was felt that this process most closely followed the DAM process.

A joint meeting between Patient Care, EHR and CIC discussed progress on the Diabetes DS project. This project has many sponsors across HL7 including EHR, CIC, Patient Care. The premise is to look at a common set of data elements that overlap from EHR and secondary uses so that this data can be exchanged. The data elements need to be harmonised for reuse in different settings.

The process involves looking at sets of data elements and then creating a harmonised set in the overlap between secondary use. 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 to have heuristics for grouping data and DCMs were mentioned as a possible solution. The project is continuing.

As previously stated, there was a lot of discussion within the Patient Care WG and other working groups about the DCM approach to clinical content development. There has been much thought recently within HL7 about the many different approaches that HL7 has to clinical modelling and some concern that this was one more 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 are based on the clinical statement pattern and CMETS that are also small models of content 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 the balloted standard - which are little used. 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.

There is currently much confusion within the HL7 community about where DCMs sit in the set of clinical models and how they are to be used. Much of this confusion lies with the fact that the DCM methodology has never been clearly elucidated and is a constantly changing thing. The original idea for DCMs was that they were a clinical artefact that was able to be accessible to clinicians and could be used for generation of a number of different artefacts including CEN13606, openEHR and HL7. The main focus within HL7 is on enabling development of reusable clinical content that is consistent and able to be used for generation of different HL7 artefacts.

The main issue for HL7 is developing a consistent methodology for these artefacts. If they are to be used for anything other than clinicians to look at and to be taken as content to the manual development of other clinical artefacts, then they need considerable more development. General opinion is that to be able to automatically generate another model, they need to develop their own reference model that would rival the complexity of the RIM or the openEHR reference model. This seems counterproductive and any process like this is going to be enormously expensive in both time and resources. Before any further models are balloted it is important to develop a proper technical methodology or adopt one that is in current existence. One such possible candidate is the openEHR archetype methodology. Archetypes are developed in a modelling language called ADL and constrain a particular reference model. The good thing about archetypes is that there is much evidence that they are very approachable for clinicians (see www.openehr.org/knowledge) and there is a considerable body of work that is already freely available in this area. A number of jurisdictions are already using archetypes as their 'DCM' approach including NEHTA in Australia as well as Sweden and Singapore. A major problem for DCMs to avoid is the 'reinventing the wheel' approach which wastes enormous amounts of money and time. It has been proven in a number of places, that openEHR archetypes can be used to generate artefacts such as CDA instances etc.

Action: IT-014 (IT14-09 and IT14-06) should continue to monitor the developments within HL7 regarding clinical content development and DCMs. Standards Australia should consider archetypes as a useful and pragmatic approach to DCM development within Australia.

18 EDUCATION COMMITTEE

The Education Committee has been asked by the Board and the Technical Steering Committee (TSC) to develop a strategic plan for HL7 International's broader educational activities. However, the plan outline presented at the meeting was not strategic, nor was it international, nor was it educationally sound. There were long and detailed discussions on many of the shortcomings, starting from an agreed need

for the required competencies of the workforce to be understood and explained. This was seen as a prerequisite for a strategy to attract funding sources and develop appropriate materials. Discussion also occurred on the requirement to assure the quality of the education provided. Many of the existing education programs have excellent material but are not structured or designed to support learning or skill development or to assure competency to perform any given task.

Though there is passion and commitment to education in the working group there is little skill either in administrative/strategic thinking or in education.

Heather Grain shared the work of the Australian Health Informatics Education Council (AHIEC) through their Strategic Workplan, developed with DOHA funding in 2009, as a document that identifies the core elements that need to be considered in the HL7 education strategic plan. Though there is no intention to go to the detail AHIEC have undertaken, there is a need to quantify the skill gaps and identify need and from there to identify methods and potential programs to improve capacity.

There was also a lack of understanding within the members of the working group of methods that support sound educational programs, as opposed to the provision of information dependent upon the recipient's energy, capacity and resources to ensure skill development.

The lack of qualified educators in the education committee, and HL7 in general, was recognised though it was interesting that those on the education committee did not know those within the community who have these skills. The skills required were the same as those confirmed by AHIEC, namely expertise in the area concerned, plus skill in methods of learning, course development and delivery, and assessment techniques and approaches. It was recognised that though senior university personnel have been involved in some of the educational offerings, these people are often highly skilled in a given area, and in research, but educational skills are often not taught to those who undertake academia and should not be assumed to be held by all of these people, no matter their eminence.

One action being considered to improve the current situation is to build educator capacity in the HL7 community. An initial approach suggested is to offer short programs on education skills for all who develop or deliver programs in the HL7 community and to require all to undertake such a program (unless they have recognised qualifications in education).

Action: Identify Australia's priority on these issues. Priority will relate to our commitments to education teleconferences over the next few months and at future HL7 international meetings. Australian guidance from the qualified educators in our recent 'delegations' (Heather Grain and Tina Connell-Clark) have been requested by the committee in the strategic development and in improvement of educational offerings.

A brief presentation to the board was made by the Education Committee on the developing a strategic plan for HL7 education by Abdul Malik Shakir. The plan is being developed following a request from the Board at the May 2010 WGM.

In terms of scope, "education" has been to include the traditional areas of WGM tutorials, e-learning, ambassador presentations, university program curricula and onsite tutorials but is not limited to these offerings. All educational efforts governed, promoted, sponsored or conducted by HL7 International or any of its work groups, committee or affiliates have been considered within scope. HL7 International need

not provide an offering directly but, to be considered within scope, the offering must be traceable to an organizational body within or affiliated with HL7 International.

HL7 is being widely adopted, which increases the need for a good, scalable education program. The aim is to produce an actionable education plan that:

- is well understood, endorsed and adopted by all of HL7 International
- includes quantitative and qualitative performance measures, baseline and target performance measurement values, and
- defines processes for on-going monitoring of educational programs world-wide.

The education strategic plan will outline:

- Stakeholder identification and needs assessment
- Education products, services, themes methods, modes and venues
- Education resources, materials, instructors, technology and funding
- Educational Processes, metrics, objectives, and goals
- Education strategic Roadmap, action items, and milestones

Discussion of the proposed plan at the Board included:

- Monitoring and evaluation activities should include follow up with implementers to determine how well HL7 training helps them accomplish successful implementations.
- Where and how HL7 International will capture and manage IP in these materials and hopefully derive revenues from royalties. It needs to be clear that educational materials are HL7 copyrighted intellectual property and cannot be copied and used free of charge or without HL7 approval.

In further consideration of this point, the advantages of having HL7 tutorials and education material (and other material such as presented papers) available in the academic setting is a good idea. ARRA is now also funding curriculum development for some areas that touch on HL7.

- The need for TSC to be advised of this important project so that it can be registered as an approved project that appears in the searchable project database.

It was noted that this highlights the need to improve internal communications within HL7 to ensure that TSC is advised of strategic projects, has the opportunity to provide valuable input on the technical aspects and ensure that projects are appropriately publicised and coordinated by inclusion in the TSC project database.

- The nature of the metrics to be used and their global applicability. Education Committee are in the early stages of planning and do not wish to limit this project to the US. They will be researching the types of metrics that are being used in other places.
- the subtle differences in how some educational programs are repurposed and the need to be cautious in how we proceed with any repurposing of content.

The overall area of educational outreach and planning needs to be supported by an extended and updated registry of products, services and venues for marketing and resource development – and capture of milestones and metrics.

Educational outreach and planning is also seen as a strategic objective that needs to be an integral part of HL7's business plan.

Action: It is vital that this strategy be practical and focused on real skill and knowledge deliverables of value to Australia. To this end Australian priorities must be established and a more sound process to the development of the strategy be undertaken

19 ELECTRONIC HEALTH RECORD WG (EHR)

The cornerstone activities of the EHR WG are 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 allow users or certified systems to qualify for access to Government eHealth 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.

Within Australia, the activities of the HL7 EHR WG are monitored by the IT-014-09 (EHR Interoperability) subcommittee – particularly where they relate to work progressing into the international arena through ISO/TC215.

The EHR WG meets weekly by teleconference (pre-breakfast Wednesdays Australian time) and has planned an out-of-cycle meeting in Chicago on 9-11 June to progress work on R2 of the EHR-S FM.

Information is regularly posted on the EHR WG wiki:

<http://wiki.hl7.org/index.php?title=EHR>.

19.1 EHR SYSTEMS FUNCTIONAL MODEL – RELEASE 2

Work on the update of the EHR Systems Functional Model (EHR-S FM) from Release 1.1 to release 2.0 has been underway for over 12 months and, while well advanced, it is a major task that involves hundreds of person-months of work spread over weekly teleconference calls, a series of face-to-face out-of-session (OOS) meetings, support by part-time contract staff volunteered by AHIMA and others, as well as discussion at WGMs.

The EHR-S FM and associated functional profiles were developed to serve an international audience but 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 eHealth incentives.

Production of the new EHR-S FM R2 involves reconciling EHR-S R1.1 (now also published as ISO/HL7 10781) with changes requested from experience with its application in producing and using a range of functional profiles to assess the functionality of EHR systems. Material is also being incorporated from a range of other sources. (Refer to section 24.1 of the Australian report on the January 2010 WGM for a complete list of the 18 principal sources being reconciled to produce R2).

The EHR-S Functional Model is one of the Alpha projects for the implementation of SAIF.

The EHR WG allocated a total of 8 quarters (2 days) to EHR-S FM R2 work at this WGM.

Originally, work on EHR-S FM R2 was being pushed for completion and ballot in March 2010 but this ambitious schedule was not achievable, even with the generous commitment of paid resources by AHIMA (American Health information Managers Association). One of the drivers for such an ambitious schedule was a mistaken belief that Canada needed R2 in order to progress its national EHR conformance testing regime but this is being addressed by the Blueprint 2010 functional profile (building on R1.1).

The current schedule for assessing and integrating the many functions and criteria available from existing and new profiles through to preparing and holding the first HL7 Informative (Committee) Level Ballot is reported below. The project will have slipped around 3 to 4 months since May 2010 with the target now being a **"spring ballot"** for reconciliation at the May 2011 WGM.

Activities	Actual/Proposed Date	Previous Target
Face-to-face OOS working session in Chicago	9-11 June 2010	9-11 June 2010
Review the proposed schedule. During the Work Group Conference Call, announce/Request all other components to be considered in R2	15 June	15 June
Word Format/Translation to XML discussion finalized	29 June	29 June
Closing of new items for R2 consideration (bring in VR, Pharmacy, ISO documents, other	1 August	1 August
Face to Face: Chicago	30/31 August	30/31 August
Discussion at October 2010 WGM Cambridge	3-7 October	3-7 October
Determine how to integrate RMES requirements	31 October	1 August
Determine how to integrate EHR Interoperability Model requirements	31 October	1 August
Harmonization spreadsheet update completed	12 November	15 August
Harmonization complete and approved by Work Group	12 November (Assumed – not separately specified)	28 September
All spreadsheet content returned to MS-Word format - Word document finalized.	12 November	2 November
Glossary Work Completed by the Canadian teams	3 December	New item – not previously specified

Activities	Actual/Proposed Date	Previous Target
Restructuring of chapters - Reformatting the DC, SP & IN Chapters (moving functions and criteria to increase clarity around how these things relate)	20 December	1-10 October
Acceptance review/revision of Functions (including statement and description, related criteria etc.)	30 January 2011	2 November
Rewrite of Chapter Front Matter	30 January 2011	New item – not previously specified
Review done/voted on by Work Group. Moved to publications	30 January 2011 - now covered by several items	2 November
Rewrite of Overview	15 February 2011	New item – not previously specified
Writing of additional chapters (Interoperability)	15 February 2011	New item – not previously specified
Notice of Intent to ballot due	29 February 2011	24 October
Notice to HL7 of proposed content	-	31 October
Publications cleans up documents	-	2 – 20 November
Final content /documents to HL7 for ballot cycle. To include XML.	-	21 November
Ballot	-	24 November to 3 January 2011
Publications amalgamate and circulate ballot comments	-	4-7 January 2011
Ballot reconciliation	May 2011 WGM – Orlando	8 January 2011

With the assistance of Sue Mitchell (provided part time by AHIMA) the MS-Word version of the R2 documentation (in the new R2 format) is being compiled progressively as each chapter of the reconciliation matrix (in MS-Excel) is completed.

Once an entire chapter is complete it is passed on to a Canadian team who will perform the glossary harmonisation process to confirm that all terminology is being used consistently and in line with preferred usage identified in the EHR WG Glossary (as documented in the EHS-S FM) and the SKMT Health Informatics Glossary developed in TC 215. Reformatting of DC, SP and IN will occur after all of the glossary work is completed.

19.2 NIST TEST PROCEDURE FOR MEANINGFUL USE

Ms Lisa Carnahan outlined the role of the National Institute of Science and Technology (NIST) in developing test procedures for ONC to assess whether clinician use of EHR systems complied with the regulatory requirements for "meaningful use" under the ARRA/HITECH conformance clause. She stressed that NIST's role is to set nationally applicable test requirements that can then be applied

unambiguously by third-party testing services that to do the actual testing. Further information is available from the NIST website at: <http://healthcare.nist.gov/>. The process to date has involved:

1. Identifying and extracting the normative text from the final rule along with some informative text and identifying relevant standards (e.g. HL7 v2.5.1) where these have been quoted.
2. Specifying test procedures -- trying to avoid adding requirements as part of the test procedures as this is a bad thing. In particular they had a problem when adding test data for CDA as this presumed quite a few additional requirements which were not actually part of the minimum specified requirements in the final rule. They eventually pulled way back from recording test data content as it is something that is mainly vendor defined [Australian note – the focus of ARRA/HITECH testing relates to interoperability in the context of systems functionality/ business process and not information interchange].
3. Finally - production of an inspection/test guide derived from the test requirements, which is being maintained as a living document.

NIST is now in maintenance mode taking comments and are keen to receive feedback. The main feedback so far has been - please don't publish any more for now until this has been digested by the public domain and implemented.

Issues raised during discussion by the EHR WG included:

- How to relate functionality requirements expressed in terms of version 2 and CDA interchange capability to those to the EHR-S FM;
- Concern at potential disconnects to the established CCHIT testing processes;
- Concern by other stakeholders that both ONC and CCHIT are not sufficiently concerned with the validity and integrity of the source record and this does not seem to be on the radar
- Lack of information about ONC's requirements for Stage 2 and Stage 3 of the ARRA/HITECH program as the concept of "meaningful use" matures – for example, how will certification of public-health reporting be addressed – how granular will the requirements be? Will they be certifying by domain (e.g. oncology reporting, infectious disease, biosurveillance) or not? and, if not, how useful can the certification be?

Lisa Carnahan is planning to attend the January 2011 HL7 ISEM/WGM in Sydney. She will be looking to meet with key contacts here.

19.3 EHR SYSTEM DESIGN REFERENCE MODEL (EHR-SD RM)

A joint meeting between Government Projects (Co-chair Nancy Orvis) and EHR WG received an update on the *EHR System Design Reference Model (EHR-SD RM)* also known as the *Healthcare SOA Reference Architecture (H-SOA-RA) V 2.0* – with Dr Steve Hufnagel leading discussion by presenting on the topic:

"Constructing a future state EHR Reference Architecture: EHR way ahead business architecture from HL7, HITSP and ARRA artifacts"

Originally, the project focussed on bringing together the following three substantial specifications affecting EHR system design and development within a cohesive architectural framework:

- HL7 EHR System Functional Model (EHR-S FM),
- HITSP Interoperability specifications/Capabilities and

- OMG SOA layers.

Renamed the EHR Systems Design Reference Model (**EHR-SD RM**) project, it has been expanded to look at potential component architectures more thoroughly to also include:

- Alignment with developments in the HL7 SOA-Aware Enterprise Architecture Framework (**SAIF**)
- ARRA/HITECH artefacts (potentially including the NIEMS framework)
- Maintaining HITSP, ARRA, NHIN and CCHIT conformance by maintaining EHR-S FM traceability.

The work is recognised as a SAIF Alpha project but is still largely in the development and pilot stage with many of the ideas being based on work with key US Government agencies. Suggestions for improvement are being sought.

Copies of the presentation are available at:

<http://hssp.wikispaces.com/file/view/Constructing+a+Future+State+EHR+Reference+Architecture+20101005.ppt>

Other slide decks and white papers are available by following the many links at:

<http://hssp.wikispaces.com/Reference+Architecture>

The following is an outline of the project drawn from the HSSP/SOA project description:

EHR-SD RM EHR System Design Reference Model

This project matures and integrates the April 2008 Healthcare Services Oriented Reference Architecture (H-SOA-RA) into an EHR System Design Reference Model (**EHR-SD RM**), using the HL7 SOA-Aware Enterprise Architecture Framework (SAIF), HITSP interoperability specifications, EHR System Functional Model (EHR-S FM) and ARRA artifacts.

Emphasis is placed on maintaining HITSP, ARRA, NHIN and CCHIT conformance by maintaining EHR-S FM traceability. Mapping and analysis of the HL7 product portfolio against the EHR-S FM is used to integrate the reference architecture with HL7 product lines and initially mature the resulting model as a technical white papers, then an informative reference model and finally a standard reference model.

There are TWO subprojects:

EHR-S CI-IM [EHR System Computationally-Independent Information-Model](#)

This project (started in June 2010) will produce a set of constrained information models called EHR-S “data profiles”. Each EHR-S data profile corresponds directly with an EHR-S FM function profile and will include one-or-more Reference Information Model classes.

Pairs of EHR-S function profiles and data profiles can be used to define business objects, which can be composed into software components, capabilities, applications, systems, message exchanges, document exchanges and/or services.

The superset of EHR-S data profiles is called the EHR-S Computationally-Independent Information-Model, which will support the HL7 Development Framework (HDF) and Service Aware Interoperability Framework (SAIF). The project will include the development and execution of a communication strategy to ensure that all affected stakeholders are engaged.

HF&EA Harmonization Framework and Exchange Architecture

The **first objective** of the HL7 Harmonization Framework and Exchange Architecture (**HF&EA**) project (also started in June 2010) is to define a notional set of architectural artifacts for HL7 projects and EHR System (**EHR-S**) development or acquisition projects.

The **second objective** is to define the relationships among HL7 architectural artifacts and how they relate to other healthcare related standards and architectural artifacts, which can support a Model Driven Architecture (**MDA**) waterfall, spiral, agile or other development methodology.

The **third objective** is to be an implementation guide for the use of the HL7 Development Framework (**HDF**) process and HL7 Service Aware Interoperability Framework Enterprise Compliance and Conformance Framework (**SAIF ECCF**) structure by which architectural work products are reused or developed, are organized into an Interoperability Specification and used throughout an architecture development project, the governance that should be enacted on these work products, and the scope of the standardization effort itself.

The **fourth objective** is to define a Healthcare Information Exchange Model (**HIEM**) for model-driven Healthcare Information Exchange Package Documentation (**H-IEPD**) and exchange architecture.

The **fifth objective** is to demonstrate how the HDF and ECCF can complement other frameworks such as TOGAF, Agile Scrum, DODAF and Zachman.

The value proposition for standards-based approach to "systems design" using standardised business system components is expected to flow from:

- **Analysis Pre-Done:** Analysts from throughout industry will have vetted and contributed to the development of thorough specifications
- **Less Customization:** COTS vendors will already be building applications to meet these specifications.
- **Comprehensive View:** Standards provide a way to ensure that requirements and design address all of the necessary issues
- **Lack of unexpected dependencies late in project:** All functions and specifications have been pre-analyzed and defined
- **Better Interoperability:** Standards based approaches will ensure development between all stakeholders are able to communicate at the project and technical level
- **Across Project Visibility:** Normalized requirements and design would allow for "apples to apples" comparison across the portfolio

Apart from giving a general update on progress, the main objectives of discussing the EHR SD RM in the EHR WG at the Cambridge WGM was to get feedback on the following questions and issues to guide future work as part of the current HL7 Alpha project:

1. How should the EHR-SD RM be represented?
 - XML DB and/or, DITA documentation? This is the present hypothesis.
 - XRS - XForms on the client, REST interfaces, and XQuery on the server?

2. What are the cases for EHR-SD RM use? Do they include: ad hoc reporting needs; Web-based tools needs; profiling needs (e.g., domain adaption vs. local use adaption)
3. How should the EHR-SD RM be balloted? - As part of the EHR-S FM? or independently?
4. Who will participate? Contributions needed from:
 - Information model sub-project
 - Harmonization framework & exchange architecture sub-project
 - Those involved with HITSP and mapping for "Meaningful Use"
 - Those with domain Use Cases
 - Those working on representation and tooling infrastructure.

Some of the points made during consideration of these issues included:

- The EHR-S Functional Model deals with the EHR component of the overall health information systems spectrum but does not span the space needed to cover other aspects such as finance, bookings, diagnostics, clinical registries etc
- EHR it is based on a functional model – the work is aimed at creating a harmonisation framework that links the EHR-S FM to individual HITSP specifications, which are based on addressing specific business needs within the health system.
- The practical outcome of using this approach was that it took 3 to 4 months to completely specify an immunization management system for the US military based on reusable systems components. The aim is that multimillion integration projects can be scaled down to more predictable, faster and more responsive activities costing a few hundreds of thousands.
- The use of such a framework can greatly enhance traceability and control of program expenditure – relating the dollars spent to the capability delivered at each year of execution. If this approach is adopted, the EHR-S FM effectively becomes a Dewey decimal system with which to index systems capability and measure its implementation
- Since May 2010 the project has been consolidating and identifying issues, opportunities and refining its strategic direction, including:
 - looking at the EHR-S FM and working out how best to leverage the functional requirements;
 - modelling tools and artefact databases – visual representations are a significant issue
 - ongoing role of the HL7 MIF as a non-standard model interchange format is questionable and the project is now seeking help on available alternatives
 - in terms of services, the project has only had to add about six new services to the many services already set out for the health sector by the HL7/OMG HSSP project
 - senior management starting to see some of the reasons for using architectural approaches
 - the worldwide supply chain model works well on a standard set of functions.

The overall aim with this work is to component-ise the information systems support for elementary business functions so that the business functions and the

information needed to support each of them can be combined and re-combined in different ways within the services architecture.

19.4 HDATA SPECIFICATION OVERVIEW

Gerald Beuchelt (MITRE) and Paul Knapp (ITS WG) presented on behalf of the ITS WG on the development of the hdata specifications for simplifying communication of health information. The preferred hdata approach is currently based on:

- Separation of syntax and health care content. The technical community defines the technical information structure and the clinical community use flexible profiles to capture clinical content
- Web services specifications implemented using scalable RESTful APIs
- Leveraging existing standards (HL7v2, HL7 v3 CDA, DICOM etc) for subcomponents of an hdata information exchange – the aim is specify containers rather than "rip & replace"
- Use of metadata to facilitate information exchange based on hierarchies of simple XML documents mapped directly to health record content
- Initial case studies now being developed surround v2 messages for laboratory and a record exchange format for CCD
- Going to ballot with the record exchange as an HL7 specification for January 2011.

MITRE is working with the HL7/ITS WG on developing hdata specifications to provide ITS technology to serve others. MITRE is also working with HL7 clinical content domain groups to come up with content profiles for populating hdata information exchanges.

There was some concern how this work related to the EHR WG's activities. It was noted that the hdata project is interested in looking for use cases behind the functional requirements in the EHR-S FM. More information is available at:

- <http://www.youtube.com/watch?v=ijNajvdlZos>
- <http://www.mitre.org/work/healthcare>
- <http://www.projecthdata.org>

19.5 HL7 DIABETES DATA ANALYSIS PROJECT

This project is a collaboration between Patient Care WG, Clinical Interoperability Council, HL7 EHR WG and others with the aim of specifying EHR interoperability use case templates (as employed in ONC/AHIC use case analysis) in parallel with HL7 approaches using DAMs and DIMs. The work has involved:

- Sampling data elements used in different contexts – through desk research on research forms, practice guidelines, quality measures; expert interviews; review of information models for existing specialised diabetes outpatient management systems
- Addition of data elements from the team modelling the diabetes DAM in The Netherlands
- Data cleansing – aligning each identified data element to a consistent definition within the context in which it is collected – and obtaining for each a precise, exhaustive, exclusive value set

- Analysis of data elements, involving: - Organisation of data elements by conceptual groups; resolution of similar elements from different samples and contexts; annotating each with its relationship to various EHR standards; and classifying them as either "atomic" or "derived"
- Build up a set of mini use-cases covering both primary clinical data collection and secondary use for activities such as research quality improvement and population use cases.
- Identify commonalities in use cases and produce normalised set. The goal was to get a broad cross section of use cases but not to try and develop an exhaustive collection of all T1D use cases.
- Data modelling – to create a graphical depiction of data elements; identifying atomic data elements and their relationships to each other and the derived elements and the potential to reuse elements
- Finding patterns that can support future harmonisation efforts by establishing relationships to existing standards such as BRIDG, HL7 DCMs, EHR-S FM and the HL7 Interoperability Model and EHR Life Cycle Model.

Examples were given showing relationships between the normalised T1D medications model – comparing it to the HITSP Hybrid Medications model, the EHR S-FM and EHR-IM – showing how they can be compared to identify common elements, gaps and differences.

The successes and opportunities flowing from this work to date were noted:

- There continues to be lots of interest in the project
- It has engaged with engaging a very diverse group of volunteers - covering various perspectives including clinicians
- Some gaps in the HITSP constructs have been identified
- The process supports and enhances patient-centric information use related to T1D.

Project leads: Don Mon, PhD (EHR WG), Crystal Kallem (Clinical Interoperability Council), Pat Van Dyke (EHR WG) and Gary Dickinson (EHR Interoperability WG)

19.6 OTHER EHR WG ACTIVITIES

As usual, EHR Work Group had a full program and was extremely well attended for its more general sessions; however, attendance was markedly lower in those quarters where detailed work on reconciling the various inputs to R2 of the EHR-S Functional model was taking place.

Apart from the matters already reported above, the following are among the other substantive matters addressed by the EHR WG at the Cambridge meeting.

- **Review HL7 Project List.**

Status of projects of interest to EHR WG was noted with some being discussed in some detail.

- **Update on EHR WG documents being developed in ISO/TC215**

In presenting an update on the activities in ISO/TC 215, Gary Dickinson highlighted the fact that the proposal he had put up on behalf of HL7 to develop ISO/TR 16223 – Standards convergence to promote EHR Interoperability had again failed at ballot as it had not been able to attract sufficient experts from approving countries. He was very disappointed at this outcome (particularly noting the negative Australian vote after negotiations in May). He is looking to

work with the relevant people (including Richard Dixon Hughes) to find a way of progressing the work that meets everybody's needs.

It is proposed that finalisation of the first major revision of ISO 20871 (HL7 EHR-S FM Release 1.1) will occur as a joint ballot with ISO/TC 215. The exact process will depend on having documents ready (mid next year) and will be coordinated through JIC.

The SKMT health Informatics glossary developed by Andrew Grant of Canada and Heather Grain of Australia is being used throughout TC 215, has been offered to the other SDOs in the joint Initiative Council (JIC) and will be proposed to the upcoming meeting of the JIC harmonisation track at the Rotterdam meeting commencing on 11 October.

- **EHR WG Glossaries**

John Ritter gave a report on the review of the glossary entries within the EHR systems functional model and invited all present to post comments the EHR-S verb hierarchy on a chart alongside the registration desk. The aim is to ensure that the verb hierarchy on which the functional requirements statements throughout the EHR-S FM and PHR-S FM are correct and widely acceptable as HL7 moves into finalisation of EHR-S FM R2.

Collaboration with SKMT and the standard ISO/IEC Information Technology vocabularies was again mentioned by Richard Dixon Hughes)

- **Data mapping to/from the EHR-S FM.**

Steve Hufnagel and Crystal Kallem presented a progress report and introduced discussion, during which some of the following points were made:

- Michael van der Zel (The Netherlands) reported that he had worked all the way through the EHR-S FM to identify CDA documents and messages needed in order to meet the functional requirements. Their next step is to map the EHR-S FM to TOGAF
- Point-specific solutions do not generalise too well – a more comprehensive tooling solution is needed to make the EHR-S FM (and profiles built on it) much more useful [Hufnagel].
- A DAM should be the next step – and this could be put to informative ballot to keep up momentum and get feedback. Ken Kawamoto (Duke) indicated that his work had not been intended to go to ballot but was developed as a scope statement.
- The challenge is how HL7 might be able to generate HL7 products directly from the EHR-S FM – the ideal is to build a knowledge base so that an organization can check the required functions (based on their own use cases), crank the handle and produce the acquisition specifications and DAM. [Hufnagel].
- Such automated processes would naturally require some intelligent supervision, review and checking but should be able to simplify and streamline the process.
- Release 2 of the EHR-S FM is a significant point at which many issues have been resolved and provides lots of opportunity for development. To exploit these types of opportunities, HDF will need to be reevaluated and aligned with SAIF. [Gora Datta]
- There are many overlaps in the clinical domains between the Clinical Operability Council (CIC), domain expert committees and, if this type of development proceeds, the EHR WG. Collaboration and common approaches (e.g. reusing the CIC spreadsheet) are vital to HL7.

The WG was reminded by Gary Dickinson (as co-chair) that the scope of this project is to investigate re-use of functions as well as re-use of use cases, re-use of actions and re-use of data sets.

- **Technology for maintaining and mapping the EHR-S FM.**

Steve Hufnagel reported on his investigation into the possibility of moving the EHR-S FM model from a combination of MS-Excel and MS-Word into a recognised information modelling environment.

The prime candidates are Enterprise Architect, Rational Rose (IBM) and Papyrus (Eclipse/ Open Health Tools); however, none of these support the needs of the EHR-S FM particularly well.

Nevertheless, such tools would be compatible with a future state where the EHR system design reference model (EHR-SD-RM) allows re-use to be more easily achieved, thereby supporting work by the Government Projects WG on re-use and:

- the automated production of interoperability specifications
- management of realm and domain specific aspects
- compatibility with industry-standard tooling (which would be greatly aided if HL7 were to move on from its proprietary MIF model interchanged format.

The WG noted that the problem in moving to a specialised modelling environment is that it would diminish general accessibility to the EHR-S FM as only modelling experts with appropriate tools could engage readily.

- **Vital Records Functional Profile.**

Michelle Williamson from US-CDC provided an update on this project (which has been discussed at some length in previous WGM reports).

20 HEALTH CARE PROVIDER AND SERVICES DIRECTORY

The Health Care Provider and Services Directory Service (HCPDS) was published as an HL7 standard in February 2010. However, the OMG RFP is still not published and there was a recent revision in September 2010, though the plan is for the OMG to issue the RFP in December. The Victorian implementation is the only major implementation however HL7 is actively seeking further candidates to implement the specification.

HL7 Patient Administration WG has established a separate Registries project for developing a unified concept for registries such as a patient, location, and provider and is interested in seeing how Patient and Provider directories overlap with this specification (and EIS, RLUS) and this will be worked out between now and the Sydney 2011 WG meeting. The scope of this project does not cover Disease Registry/Notification services but otherwise the project scope statement is still under discussion.

Action: IT-014 and NEHTA to monitor progress of a Patient and Provider Directory SFM and identify national priorities for this work.

20.1 ENTITY IDENTIFICATION SERVICE

The Entity Identification Service (EIS) is known as the Identity Cross Reference service (IXS) by the OMG. EIS is now a HL7 normative specification and OMG spec is in the FTF (Finalisation Task Force) stage, the main implementation is the Italian (European) epSOS project which architecturally is using IXS to wrapper a PIX/PDQ implementation. There is also a MIRTH (open source) implementation which is being used by the NHIN.

It is likely that the EIS/IXS specification will form the baseline for any work conducted by the Patient Administration WG for a Patient and Provider Directory SFM.

Action: IT-014 and NEHTA to monitor progress of Patient and Provider Directory SFM and ensure harmonisation with existing ISO work in this area.

20.2 PRIVACY, ACCESS AND SECURITY SERVICES

The PASS (Privacy, Access and Security Services) is a SAIF Alpha project. There are several streams of work and currently only the Audit services have been successfully balloted and therefore are a HL7 DSTU. This Audit services project was heavily informed by the IHE DICOM specification which contained the Audit functions which were adopted in the SFM.

There is already implementation of the Audit work in the OHT that leverages Misys tools from OpenATNA (which implements an Audit Record Repository of the IHE Audit Trail Node Authentication (ATNA) profile) and there are plans to have orchestrated solutions of PASS services with other service specifications available in OHT in the future.

An Authentication model is also being worked on using SAML 2.0 during this work group. In the future an Access control and an Identity resolution interface that will provide a common trust model between parties will also be developed.

There are currently no plans for an Implementation Guide to orchestrate services with PASS services in HL7 however this is acknowledged in the long term as a necessary body of work to be conducted.

The HSSP PASS (Privacy, Access, and Security Services) project has been an exemplary SAIF Alpha project that has attempted to use the ECCF structure to define their Access Control model. This specification has reached DSTU status following successful reconciliation of comments. The PASS Audit specification was balloted DSTU in Cambridge. It also follows the SAIF structural approach to interoperability.

20.3 SOA SERVICES ONTOLOGY

The project in scope is to develop a Health Interoperability Service Ontology encompassing the description and classification of healthcare orientated services. An aim is to provide a common descriptive framework for naming and specifying services in the HL7 realm. This project is being conducted in collaboration with the HL7 Vocabulary WG.

Action: IT-014 and NEHTA to monitor the development of the SOA Services Ontology and provide input into the development based on local experience and requirements.

20.4 UML AND MIF

This project is to understand the crosswalk between UML and MIF including a detailed collation of the MIF. The OMG is about 80% complete on the mapping and correlation of these and it is expected that the report will be published by the HL7 meeting in Australia. All the work is being documented in a wiki that will allow all users access to the information related to correlation project.

The project has been a little dormant between this meeting and the last meeting, but there was agreement to start working towards a final conclusion for the first round: a detailed consideration of alignment between UML and MIF, and start working on round 2 of the work, which regards recommendations to OMG for additions to the UML standards suite, and recommendations to HL7 for how to better align with OMG's view of how such standards based models can serve the industry.

21 IMPLEMENTATION AND CONFORMANCE (I&C)

I&C have been recognised by both the ARB and TSC as the appropriate group to see through implementation of the SAIF ECCF through both owning the base framework as well as the HL7 ECCF Implementation Guide. There continue to be issues in I&C taking up this mandate as the scope of ECCF is different than their previous work and adds additional requirements beyond the more traditional Platform-Specific conformity assessment. There continue to be issues around the basic concepts of conformity assessment. It should be noted that ECCF leverages the ISO 17000 conformity assessment work. This approach is now also the basis for related work in Canada (Infoway), the US (ONC), and Australia (NEHTA). This alignment between ECCF and I&C is crucial for the ongoing realisation of SAIF and architecture compliance within HL7.

Jane Gilbert of AHML in Ballarat was re-elected co-chair of the Implementation/Conformance Work Group. Jane had not been able to attend the Cambridge meeting due to other commitments.

22 ITS

The ITS group finalised the RIM Serialisation. This allows for direct transfer of any V3 model as a RIM graph with constraints. Note that the availability of this wire format increases the alignment between v3 and openEHR; the impact of this will become more evident as implementation proceeds.

The ITS group continues to work closely with Structured Documents regarding the implementation lessons learned from greenCDA. The group is using the greenCDA work as a pilot to inform the more general μ ITS project, which deals with simplification of v3 models. This work also offers the possibility of increased alignment with openEHR.

A significant new piece of infrastructure is being introduced. This is known as "hData", which is a specification that has been brought to HL7 by the Mitre corporation. It's a radically new approach for HL7, and it's not yet clear whether it has any useful alignment with the rest of the work that is happening. It will be balloted during the next ballot cycle, and the Australian community is strongly recommended to examine the hData proposal, particularly from a strategic perspective – if hData passes ballot

easily this will be an indication of broad support that could lead to this approach having considerable influence over the future direction of HL7 specifications.

Action: That IT-014 publicises the hData ballot and recommends that Australians participate in the ballot.

The ITS group indicated in the planning meeting for Sydney that the HL7 Web Services profile would be reviewed during the WG. Any parties with an interest in the specification should take note of this and plan to participate in the meeting.

23 MARKETING

23.1 MARKETING GENERAL

An updated Marketing Plan was approved earlier in 2010 (prior to the May 2010 WGM in Rio) and there resulted in significant reporting of HL7 in the US media. HIMSS 2010 in February was also very successful for HL7. A new marketing campaign - “HL7 Can Help!” – was successfully introduced as part of these initiatives.

At the Cambridge meeting, the CEO, Chuck Jaffe, reported that:

- HL7 has hired Martopia, a Chicago-based marketing firm with experience in multiple verticals, to assist with getting HL7 products and corresponding descriptions online
- The initial contract phase will support development of product descriptions for high-level product groups and will include HL7 website support
- A secondary phase will support development of detailed product briefs.

The first of a series of marketing webinars, entitled *The HL7 Healthcare Connection*, continues to evolve in scope and content.

HL7 Australia should track progress of the Martopia work, with a view to giving timely input considering whether any of the resulting materials can be used to assist in publicising HL7 capabilities in Australia. Such work should also be relevant to HL7's

Action: HL7 Australia to follow progress of the Martopia work, with a view to ensuring that the resulting outputs are relevant to HL7's international context and how the resulting materials can be used in the Australian to assist in publicising HL7 capabilities in Australia.

23.2 EU OFFICE

The HL7 Europe office is now operational (as an outpost of HL7 HQ) with the business requirements for incorporation as a Belgian foundation, documentation and establishment of a physical presence in Brussels being completed in Q3/2010. Bylaws have been developed to meet the needs of EU regulation but leadership roles are not currently identified.

In reporting on this progress, the CEO, Chuck Jaffe, gave particular thanks for the leadership being provided by Catherine Chronaki, Affiliate director on the Board of HL7 International, who is based in Greece.

At a practical level, the relationship between the HL7 Europe office and the local Affiliates in Europe still needs to be worked through, with some form of advisory

structure comprising the chairs of the European Affiliates (a European Council) being under consideration.

Funding has been provided for 2010. A draft business plan for HL7's proposed EU activities in 2011 has been presented to the HL7 Executive Committee with line funding in the 2011 budget being under negotiation. Opportunities for 2011 include an HL7 EU Newsletter, "sponsorship" program, EU Advisory Board, and possibly an HL7 EU meeting in 2011.

An HL7 EU website (<http://www.hl7.eu/>) has also been set up but is still in the early stages of development.

Progress with HL7 EU outreach activities in the following areas was noted:

- epSOS. This program piloting pan-EU interoperability in e-health is growing with more countries electing to participate and will deploy CDA as a technical specification for both ePrescribing and longitudinal health records.

Agreement with HL7 for use of HL7 standards has been negotiated but not signed and there will be some funding for HL7 but it is unlikely to be significant. The role of HL7 vis-à-vis IHE remains unclear, both from a standards and an EU governance perspective. A program lead for HL7 involvement needs to be identified.

- SEGHOVIA: Contractual agreement with HL7 is pending for participation in this initiative. Some 40 organisations have been invited to join the initiative, which supports the eHealth Governance Initiative in the EU through the development of a "Thematic Network" and is now expected to get into full swing by early 2011.

The project has a budget of €500k from DG-INFOS and the Executive Agency for Health and Consumers, a timeline of 36 months and the objective of integrating eHealth into EU health policy. HL7's role is outreach and standards identification and it will receive funding to pay for support and meeting attendance – with Catherine Chronaki being the HL7-EU program lead.

- ARGOS: This is a high-level EU-US project to coordinate Health IT, including standards. The US management contract for ARGOS has been awarded to AMIA. The role of HL7 in the ARGOS project supporting coordinated resource development to be highlighted in meeting in Washington on 11 November. It will be interesting to see how well the ARGOS initiative prospers in an environment where the US regulators have set up internally focussed governance structures to deliver local standards for "Meaningful Use" with tight deadlines (again).
- Collaborative initiatives: high level understanding has evolved with CDISC and Continua over working together on EU projects. The initial interest is responding to an RFP (Objective ICT-2011.5.3 Patient Guidance Services (PGS) on safety and healthcare record information reuse)
- EMEA (European Medicines Agency) invited HL7 to give a keynote on secondary use of healthcare data at conference in September in Zagreb and in October in Berlin. An HL7 workshop has also been under development for Eastern Europe and Russia.
- Other activities include outreach to ISHEP, PhUSE, woHIT, etc.

Arrangements for utilisation of HL7 intellectual property in EU pilot projects remains an issue.

Questions about outside funding from other countries to help support the cost of running the EU office were raised. The CEO reported that it had been hoped that the EU office would be cost neutral in 2011. The European Affiliates and HL7 HQ

are still working on funding of the EU office but, as yet, there is no clear picture of how this work out. Catherine Chronaki emphasised the success that HL7 Europe has had with SEGHOVIA, which will not bring revenue into HL7 but it is a strategically important step.

23.3 WHO MEMBERSHIP

HL7 has been invited to become an organization member of WHO following its positive engagement in the Rockefeller/Bellagio program, further substantiated by publishing articles in *Health Affairs* and its many conference contributions. Its involvement will be coordinated through WHO's eHealth & Health Metrics Network activities and has been supported by Regenstrief and OpenMRS.

Objectives and deliverables for HL7 involvement as a WHO organizational member are being defined in collaboration with WHO.

23.4 OTHER INTERNATIONAL OUTREACH

In his various reports to the International Council, the Board of Directors and the general membership, Dr Jaffe made particular mention of currently planned outreach activities involving the following international organisations

- *OMG (Object Management Group)*: educational development (and, also, potential work on extending UML modelling capabilities)
- *OHT (Open Health Tools)*: Shared Artifact Library (Registry)
- *PhUSE*: EMEA harmonization with eHealth
- *GHTF (Global Harmonization Task Force)*: consortium of international regulatory agencies for harmonization of standards for devices and health information systems
- *WHO*: Council for eHealth Africa
- *IHTSDO*: initiation of joint licensing agreement

23.5 US OUTREACH - OFFICE OF THE NATIONAL COORDINATOR (ONC)

HL7 international has been disappointed by the lack of any specific response to a financial proposal for US Government development and support of the HL7 standards that was put to Office of the National Coordinator (ONC) in DHHS in April 2010. This proposal was submitted following meetings with key stakeholders (NLM, NIST, and ONC) and adjustments had been made as per their recommendations.

There are two types of funding available for which HL7 International is potentially eligible:

- ARRA (HITECH) funds: these stimulus funds are now largely gone and were intended to address near-term objectives but typically required some form of competitive contracting (which was seen as a potential barrier for HL7);
- Funds for long-term objectives tied to a sustainable business model – potentially as part of on-going CMS program funding.

In line with the second objective, a proposal to license HL7 IP for nation-wide use in the USA has also been under discussion with DHHS and the ONC but had not progressed significantly by the time of the Cambridge meeting.

Other agencies, such as CDC have recently approached HL7 International seeking terms on which they could use relevant parts of HL7v2.5.1 and the Advisory Council has recommended that timely engagement with US interests over use of HL7 IP rights is a priority.

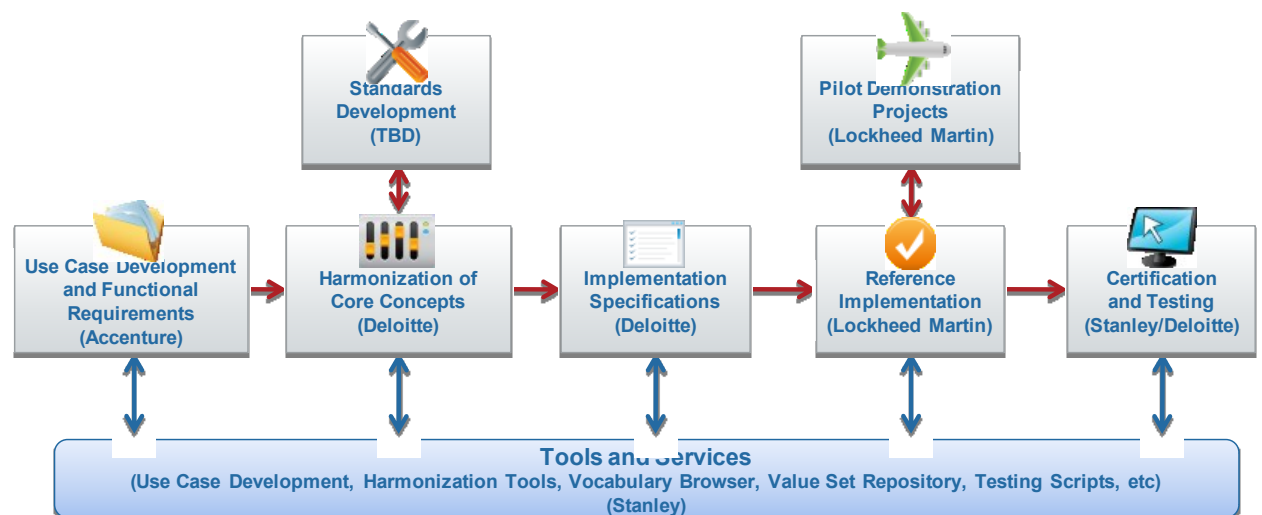
Negotiations with stakeholders (NLM, NIST, ONC, CMS, CDC, DoD) continue. Stakeholder sentiment reflects increasing support for national (Federal) funding. ONC Standards Committee testimony reflected growing willingness to pay for HL7 IP through a licensing model (perhaps managed by NLM) and Standards Committee members voice consistent and vocal support for a Federal funding model.

Doug Fridsma (Head of the ONC Office of Interoperability and Standards) attended the Cambridge meeting, discussed ONC plans with the HL7 leadership and, also, accelerated completion of high priority specifications.

As covered in previous reports from the Australian delegation, ONC issued a series of RFPs for implementation of its "Standards & Interoperability Framework", with the objectives of:

- Promoting a sustainable ecosystem that drives increasing interoperability and standards adoption
- Creating a collaborative, coordinated, incremental standards process that is led by the industry in solving real world problems
- Leveraging “government as a platform” – providing tools, coordination, and harmonization that will support interested parties as they develop solutions to interoperability and standards adoption.

The various components of the S&I framework and the companies selected to lead their delivery are set out in the following graphic (taken from presentations by Fridsma – now on ONC website):



Of significance to HL7 International is that the RFP for SDO management was not awarded and will be retendered; however, based on the time taken for the earlier RFPs, it is likely to be months before the Standards Development component is awarded.

The earlier RFPs required a pre-approved contractor for administrative management, so HL7 International was not able to bid directly but joined bids put forward by several of the eligible contractors (but apparently without any noteworthy success).

HL7 is hopes to be an ultimate grant recipient for some of the work from the ONC RFPs, although the amount, pathway and duration of such work is not clear.

The approach to interoperability and standards being adopted by ONC is designed to align and integrate with the US Government National Information Exchange Model (NIEM) which originated from a need for better interchange of information between security, justice and law enforcement agencies. The ONC aim is to introduce a Health Information Exchange Model (NIEM Health) that is harmonized with NIEM and which will provide a requirements framework against which existing standards will be mapped and new work outlined.

Given that the NIEM was developed without reference to Health sector use cases and against quite different business imperatives, the practical feasibility of leveraging much value from NIEM has been questioned by some experts but, at a more detailed level, the ONC/NIEM approach to requirements definition, modelling, reference implementation and specification development is close to contemporary thinking in HL7, Australia and the wider IT industry.

The elementary unit of ONC S&I work is the IEPD (Information Exchange Package Documentation) - a collection of artefacts that describe the construction and content of an information exchange that is reusable in different contexts. IEPD's are planned to be developed through a six-stage "lifecycle" process comprising:

1. Scenario planning
2. Analyse requirements
3. Map & model
4. Build & validate
5. Assemble & document
6. Publish & implement

This IEPD Lifecycle process is aimed at the first three main processes in the S&I framework illustrated in the above diagram (i.e. from use case through to implementation specifications) and is very similar to the approach that was being followed by AHIC under the previous administration.

The role which HL7 will be allowed to play in ONC's future plans will largely depend on the extent to which its processes conform to ONC (and ONC's advisers) views of "best practice". For example, ONC has stated that the S&I Framework is to be based on a model-centric approach that must:

- Provide traceability from Use Case and Requirements through to one or more implementations
- Provide semantic and syntactic modelling constructs to support defining the information and behaviour that are part of exchanges
- Support the need to harmonize with existing standards defined at different levels of abstraction – and support the OMG/MDA paradigm of: Computational Independent Models (CIM); Platform Independent Models (PIM) and Platform Specific Models (PSM)
- Be adoptable by different organizations
- Be able to integrate into NIEM process

ONC is looking to the next steps needed to progress it's S&I agenda as being:

- Creating a NIEM Health standards harmonization process and governance framework
- Establishing a roadmap for existing NHIN standards, MU (meaningful use) harmonization, and non-MU health information exchange specifications
- Establishing a repeatable, iterative process for developing widely reusable, computable implementation specifications
- Establishing the tooling and repositories needed
- Establishing the practices and guidelines for modelling
- Enabling semantic traceability so that useable code can be traced back to original requirements and definitions
- Promoting transparency and collaboration from broad range of health stakeholders

Engagement with the e-health SDO community remains a stated priority for ONC, although their processed for doing this and the extent of engagement are still unclear.

The CEO, Chuck Jaffe, recorded his thanks to Doug Fridsma, Chuck Friedman of the ONC for their input to HL7 and its activities.

Ted Klein (Vocab WG) also reported that he had given a presentation and testified on behalf of HL7 at a panel hearing of the ONC HIT Standards Committee, Vocabulary Task Force Workgroup in Washington DC on 1-2 September 2010.

Others representing standards organizations and professional societies on the panel that day included Bron Kisler (CDISC), Marjorie Rallins (AMA), Floyd Eisenberg (NQF), Lisa Miller (X12), and Sundak Ganesan (CDC). Information on the meeting, as well as a copy of written testimonies may be found at <http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3004&PageID=20395>

23.6 US OUTREACH - OTHER AGENCIES AND GROUPS

Engagement with agencies and groups on the following matters was reported and noted at various points in the Cambridge meeting (including reports to the Board of HL7 International).

- Single source funding support for HL7 development and US-national licensing of HL7 intellectual property remains a high priority as identified during this year's HL7 annual retreat, but substantive funding through this model seems unlikely inside the next 6 to 9 months.

An expert in government relations, Dr Doug Peddicord of Oldaker, Belair & Wittee LLP has been engaged to enhance liaison with key members of Congress in relation to measures to secure funding for national licensing of HL7, as was done by CAP in relation to funding the national licence for SNOMED CT from IHTSDO.

- The annual retreat proposed much broader engagement with specific Federal agencies with a view to identifying more appropriate value propositions to

secure their support. This has been progressed and many agencies individually expressed willingness to provide supplemental funding.

Virginia Riehl was awarded a contract to supplement high level contact with key supporters in Federal agencies. Direct payment from all US Federal agencies was only \$53K in 2010 up from \$48K the year before. This is at least an order of magnitude less than many would consider reasonable.

- VA. The CEO thanked the US Veterans Administration for their contributions to HL7 leadership – particularly through the work of Linda Fischetti and Frieda Hall and in opening up dialogue with other key agencies. There is regular and ongoing dialogue.
- FDA. Revised electronic submission requirements for clinical trials data are being prepared in collaboration with CDISC supported by new leadership in Office of the Commissioner - with Dr. Vicki Seyfert-Margolis taking over management of the electronic submissions initiative.

HL7 (RCRIM) activities will shift to emphasize strong collaboration and involvement of CDISC.

- CDC. Licensing of v2.5.1 implementation guides for use in disease reporting throughout state and regional health departments has been progressing, despite considerable differences over appropriate compensation for use of HL7's intellectual property.
- NIH / NCI. Support of work on SAIF and on BRIDG is continuing – with close scrutiny of activities and resources following changes of NCI leadership.
- NIST (National Institute of Science and Technology). As the premier authority on conformance testing in the US, NIST has the task of working with ONC on conformance and compliance regimes needed to support the new "Meaningful Use" criteria and implementation of the ONC Standards and Interoperability Framework. There is potential for HL7 to be involved with at least two funding sources currently under consideration, but even if HL7 is involved most of the work may have to "pass through" to developers and implementers:

One of these sources relates to development of tooling for conformance and compliance testing. RFPs have been released, and HL7 has been asked to participate as a subject matter expert. Follow-up meetings to date have been productive, but no contracts have been let yet.

- CMS (Centers for Medicare and Medicaid Services). CMS has a huge dependency on HL7 standards but this use of HL7 IP largely goes without any significant financial return to HL7. Discussions on this theme continue as the state-based Health Information Exchanges (HIEs) need increasing access to HL7 specifications as clinical providers move to supply HIEs with information from their various EMR systems in electronic format in order to become eligible for "meaningful use" subsidies. Almost none of the state HIEs had previously sought to join HL7 or licence HL7 IP directly; however, negotiations have begun with some (Tennessee, California, New York).

Concerns remain about possible CMS intentions of passing HL7 IP on to state-based HIEs without licensing or approval from HL7.

- NCPDP. The NCPDP leadership has agreed, in principle, to evaluate of the HL7 RIM as the basis for their information interchange models supporting pharmacy-based primary care programs and a face-to-face meeting was held with NCPDP in Scottsdale, Arizona in the last week of August to progress collaboration at Board/executive level.

- X12. Proposals to align X12 information models more closely with the RIM and for collaboration between X12 and HL7 work groups
- Significant change in the posturing of the X12 leadership, now unwilling to discuss tighter alignment with RIM and more effective coordination with HL7 WGs
- ONC's lack of stated commitment to collaboration seen as an obstacle to finalizing agreement, but more effective coordination is anticipated after SDO Management award has been finalized
 - NQF (National Quality Forum)
 - Continued collaboration on eMeasures coordinated by Bob Dolin
 - Pressure coming from ONC to reduce dependency on RIM
 - Funding for standards development, originated in CMS (DHHS) may be reduced or eliminated.

24 MODELING AND METHODOLOGY (MNM)

Most of MnM's meeting focused on purely technical issues not of general interest (RIM and core principles ballot reconciliation, v3 interversioning), or the discussions are reported elsewhere in this document (e.g. vocabulary, architectural and behavioural framework projects).

25 ORDERS AND OBSERVATIONS (OO) AND LABORATORY

Australia had previously submitted a specific requirement, i.e. withdraw report (e.g. in case of error in the lab test work done). This is not a concept that is familiar to US realm. In US errors in lab reports are rectified by sending amended reports. There appears to be no follow-up from Australia after the storyboard was submitted. It is unclear who/which entity from Australia submitted this requirement. Australia should follow-up on this requirement if it is to be progressed further.

26 PHARMACY

The Pharmacy meeting covered a significant number of topics. These are summarized in the following subsections.

26.1 HL7 V3 TOPICS

26.1.1 BEHAVIORAL MODEL

A behavioural framework has been developed for composite order:

See HL7 wiki – http://wiki.hl7.org/index.php?title=Conceptual_BF_Document), which is focused primarily on Lab orders.

Pharmacy is requested by OO to take a topic inside pharmacy and to determine whether the current BF is adequate and contribute to improvement of the BF, especially in order updates and order replacement use cases.

Composite order model is considered the common reference for templates from domain

specific orders (e.g. pharmacy orders, lab orders http://wiki.hl7.org/index.php?title=Composite_Order)

There are questions about:

(a) Whether pharmacy's common product model and other pharmacy cmets and pharmacy order models are aligned, and

(b) How they are aligned with clinical statement. Analysis will need to be done by Pharmacy WG.

Medication CMETS are based on common product model. These CMETS had been balloted once. But not progressed further as there is a need to identify how these CMETS are derived. The current belief is that these CMETS are derived from the common product model. Analysis will need to be done by Pharmacy WG.

Issue on the use of Data Type 1.1 versus 2.0 is raised. Currently all pharmacy models, IDMP, and ICSR are based on R1.1

It was clarified that HL7 had a mandate that from 2011 all ballots would need to be based on R2.0. This mandate does not affect ballots that are currently in progress. However new ballot materials that are developed for 2011 ballot cycles will need to be aligned with data type R2.0.

26.1.2 ISSUE ON SUPPLY QUANTITY

There have been extended discussions (via pre Cambridge meeting conference calls, emails and also at the October WGM meeting session) on the issue of representing and interpreting "Supply Quantity".

For example:

What is the interpretation of "Supply, quantity=50, product playing entity.code='package of 25 tablets'"?

Literally, it would mean supply 1250 tablets. But it could also (more commonly) be interpreted as supply 2 packages of 25 tablets.

Action Item: To write a harmonisation proposal to request the addition of a "supplyUnitCode" attribute to the Supply act (mirroring the administrationUnitCode attribute in the Substance Administration act).

26.2 DIET ORDERS

Diet order in v3 is at best expressed as "Supply". This is considered as a miss-fit for the required purpose. Medical diet and nutritional supplement orders can be complex. The V3 "Supply" class is considered inadequate for complex orders.

In V2.x all "orders" are considered as medical orders that must be placed by doctors. But in practice they can be ordered by dieticians. There are also needs to express diet intolerances and preferences.

Examples include:

- NPO orders, including timing
- Post-surgical progression strings of order – multiple "standing orders" from clear fluid to resume normal/therapeutic diet
- Complex (combination) diet orders, e.g. 4-g protein + 2g sodium + 2g potassium + low phosphorus + 1500 ml fluid restriction; low cholesterol + low saturated fat + 2gm sodium

- Bone marrow transplant or immune compromised patient with GVH (graft vs host disease) requiring elimination of food ingredients, e.g. fresh fruits, vegetables, smoked or raw fish (sushi), etc
- Tube feedings
- Infant formula orders
- Texture modifications, e.g. pureed, chopped

It is recommended that there should be two categories of requirements:

- Diet orders
- Expression of diet requirements or restrictions in clinical statement or care statements (such as in discharge summaries, referrals, EHR extracts, etc).

The diet group agreed to start relevant projects for each category. Co-sponsors are OO, Patient Care, Pharmacy and EHR. The first step is to create a project statement; and to focus on use case development. Present requirements need to be forwarded to relevant groups for project initiation.

CDA Pharmacy Projects

Pharmacy WG has been alerted to a number of international pharmacy projects using CDA for communicating prescription, dispensing, etc. They include the NZ and the more high profile pan European epSOS pharmacy CDA project, etc.

The epSOS pharmacy project finalized its CDA specification documents in September for aF2F meeting in Brussels on 9-10 September at which the specifications were presented, minor issues addressed. The specifications were released as “Draft for Public Comment” on 30 September after final editing work.

As CDA R2 passed normative ballot in 2005, its more generic schema is not fully aligned with models/schema developed by other WGs after 2005. For example, it is not functionally equivalent to Pharmacy DIM, there exist issues related to the adequate representation of prescription and dispensing requirements in CDA, for example, the representation of detailed medication composition. These requirements result in the extension of CDA R2 schema with CMETs or DIM fragments from Pharmacy. It is noted that this approach is accepted by IHE Pharmacy community as well. Some of the Australian extension approaches were discussed and supported by Pharmacy WG.

The Pharmacy WG expressed concerns about the inability of CDA to handle prescription and dispensing workflow requirements. epSOS delegates indicated that CDA is used to transfer information about medication. The workflows around prescription and dispensing would be managed outside the document using IHE defined workflow management infrastructures.

It is recommended that various domain workgroups begin to work with Structured Document to develop a set of domain templates for use in CDA R2/R3.

It was agreed that when SDWG develops future CDA implementation guide – pharmacy will be invited to be co-sponsor to develop templates that involve pharmacy contents.

Intent: pharmacy and SDWG specifications reference each other's contents where appropriate (there is difficulty in how this can be implemented). [in future it will be extremely useful for new CDA implementation guides to implement this intent].

26.3 IDMP

The IDMP project comprises the following:

prEN ISO 11238 Health Informatics – Identification of Medicinal Products – Data elements and structures for the unique identification and exchange of regulated information on Substances

prEN ISO 11239 Health informatics – Identification of medicinal products – Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging

prEN ISO 11240 Health informatics – Identification of medicinal products – Data elements and structures for the unique identification and exchange of Units of Measurement

prEN ISO 11616 Health informatics – Identification of Medicinal Products – Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information

prEN ISO 11615 Health informatics – Identification of Medicinal Products – Data elements and structures for the unique identification and exchange of regulated medicinal product information

Current Status:

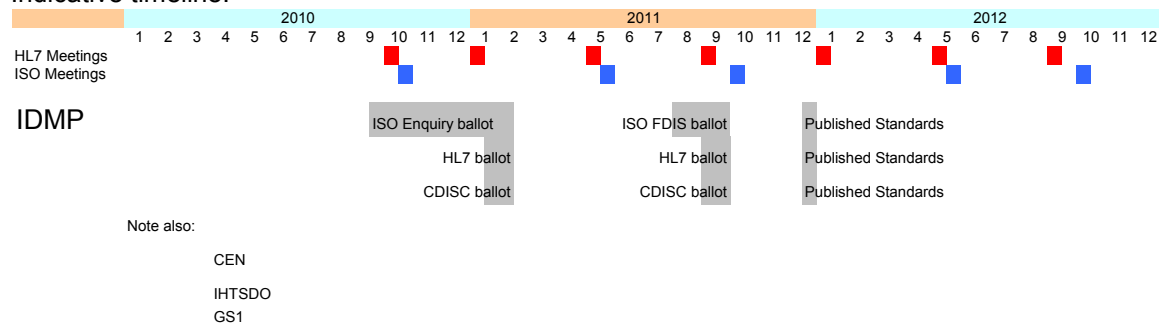
5 ISO Draft International Standards entered ballot (ISO joint with CEN) on 23 September 2010.

The ballot will close on 23 February 2011.

It is anticipated that HL7 and CDISC will ballot to co-terminate.

Testing is about to commence in multiple jurisdictions (ICH).

Indicative timeline:



26.4 HL7 V2.X TOPIC

The topic of “discontinue/new order in V2 OMP” was raised at a joint Orders and Observations (OO) meeting.

Orders can be changed (replacement order). The related orders will need to be linked. Mechanism for linking is defined in Chapter 4. Pharmacy WG will discuss this topic further in scheduled conference call.

A V2.8 change request for Immunization history has been received from HL7 US members.

The requirement submitted includes message segment for observations (OBX) to capture and send clinical information such as reason(s) for not/contra-indication(s) for giving vaccine, or past history of adverse reactions to previous vaccination. It is proposed that a new OBX segment to carry the relevant observation information. The OBX segment(s) follow(s) PID. This proposal was accepted.

Joint PCWG and Clinical Statement Meeting:

The meeting identified the need to continuously work on a number of topics:

- Composite Order model – identification of what orders are and how best to model them within the composite order model.
- Identify what is the effect/impact of the composite order model and clinical statement pattern (and impending changes) on patient care’s care statement
- The relationship of clinical statement pattern and CDA R3 right hand side (which will have full RIM/RIM-style structure). It was agreed that the Clinical Statement pattern would function as the “next layer” for CDA, thus serving as constraint and hence the default template for use in CDA.
- It was also determined that the clinical statement pattern by itself is broad and will require further “templating” mechanisms to provide specificity to meet different use case requirements.

Templates are required to ensure all detailed requirements are to be adequately met and to drive harmonization. Need to work on how to define a template to ensure they are easily re-useable. The challenges are that templates require to be modelled correctly with proper style and the right level of granularity.

Patient care WG is requested to compare its care statement with latest clinical statement pattern details (current + decisions made at Cambridge meeting), identify any variances; raise issues for discussion with CS at joint call, and also at joint meeting at Sydney.

It is established that Clinical Statement pattern may undergo a new round of ballot commencing January 2011 with target completion in May 2011.

As one or more Patient Care Working Group co-chair may be absent from the January 2011 meeting in Sydney, it may not be possible for PCWG to progress the Care Statement topic to an adequate quality for September 2011 ballot cycle.

26.5 SECURITY ONTOLOGY PROJECT

The Security WG presented the Ontology project. This recently approved project has been meeting weekly to discuss Security ontology with members of the Vocabulary and SOA WG who are also operating in the same space as part of the SAIF effort. Currently the WG is focusing on an ontology that covers RBAC (Role-Based Access Control) which has a balloted Vocabulary already.

The motivation for the Ontology for Security is to identify important concepts in Health IT security and privacy such as standardising names, defining definitions precisely and classify in a taxonomy. It also aims to promote interoperability through a common vocabulary for access control, privacy protection across organisations and implementations. The goal is there to support consistent and effective implementations.

They have adopted OWL 2.0 (Web Ontology Language) as the method of expressing the ontology and are using the Protégé tool. Using this tool they have built the SecurityAndOntology.owl ontology. Sample branches include Organisation, UserIdentification, SecurityRole and Permission.

Plans are to finish the HL7 RBAC modelling (complete classes, RBAC Objects) and have some peer review after establishing an evaluation criterion for the model. Another goal is to be able to demonstrate the use of the ontology to grant or deny access requests.

Action: IT-014-04, IT-014-09, NEHTA and relevant Australian experts to review and provide further Australian input to ensure that the Security and Privacy Ontology is correct and that any local requirements can be covered in the model.

27 ORGANISATIONAL RELATIONS COMMITTEE (ORC)

Scott Robertson presented the Statement of Understanding (SOU) template that the Organizational Relations Committee (ORC) is recommending that HL7 International use as a single common framework for documenting its relationships with outside organisations.

Having reviewed the various MOUs and Associate charter agreements, the ORC came to the conclusion that there are no clear-cut rules or clear business rationale about when one or other form of document is used to record such arrangements – each was different, although the relationships were essentially similar. The ORC therefore decided to condense these various forms of agreement into a single document –the SOU.

The SOU is intended to document longer-term relationship between HL7 and another organisation. It is not intended to be used to document an agreements relating to a specific one-off project. Such activities should still be governed by specific project-oriented agreements (identifying deliverables, responsibilities etc).

The Board and the executive team need to review the SOU template to ensure that it is capable of accommodating all of the proposed types of business relationships. It was considered that it may also be suitable for extension to cover such relationships entered into by HL7 international affiliates. Affiliates will be asked to review and comment on the document before the November meeting.

During discussion the importance was recognised of highlighting the need to identify and capture the business drivers behind a particular relationship, what should be common in documenting all relationships, what can be varied to suit circumstances, and what is inappropriate to attempt with the SOU templates. Based on these comments it is likely that further refinements and better contextual documentation is needed.

Action. When requested, HL7 Australia to review the proposed SOU template and make appropriate comments.

28 PATIENT CARE WORKING GROUP

Activity within Patient Care (PC) WG remains a key focus for Australian work at HL7 and aligns closely with Australian work at IT-014-06-06 on Collaborative Care particularly Referral and Discharge Communication (including review and update of previously published Australian standards). It is an area where clinical input is important.

PC WG is the peak group defining how clinical information is represented in HL7 standards. The WG is responsible for HL7 Version 2 standards for Referral and Collaborative Care as implemented in Australia and the Care Provision topics in the Version 3 area. PC WG members are mostly IT-capable clinicians and technology experts who work with clinicians.

PC works closely with other groups where they need to represent clinical concepts - mainly Structured Documents, Clinical Decision Support, Orders and Observations, Community Based Collaborative Care and EHR. It works closely with Modelling and Methodology (MnM) and Vocabulary with facilitators from those groups being active in PC WG meetings. It is also one of the original partners in the Clinical Statement Project and continues to work with the recently formed Clinical Statement WG.

Australia was well represented in PC WG with Klaus Veil and Dr Stephen Chu currently holding two of the four co-chair positions. Other Australians attending for particular items included Dr David Rowed, Dr Hugh Leslie, Dr Andy Bond, Grahame Grieve, Sarah Gaunt and Richard Dixon Hughes.

With two co-chairs from Australia, one from The Netherlands and one from UK this is now a totally internationally-chaired WG with strong attendance being sought for Sydney (although one of the co-chairs, Dr William Goossen, indicated that he may not be able to attend).

PC WG has a large, and at times confusing, number of projects in various stages from early concept through to (and beyond) DSTU ballot.

The bulk of the current message development work is in Version 3; however, the analyses, use cases, methodologies and representations developed, together with the HL7 work on Detailed Clinical Models, are of importance to Australia regardless

of the ways in which they may be implemented in different message and document formats around the world.

Topics addressed at this meeting included:

- V2.8 proposals from Australia (OBX after PID) – accepted
- General RMIM for assessment scales – there was much discussion of this - particularly concern at the large number of obvious errors that had not been picked up by the editing process, reducing confidence in the quality of work that had led to its production.
- Preparing to ballot D-MIM for Care Statement R2 based on evaluation of

Version 3 balloting of Care Provision is a major topic, with normative content at the DSTU (Draft Standard for Trial Use) stage and other ballot sections being informative.

A considerable amount of time (not all of it productive) was spent on the outcome of the HL7 informative ballot on Detailed Clinical Models (DCM) that had been put forward by Dr William Goossen from The Netherlands.

DCM activity at HL7 PC WG is now being monitored closely in light of potential incompatibilities with good clinical governance and the more generic standards being progressed with assistance of Australian experts in ISO – with a view to ensuring that its scope meets Australian needs and doesn't divert excessive resources from other work.

Action: IT-014 (IT-014-09 lead – in collaboration with IT-014-02 and IT-14-06-06) and NEHTA to continue focussing on ISO DCM standards and to seek to ensure that development of DCMs under aegis of HL7 PC WG conforms to emerging ISO requirements.

28.1 CARE PLAN

There are re-ignited interests in care plan. It is a topic within Patient Care Working Group (PCWG). Canada in particular has expressed strong interest, among others from US (national quality forum). The current HL7 care plan wiki page identified a number of project activities but with no timeline and resources allocation. It has been proposed that countries such as Australia, US and Canada supply care plan use cases to PCWG for inclusion as part of the project development. A conference call will need to be established soon after Cambridge meeting to review the wiki project plan with the goals to revise/refine the plan, establish timeline and assign activity coordinator or lead.

The use of CDA in a Patient Care Statement – this is a Canadian requirement. CDA is used as a payload where the trigger events were specific to particular actions (e.g. creating a referral, creating a report-style observation etc).

However, it appears that the Canadian implementation of CDA in this context is extremely “loose”. Its use of extensions in the CDA body is not well aligned with the Reference Implementation Model (RIM) constraints. This practice raises concern and is determined to be non-conformant.

Action: It was proposed that Canada Infoway should list and discuss extension requirements and CDA alignment with Structured Documents WG, Australia should consider our requirements also.

The use of “Symptoms, Problem, Diagnosis” in Canada – Infoway articulated the need for PCWG to provide guidance on how these concepts are related to each other, particularly how their relationships should be modelled in the care statement.

It was recommended that:

- (a) Canada should develop statements/use cases on how it intends to use these concepts,
- (b) Clear definitions should be developed on these concepts based on the Canadian use cases and wider clinical domain requirements.

Heather Grain from Australia will provide a template for submitting terms to the HL7 glossary for use for this purpose. The template will be published on the wiki and everyone works with this.

Canada will lead this work and Australia will support and contribute.

Action: IT-014 and IT-014-02 and IT-014-06 need to be aware of any requirement to active contribution and consideration of resource requirements.

29 SECURITY

29.1 US INITIATIVES

The WG discussed a number of initiatives that are currently ongoing or planned in the United States regarding secure information exchange.

29.1.1 NATIONAL HEALTH INFORMATION NETWORK (NHIN)

NHIN Direct (to be renamed according to Security WG members) is the set of standards, policies and services that enable simple, secure transport of health information between authorized care providers. NHIN Direct project has been around for several years however it is gathering momentum. There are implementation geographies (about 6) that are trialling the specifications. The idea is to enable a mechanism for communicating with providers that are out of reach of the main RHIO. From a privacy and security viewpoint there is an established Security and Trust Workgroup with the goal to:

- Enable trust at scale, but allow for individual reciprocal trust decisions
- Define key roles for certificates and signatures
- Define approaches and pros/cons to certificate-based signatures.

NHIN Direct has released Addressing Specification which describe the interoperable foundation for universal addressing. Based on an ordinary email address, the Health Internet Address can be used in SMTP secure transport and XDR SOAP messages to indicate senders and receivers of direct transactions. Both specifications can be found at <http://nhindirect.org/specifications+and+service+descriptions> .

In addition they have created an open source project that has a secure email service through a proxy client with both Java and .Net reference models available.

29.1.2 FEDERAL IDENTITY CREDENTIALING AND ACCESS MANAGEMENT (FICAM)

FICAM is a program to promote interoperability between Federal Government in the US in relations to authentication, access control and auditing. It provides agencies a mechanism to access PKI through a trusted model for agencies leveraging the Federal Bridge CA architecture. FICAM provides a mechanism through a Federal Common Policy to allow other CA's to be trusted.

There are some similarities between the FICAM project and initiatives undertaken in Australia by AGIMO. There may also be some information of interest in relation to the trust models established in FICAM that may be reference models for use in Australia.

29.1.3 NATIONAL STRATEGY FOR TRUSTED IDENTITIES IN CYBERSPACE

The National Strategy for Trusted Identities in Cyberspace is a US Federal Program which seeks to develop an environment where individuals and organizations can complete online transactions with confidence, trusting the identities of each other and the identities of the infrastructure upon which the transaction runs.

A draft of the strategy is currently open for public review. The strategy was born out of a realisation the business verticals are creating their own non-interoperable solutions. The goal is to create a strategy for guiding all industry (including Health) on developing interoperable trusted identities.

In the National Strategy all Federal agencies are directed to follow the FICAM approach and it is extended to ensure that federal services are able to accept identities and credentials from at least one private sector identity provider.

30 SERVICE ORIENTED ARCHITECTURE (SOA) & HEALTH SERVICES SPECIFICATION PROJECT (HSSP)

Within HL7, SOA is the work group charged with providing a service-oriented architecture view of the HL7 world. The HSSP has been a major part of that work (in collaboration with the Object Management Group (OMG)). Ken Rubin chaired the WG and the general theme was that the SOA SIG is changing its role from developing service specifications to supporting other stakeholders to develop their domain specific specifications such as Security, Decision Support and Terminology. As part of this an Outreach, Education and Mentoring project has been established within HL7. Whilst the project scope is still under development, the plan is however to develop the SOA WG as the mentor and centre of expertise for services specification development and adoption.

There will a 1.5 day version of the "SOA in Healthcare" conference along with the HL7 WGM in Sydney, January 2011. This conference series ran for a third year in Washington DC this year supported by HL7 and the OMG. The full size version is a three day event focussed on case studies of SOA experiences in healthcare combining both business and technical tracks. The Sydney event will continue HL7 and OMG support but will be a shortened event linking from healthcare through to mainstream SOA in IT. The proposed list of speakers includes a couple of IT luminaries as well as a popular selection of previous "SOA in Healthcare" speakers.

The Architecture Review Board (ARB) and HSSP/SOA groups met during the Cambridge meeting as part of their ongoing commitment to forging a greater working relationship. The session was an opportunity to reconcile the relationship between the SAIF analysis and design approach along with the HSSP Practical Guide to SOA.

There is an inherent symmetry between these pieces of work as the underlying services paradigm permeates both areas of work. Now that Steve Hufnagel has joined the ARB and as primary author of the series of SOA guides, it is more likely that the approaches will coalesce. Sessions between the ARB and SOA are always interesting affairs.

The main point of contention during this session was the position by Bernd Blobel that the SAIF, through the Enterprise Conformance and Compliance Framework (ECCF) matrix, were misinterpreting the relationship between RM-ODP viewpoints and OMG MDA levels. While there is a valid basis for this position, it should not be a reason to discard the work in total, rather it was recognised that further work was required to position these approaches through a broader basis than just the ECCF Specification Stack matrix. Steve Hufnagel and Andy Bond undertook to produce an executive overview of SAIF that gave an alternative point of focus (rather than the ECCF) and would more accurately present the relationship between RM-ODP viewpoints, OMG MDA, SAIF, and the SAIF frameworks.

The following is a review of the current projects related to SOA SIG:

30.1 CLINICAL TERMINOLOGIES

The Clinical Terminology Services Specification (CTS2) is currently a DTSU and the period has been extended (beyond 2 years) to allow the OMG process to complete. To date two implementations of the specification are in development in response to the OMG RFP, one by ii4sm (the Swiss-based International Institute for the Safety of Medicines) and the other a joint collaboration between the Mayo Clinic with the NCI (using Apelon). There is also informal involvement with the International Health Terminology Standards Development Organisation (IHTSDO) that they will endorse the submission once finalised with the OMG.

Both organisations have taken different approaches in their submissions, Mayo taking a REST and the ii24SM taking an ontological based approach using OWL. The two groups are now however harmonising their approach to jointly present a common UML model.

I4sm approach wants the service to deliver rich ontology's in OWL from the service. Kaiser Pemanente noted they have a budgeted project to move SNOMED to OWL in conjunction with the IHTSDO and that there is already an open source tool to extract SNOMED from the NLM (National Library of Medicine) and convert to OWL, however the conversion creates a 20G file. However the converted data file can be used in Protégé to make context sensitive queries on SNOMED.

One issue however is that the current scope of CTS2 is a subset of the full vision held by the Vocabulary WG, primarily in relation to the management of value sets. There is currently an unresolved question as to how to address this gap. The problem is owned by the Vocabulary WG and the pathway to an eventual consensus and harmonisation is still unclear.

February 2011 is the revised deadline for the publication of the OMG specification. However there are already 8 agencies currently implementing the HL7 SFM specification (although their implementation will likely be non-conformant with the OMG spec).

Action: IT-014 and NEHTA and relevant Australian experts to monitor activity in the space to ensure harmonisation with Australian initiatives and the outcomes of the OMG RFP process in February 2011. Advise to be provided to the Australian Vocabulary WG co-chair to assist in strong representation of our requirements and views.

31 STRUCTURED DOCUMENTS (SD)

The bulk of Structured Documents work is split between work on implementation guides for CDA R2, and development of CDA R3.

31.1 IMPLEMENTATION GUIDES

The implementation guides that are relevant to Australia are discussed elsewhere in this document. SD's primary interest is acting to ensure consistency between the implementation guides as much as is appropriate

31.2 CDA R3

The next version of CDA R3 is under development now. Many change proposals have been made, both big and small. An inevitable consequence of the wide spread interest in and adoption of CDA will be that R3 will be substantially more complex, as the scope of its capability increases. The central problem is how to control the impact of the increased complexity.

IT appears that the CDA R3 standard is still at least two years from completing the development and ballot process.

32 VOCABULARY

The Vocabulary WG met from Sunday to Thursday, forgoing a meeting on Friday (which would normally have been held) due to key members need to attend the ISO meeting in Europe which began on the following Sunday.

32.1 DISPLAY NAME

This issue relates to the need/or otherwise to display the text included in the message exactly as it was in the message, though in a number of cases (e.g. translation, synonyms used for given purposes) this is not always appropriate. There is a US regulatory requirement that the text displayed be the same as the text in the message. The meeting agreed that it is essential that the message display name must be persisted.

It was recommended that for CNE data type you would use preferred text, with CWE data type you would use alternate text. Explicit guidance is needed for the receiving system. This will need to be tested against the general scenarios that are established. For Release 1 CD data types have few limitations on the use of display type similar to CWD. The intent is to have the same recommendations for V2 and V3 implementations. The Release 2 guidance provided is relevant to R1. These should be combined.

There is also a coding string CNECWE data types – this is associated with the value set assertion in the binding. The coding strength will show you where to look for the display name.

The Guidance needs to be more specific on how to resolve these issues. The guidance also needs to indicate the code to use when the content is/is not part of the code system.

There is an outstanding issue which may require an additional project to handle the matter of translation into different representational forms such as pictorial languages.

Extension: if you have a name space an extension is part of the code system. LOINC doesn't offer this alternative at the moment.

If a jurisdiction wants to create an extension to a code system e.g.: LOINC, then the original text must provide a method to indicate the text associated with the code to allow the use of the correct text by the receiver.

32.2 CORE PRINCIPLES

The Core Principles document identifies the principles for management of terminology and terminology binding within HL7. This document is nearing completion. Ballot reconciliation was almost completed and will be finished in time for the document to go to ballot prior to May next year.

Action: This document is one that needs to be carefully reviewed by NEHTA and IT-014-06 in particular as it relates to the incorporation of vocabulary in CDA content.

32.3 ANATOMIC PATHOLOGY VOCABULARY CONTENT PROJECT

A potential project was discussed on the development of terminology content, particularly the metadata required. Anatomical pathology could build the use case and present a straw man of the work item to vocabulary. The major requirement is to identify the metadata necessary and how to evaluate what is used and needed.

The sense of the room is that this should be a joint project on the ability to identify, describe and distribute vocabulary binding for Anatomic Pathology. The project scope statement will be developed by Ted Klein from Vocabulary.

32.4 VOCABULARY BINDING – ANATOMIC PATHOLOGY

Ted Klein gave a background to the information in core principles and their relationship to the V3 model. Particular topics of relevance from the core principles included:

- Vocabulary declaration
- Vocabulary conformance – allows systems to determine whether the content received is valid (it includes but is not limited to vocabulary requirements).

The issue is that R2 CDA has difficulties with terminology. 10% are breaking terminology meaning and content requirements when the message is sent. This can

be solved using vocabulary core principles binding components. We need to consider how we handle this. It is not in R2 but will be in R3.

To make this implementable it defines the pieces of information that have to be specified to constrain the message. In an implementation guide it is possible to constrain something only to a concept domain, but in that case the concept domain must be bound in the realm.

32.5 VOCABULARY AUTHORITY REFERENCE ANATOMIC PATHOLOGY

An existing project on this topic was prepared by Anatomic Pathology and they have been asked by CDA to seek vocabulary input. This may be a useful extension to data types. CDA documents will be sent from one place to the other. The author has no way of making available to all downstream recipients the 'pick lists' from which the values of the instance were selected.

Objective: to enable the author of the CD to make the value sets used in the creation of said clinical document accessible to all downstream recipients of the document regardless of whether the values used in the set come from publicly available standards, such as SNOMED CT, LOINC etc., from locally created lists, such as 'specimen type' or from any combination of the two within the same document independently for each discrete data field.

Application of CTS2 principles will allow this problem to be solved but it is also a reason for local data uses to be registered as OIDs. Such registration ensures that the content are registered and that it is possible to identify who is responsible for the value set and you can get data values. There is a use case to have service access to the HL7 OID registry.

Local code systems require the local person to register the local code system and make this information available to others and identify how the information is available to others. The technical elements to solve this problem are largely in place but the human factors and policies to govern and change behaviour to achieve these outcomes are not controlled.

32.6 ISSUES DISCUSSED WITH MNM

Structural requests for change should be submitted only once a year for the summer cycle. This documentation will be enhanced on the wiki.

- Universal bindings – when do these need to be reviewed by international council (CS bindings in RIM). The suggested process is that the requirement will go to Harmonization first then international council (defer confirmation until after international - it would be available for use though right after harmonization meeting)
- Concept domain style guide. What should the type and character length be for concept domain? This is an outstanding issue.
- FormalProperNameis want Upper camel case, no spaces or punctuation, with hyphen & underscore allowed 60 characters
- Core principles – will not ballot during the next cycle. We are intending to go to ballot before the May meeting.

32.7 GLOSSARY PROJECT

A harmonisation proposal on terms and definitions will be sent to HL7 from an ISO ballot on Mapping of Terminologies to Classifications. Vocabulary group have seen these dispositions in the past. The group request that when the request for vote arrives from ISO that the HL7 executive seek Vocabulary input on our response.

The glossary work item has stalled at steering division on a number of occasions but the project scope statement has been modified now to include publishing as joint sponsors and it is now expected to progress.

The Green sheets have been entered into the SKMT.

There are ongoing discussions on the processes HL7 will use to maintain and manage harmonisation of definitions. However the automatic loading of HL7 V3 glossary will be completed into the SKMT by the end of November.

32.8 IMPLEMENTATION GUIDELINES FOR CONFORMANCE OF TERMINOLOGICAL SYSTEMS

Beverly Knight presented the draft of this work in ISO and the document will be sent to the list for comment. If there are sufficient comments, issues or questions then this work will be discussed on calls.

32.9 OBJECT IDENTIFIERS (OID) PROJECT

This project now has a wiki page. Active review of the work document is ongoing, and comments from the HL7 Vocabulary community are welcome.

32.10 MAINTENANCE PROCESS FOR HL7 VOCABULARY

Problems include:

- Terminology authorities release terminology. Some provide a re-release and others do not. SCT has alleviated this by using a 30 day period to review.
- Examples are being sought on how and why these problems occur and cause safety issues
- SDOs should announce when the release will be issued
- A change file would be nice for SDOs to produce this. This is an activity that we all do so not the best use of our time.
- It affects customers and vendors as well as organizations like NLM & SC
- Ongoing maintenance is resource intensive, CTS2 will help and always underestimated

There is a need to exploring other ways of managing value sets and code systems. Currently the tooling is all done by hand to manage LOINC and SNOMED CT in the MIF. Allow HL7 to take advantage of other terminology authorities. Our existing tooling is not easy to use with other terminologies.

The objective is to move away from the HL7 maintenance of terminology to HL7 drawing as much as possible from externally managed terminologies for specific purposes for HL7 purposes.

There is a need to develop agreements with content providers:

- Permit the HL7 use of content by all HL7 members
- The acquisition of an approved extension space

- Inclusion / exclusion criteria that determines whether or not content should be managed by:
 - HL7 terminology
 - An HL7 extension to a terminology
 - Submitted to be included as part of a core terminology

This should include how to manage precedence of legacy content

- Develop / obtain HL7 tooling that:
 - Can represent multiple source terminologies simultaneously
 - Can develop value sets that draw from multiple source terminologies

- Evaluation of the state of the current HL7 vocabulary
 - Develop the criteria for evaluating content criteria for transition to an HL7 extension or extension to a terminology core
 - Q/A on the existing value sets to ensure alignment of content with intent

- Determination of what standard terminologies (or sub-sections of a standard terminology) should be used for what purpose (domain)

- How to communicate the migration to users and provide guidance on how to migrate to external content. What are the options on how to successfully migrate?

Action: NEHTA need to be aware of these issues and to consider Australia's required action/s.

32.11 VOCABULARY TOOLING

An overview of identified tooling requirements included:

- Tools to support vocabulary harmonization
 - Most proposals are approved with modifications made
 - The content must be manually added to repository (this is an error prone process)
- If a value set is needed that is drawn from an external code system, it must be added manually
- No easy way to access changes
- Cannot represent multiple code systems in a value set
- The IHTSDO Work Bench
 - We have performed a feasibility to determine HL7 terminology can be integrated into it
 - Currently we have an open project to do the next steps to figure out how to represent HL7 terminology in the Work Bench
 - Using MIF is possible but the Work Bench has more capability for sharing and long term.

- A discussion on the issues with the current Work Bench took place but no firm decisions were made and clarification on these issues is required from IHTSDO.

Action: NEHTA IHTSDO governance members to be made aware of current issues to inform IHTSDO and inform HL7.

32.12 BINDING SYNTAX (DISCUSSION WITH IMPLEMENTATION CONFORMANCE)

Topics – binding syntax; scope statements in varying degrees of development; guide for best practices for implementers; vocabulary model; ISO technical report on conformance.

Binding syntax –Frank Oemig outlined some of the issues associated with model binding and context binding. Ted discussed recent changes to the model binding and implementation binding rules. All binding in implementation guides is model binding. Context binding is for the use of code systems across the entire realm that developed the implementation guide(s). From this a set of sub-value sets may be defined for use in particular implementation guides.

Much of the recent change has been the result of experience in trying to implement the earlier versions of vocabulary binding. In some places in the documentation it is recognized that explicit examples of use for both model binding and context binding need to be provided. A context binding is asserted by a realm authority. If context binding originates from multiple authorities, how is this managed over time? This is more a problem for universal implementation guides as opposed to realm specific Implementation Guides. This leads to issues surrounding realm specific constraints for universal Implementation Guides. IHE is claiming to release such types of guides along with bindings that can only be used in the US. The bindings must be assigned in such a way that realm based constraints can be applied when required.

It is being proposed that there are subclasses of IGs that are realm based derivatives of universal guides. Each of the subclasses of IGs must be proper constraints on the universal guides/models. This seems to be a difficult requirement in practice. Current thinking is that an IG describes the interoperability space in which it is intended to operate. If one realm, then it must be specified the scope of the domain in which it is to be used. In some cases the scope of the IG may cross realms for a specific domain.

In the last iteration of core principles reference realm was added. You can bind to this reference terminology during development of models. This however, cannot be enforced across realms. In all cases this is nothing more than a constraint hierarchy. The alternative is a series of domain specific IGs which are difficult to manage and maintain. It is desirable to have more universal representation that can be properly constrained for each particular implementation.

A diagram making this clearer will be added to core principles.

Canada described the approaches that they are using in the creation of their IGs when used in different domains (e.g. pharmacies vs. EMRs). The question is whether there are differing vocabulary bindings when using these IGs in these different domains? While these can be constrained differently, it is not desirable to have different value set bindings in these different uses.

The only graphics that currently exist describing uses of vocabulary assertions are in the Chapter 5 of the Core Principles Document. There are no graphics referring to Implementation Guides.

32.13 E-RULES FOR COMPOSITIONAL GRAMMAR / POST-COORDINATION

There is a need to have a standard structure for implementation guides and there are difficulties in Canada where vendors can't go from one province to another easily. It is difficult to find the required business rules. We need to find the common implementation requirements and to be able to identify specializations in specific states or realms.

For example: Reference realm binding indicates the reference terminology for this domain (to handle country specific requirements). This offers automation and registration and availability of this functionality and eases the implementation guidelines. Every time you build an implementation the constraints are likely to be different which means that the model is different.

There are significant consequences of model binding and concept binding on implementation complexity.

There is a need for an overarching picture of the implications – perhaps the Ven diagrams in core principles could serve this purpose.

Suggested 'rule': You cannot have different vocabulary if you are doing flavours of implementation guides for different communities that are supposed to be working concurrently and sharing information.

Action: Consider the impact upon Australian implementation guides and standards. IT-014-06.

There is a need to be able to deal with manual code system changes (e.g. ICD). Though the working group does not want to issue a new implementation guide just because a code system has a new release the management of this situation is under further consideration. The recommendation is to drive the effects that you have to maintain to as small and few as you can manage. These should not be in the guide, but in a referenced document of required content. The guide is a single document and a distribution process which gathers all the required components to ensure consistent packages.

Strategic direction suggested:

We need information to advise people on how to effectively design and package implementation material including implementation guides.

32.14 VOCABULARY DECLARATION ISSUES

The vocabulary declaration contains terminology guidance for those who will constrain it. The information in core principles is identical with what is in Model Interchange Format (MIF) 2 – the current versions are now consistent. The vocabulary declaration is insufficient to manage the requirements. There may be a concept domain and may be constrained to a sub-domain or it may be constrained to specific value set assertion.

There are identified issues found when thinking through all the binding processes and real world usage.

- When binding to code collections you bind to one or more code assertions rather than directly to a value set.
- The use of a model binding for vocabulary means that the terminology is set for the model in all cases. This can be restricted or modified at the realm level through context binding and are specified and maintained by realm authorities. Model bindings always take precedence. If something goes to implementation and has not been model bound but only constrained to a realm domain – the model may to be interoperable.

A value set assertion is a piece of mechanism to express the coded vocabulary constraint for a coded model element or datatype property:

It defines a collection of value sets to describe the constraint.

It declares the coding strength (extensibility) of each of these value sets.

It declares the stability over time of the constraint.

There are difficulties where items are required that we do not yet have the mechanisms to support them. For example there are difficulties finding relevant OIDs. There are concerns about the fact that value sets can be specified by name as well as OID and we will need to investigate this further at the next meeting.

Discussion on conformance requirements occurred. The notion of mandatory is an attribute in the rim rather than in the vocabulary. The interpretation of the null in the root goes back to this.

A joint project with IC to put together the syntax to express the value set assertion. Vocab and IC are still working on the binding syntax. There is a wiki describing this called binding syntax. The requirements come from core principles and the grammar is defined but still being worked on.

Backward compatibility is an issue for modelling of implementation guides. The detail can be incorporated, though less straight forward. This is about referring to the definition not the definition itself. The identity of a value set refers to what you persist; when it expands it expands to a list of concept IDs.

Discussions have occurred about how to push this process forward to get people using it and providing feedback on the utility of the process suggested in the binding syntax.

Review of the CDA Implementation Guide for genetic testing is being considered. The intent is to ensure that CDA is not slowed down with all this vocabulary substance. Now that the vocabulary component is stable enough we would like this to come forward for testing.

We do not have in the binding infrastructure rules about binding across attributes or across values, there are no dependencies. This is a desired mechanism but does not exist at the moment. Such constraints fit best at the template level.

Whether stable or dynamic – a value set definition is required. There are many issues around V2 binding for implementation guide. There is a desire to undertake the work for V2 binding but is there value, is this something we really need?

A universal guide is useful as a starting template for the development of realm specific version of that guide to support multilingual and jurisdiction based rules and requirements.

Action: Vocabulary declaration will be a major item for discussion at the Sydney meeting. IT-014 should circulate Core Principles Documentation, and consider including in next year’s work program an explanatory document or short educational initiative of the utility of this document.

APPENDIX A – HL7 VISION, MISSION & STRATEGIC INITIATIVES

HL7 VISION

HL7's vision is to create the best and most widely used standards in healthcare.

HL7 MISSION

Our mission is to provide standards for interoperability that improve care delivery, optimize workflow, reduce ambiguity and enhance knowledge transfer among all of our stakeholders, including healthcare providers, government agencies, the vendor community, fellow SDOs and patients. In all of our processes we exhibit timeliness, scientific rigor and technical expertise without compromising transparency, accountability, practicality, or our willingness to put the needs of our stakeholders first.

HL7 STRATEGIC INITIATIVES

1. 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.

2. 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.

3. Facilitate HL7 standards adoption and implementation.

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

4. Define an overarching and internally consistent interoperability framework.

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

5. 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.

6. 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.