# IT-014 Health Informatics Committee

## Australian Delegation Report

## HL7 Working Group Meeting

## Rio de Janeiro, Brazil, May 2010

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

- *Richard Dixon Hughes (Delegate)*
- *Heather Grain (Delegate)*
- *Vince McCauley (Delegate)*
- *David Rowed (Delegate)*
- *David Rowlands (Delegate)*
- *Michael Stein (Delegate)*
- *Grahame Grieve (Delegate)*
- *Andy Bond (NEHTA)*
- *Stephen Chu (NEHTA )*
- *Tina Connell-Clark (NEHTA)*
- *Sarah Gaunt (NEHTA)*
- *Andrew Howard (NEHTA)*
- *Andrew Caswell (Standards Australia)(Part-only)*

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# 1 RECOMMENDATIONS ARISING FROM THE MEETING

The principal issues actions and recommendations identified by the Australian delegation at the May 2010 HL7 Working Group Meeting (WGM) in Rio de Janeiro are summarised in this section.

| Topic | Issue/Action/Recommendations |
|---|---|
| HL7 Meeting 2011 – Sydney | It is proposed that meetings of the HL7 Australia Advisory Committee for the January 2011 HL7 WGM in Sydney be convened as soon as possible to address issues raised by the HL7 International WGM Task Force, the Finance Committee, the Executive Committee and the Meetings staff, including:<br>• Financial viability and cost control<br>• Raising participation through targeted marketing<br>• Side events and partner programs to encourage international attendance<br>• Confirming accommodation options for international delegates<br>• Planning relevant education programs including refinement of the classic WGM tutorial offerings and identifying the potential for satellite and master class events, and<br>• Most importantly, managing relationships with HL7 International and their expectations (given that the Sydney meeting will be considerably different in some respects).<br>**Action: HL7 Australia to review, manage and progress the above aspects of the January 2011 HL7 WGM proposed for Sydney.** |
| Education for Sydney WGM | The educational requirements for the meeting in Sydney in January, 2011 need to be reviewed. Heather Grain has suggested that a small team with relevant experience and skills be formed to assist in this task, noting that she is reviewing the currently available content and that she and Tina Connell-Clark are also reviewing competency requirements and assessment processes.<br>**Action: HL7 Australia to form a group to review educational requirements for the meeting in Sydney in January, 2011.** |
| HL7 v2/v3/CDA Task Force | This Task Force (TF) looking at issues surrounding HL7 product uptake and strategy using a widespread consultation process. Several key Australian representatives have been interviewed. Richard Dixon Hughes and Grahame Grieve are members of 10-member TF<br>**Action: Australians on the HL7 v2/v3/CDA TF to encourage outcomes that address the diversity of opinions and views offered through the consultation process.** |
| International Council and Affiliates:<br>1. Review & renewal of Affiliate Agreements | The current Affiliate agreements expire on 31 December 2010 and are being reviewed by HL7 International. A draft of the new common-form agreement is expected from HQ soon, after HL7 receives feedback from their attorneys.<br>**Action: HL7 Australia to review Australian requirements and consider proposed changes to the Affiliate agreement.** |
| International Council and Affiliates:<br>2. Australian requirements for IP | 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.<br>**Action: HL7 Australia Board to review Australian requirements for use of HL7 IP, including discussion with Standards Australia as appropriate.** |
| International Council and Affiliates:<br>3. Nomination of HL7 Australia technical lead | Better technical communication between Affiliates and the TSC is needed to ensure that the HL7 work program is informed of Affiliate needs. An arrangement to form a network of Affiliate technical leads will be trialled for review at the next WGM.<br>**Action: HL7 Australia Board to identify and nominate a technical lead to be the communication channel between HL7 Australia, the Affiliate community and the TSC on HL7 technical issues.** |

| Topic | Issue/Action/Recommendations |
|---|---|
| | Work on community based collaborative care is of considerable relevance to the development of eHealth in Australia and there is a need to ensure that Australian needs are addressed and progressed as part of mainstream HL7 standards work. The previous use of the CBCC WG to focus on client privacy issues (to the exclusion of other collaborative care content) has delayed this objective but with two Australian co-chairs, it is time to move the original agenda forward.<br><br>**Action: HL7 Australia, IT-014 (and subcommittees) and Australian delegations to upcoming HL7 WGMs to:**<br>**(1) Promote continuation of work within CBCC WG on defining the needs, workflows and information needed to support community based collaborative care delivery in Australia**<br>**(2) Promote close collaboration and joint activity between CBCC, PC and CS WGs in progressing this work to meet Australian needs**<br>**(3) Support Security WG having the lead role within HL7 on all matters relating to the management of security and privacy, guided by use cases from CBCC and other domains, and**<br>**(4) Inform, engage and encourage participation from the states/territories in CBCC work which produces implementable v2 and services standards.** |
| Proposal for HL7 to define "data profiles" | Based on work with key US Government agencies, a proposal has been put forward to EHR WG that HL7 define "data profiles" to complement the functional profiles used for certification against the EHR-S FM. There are many local forces in the US driving HL7 in this direction, potentially at odds with more structured approaches such as ISO13606, openEHR and HL7v3. It is important that HL7 has a strategy and approaches for meeting such needs in ways that are compatible with its other products and necessary national and local variations in the resulting data profiles.<br><br>**Action: IT-014-09 to review proposed scope of HL7 data profiles project on with a view to commenting on overlaps with work on other HL7 information artefacts, ISO18308, ISO 13606, openEHR and national reporting regimes in Australia.** |
| Leveraging US investment in conformance testing technology | In the US, NIST (National Institute of Standards and Technology) has been commissioned to develop testing processes, validation testing tools and interoperability testing tools for assessing conformance to "Meaningful Use" criteria. These developments will be available in the public domain via an integrated portal for all testing including V2, V3, XDS and DICOM integrated under a single web service paradigm accessible by other agencies and, potentially, international communities. NIST capabilities will include validation services; automated generation of messages/documents with test data; and "test agents" to simulate interactions with the system under test - with a test harness controlling execution of the test. For more see: http://healthcare.nist.gov.<br><br>**Action: Australian eHealth programs should consider partnering with NIST in developing test tools rather doing so independently.** |
| Update of HL7 models for Allergy, Intolerance and Adverse Reaction; | Update of the Allergy/Intolerance and Adverse Reaction topics is very relevant to the NEHTA clinical data group work. Active engagement and contributions from Australia are essential. There is also a need for coordination through IT-014 with work on related topics at ISO.<br><br>**Action: Stephen Chu, David Rowed and Heather Grain to review proposed HL7 work on the Allergy/ Intolerance and Adverse Reaction topics and make recommendations to IT-014, its subcommittees and HL7 Australia on how all Australian interests should be informed of, engaged in and encouraged to participate in this work.** |

| Topic | Issue/Action/Recommendations |
|---|---|
| Update of HL7 models for Health Concern and inclusion of Problem/Diagnosis | As with allergies, intolerance and adverse reactions (above), update of the Health Concern topic and incorporation of Problem/Diagnosis also has high relevance to NEHTA clinical data group requirements and similar needs for coordination with other IT-014 and ISO activities.<br>**Action: Stephen Chu, David Rowed and Heather Grain to review proposed HL7 work on the Health Concern topic, Problem/Diagnosis and Concern Tracking and make recommendations to IT-014, its subcommittees and HL7 Australia on how all Australian interests should be informed of, engaged in and encouraged to participate in this work.** |
| Need for Australian input to current work developing HL7 Care Plan standards used in team-based care | The HL7 Care Plan project is currently developing specifications for active patient-focussed condition management by collaborating care providers and has particular relevance in Australia in primary care and allied health where the HIC is funding team-based care planning processes via the MBS. Active work is already underway and would benefit greatly from focussed Australian input, given Australia's experiences in collaborative care.<br>**Action: Stephen Chu, David Rowed and IT-014-0-06 to make recommendations to IT-014, its subcommittees, HL7 Australia and IHE Australia on how the wide range of Australian interests should be informed of, engaged in and encouraged to participate in the HL7 Care Plan project work.** |
| Need for Australian position on and input to work on alignment and update of Care Statement, CSP and CDA clinical content. | The update HL7 Care Statement and its alignment with the shared Clinical Statement pattern (and related CDA classes) has high relevance to NEHTA clinical data group requirements and active engagement and contributions from Australia are considered essential. Like Health Concern, Allergy/Intolerance and Adverse reaction, there is a need for Australian input to be coordinated with other IT-014 and ISO activities.<br>**Action: Stephen Chu, David Rowed and Heather Grain to review and consult with Australian stakeholders about the preferred Australian position on the purposes and direction of work on the Care Statement topic in relation to the Clinical Statement Pattern (and related CDA classes) and make recommendations to IT-014, its subcommittees and HL7 Australia on how Australian interests should be informed of, engaged in and encouraged to participate in this work, where relevant.** |
| Australian DCM experts need to review proposed HL7 DCM activity. | There are a range of DCM projects in various stages within HL7, loosely linked to DCM work at ISO that involves Australian experts. There is greater need for wider local engagement and consideration of proposed DCM activity at HL7 PC WG to ensure that its scope meets Australian needs and doesn't divert excessive resources from other work.<br>**Action: IT-014 (IT-014-09 lead – in collaboration with IT-014-02 and IT-14-06-06) and NEHTA to engage more widely on DCM work and actively contribute to PC WG discussions on development of DCMs in HL7.** |
| Need for Australian position on progressing collaborative care communications in v2 | The best way of progressing Australian requirements for collaborative care communications (including referral and discharge referral) and of providing expertise and input to influence HL7's approach to clinical communications needs to be reconsidered.<br>**Action: IT-014-06-06 and HL7 Australia to examine how to best progress requirements for Clinical Communications in HL7v2 over and above Ch 11 and 12 maintenance starting with clarification of constraints on document, archetyped data , documents and workflow, and responsibility indicators in v2 Clinical Messaging.** |

| Topic | Issue/Action/Recommendations |
|---|---|
| Need for better informed Australian position on use of v2 and CDA together in clinical communication | There is also a need for an Australia position on how to use of CDA for reporting and communicating clinical orders, requests, and intents and reconcile potential conflict of moods in the clinical statement part of CDA with sender receiver responsibilities specified by the implied dynamic model of a surrounding v2 message (or transport layer). This should be done with input from experts the HL7 Patient Care, OO, Structured Documents and CBCC WGs, be consistent with the purpose of CDA, and address the significance (or otherwise) of HL7's deliberate exclusion of a control wrapper for CDA.<br>**Action: IT-014-06, IT-014-06-06 and NEHTA to review, seek clarification and form a consistent Australian position on use of CDA for reporting and communicating clinical orders, requests, and intents within v2 messages.** |
| Development of payload to support SOA interoperability in primary care | An Australian recommendation has been accepted for work on defining patient care payload specifications for primary care collaboration in SOA interoperability environments. This is also directly relevant to short-term "meaningful use" goals for US ARRA (HITECH) incentives, timely action is needed to ensure that it progresses appropriately without losing relevance to Australia.<br>**Action: HL7 Australia in collaboration with IT-014, the RACGP and relevant standards bodies seeks DOHA/NEHTA funding for a project to review the IBM GPCS, update requirements as appropriate, and organise it into a services-based framework and a consistent scope for adoption as part of the approved HL7 project being progressed by the HL7 PC and SOA WGs.** |
| Support for defining and registering common care provision terms in ISO Glossary | The Patient Care Vocabulary and Glossary Project is being initiated to reduce differences of interpretation delaying modelling of care provision and is based on working with Vocab WG and Heather Grain using the ISO SKMT tool and eHealth standards glossary.<br>**Action: IT-014 and its subcommittees and HL7 Australia collaborate with Australian clinical and terminology groups to work toward greater consistency for the concepts needed within the Patient Care domain.** |
| Monitoring likely impact and issues from promotion of GS1 GSRN for patient and provider identification | GS1 is developing unique patient and provider identification using their GSRN (Global Service Relation Number) format to complement and assist data collection and interoperability. Although being heavily promoted, there are significant practical issues to be addressed in any wide-scale adoption of 18-digit GSRN identifiers to underpin patient identification in:<br>**Action: IT-014 to:**<br>**(1) investigate and report on the need to adopt the GS1 GSRN Patient and Provider Identification standard for representing unique identifiers; and**<br>**(2) monitor HL7 activities to see the uptake of this standard particularly in areas such as medical devices or structured patient labelling.** |
| Recommendation to monitor proposals for new standards related to pharmacovigilance reporting | Driven by UK NHS, new work items for communications standards in the area of "risk Management plans for registered products" and "Periodic safety update reports" from pharmaceutical companies are being prepared. Collaborators include EMEA and ICH. Measures to manage and standardize reporting of hazards associated with medicines and for preventing harm to patients are relevant to Australia and therefore developments in this area should be monitored.<br>**Action: IT-014 to monitor developments in the area of standards for the reporting of new information about hazards associated with medicines and for preventing harm to patients.** |

| Topic | Issue/Action/Recommendations |
|---|---|
| Example of how to develop extensible composite models – for consideration by NEHTA for developing and refining clinical information specifications | Pharmacy and OO WGs developed a harmonised composite model for pharmacy orders by merging and harmonising models from the Pharmacy and OO domains and a process for extending it to meet specialised needs. The process used is potentially applicable to some current NEHTA work.<br>**Action NEHTA to consider the approaches used to develop a harmonized model for the extensible composite Pharmacy/Medication order and to extend it for domain specialisation – as potentially applicable to development and refinement of NEHTA clinical information specifications, especially the "Core Information Components" for discharge summary and referral.** |
| Recommendation for Australian (NEHTA) participation in AfMS specification work | AfMS (Administration of Medicinal Substance) is a useful and important work item which will impact on information model and terminology development for electronic prescription and medication administration recording.<br>**Action: Australia (with NEHTA lead) should monitor the progress and participate in project arising from the AfMS work item.** |
| Recommendation for Australian (NEHTA) participation in ISO dose syntax work | Dose syntax is a highly complex and difficult topic in medication order model from which Australia can learn while also contributing. Australia/NEHTA should monitor the progress and participate in project arising from this work item.<br>**Action: Australia (with NEHTA lead) to monitor progress and participate in project arising from the ISO Dose Syntax work item, particularly if it is endorsed as a joint work item with HL7 and CEN through JIC.** |
| Recommendation for Australian (NPC) participation in joint ISO-led IDMP work | The Identification of Medicinal Product (IDMP) and prEN ISO 11238 (data structure and elements for unique identification and description of substances and specified substances) have relevance and utility to Australia's NPC (national product catalogue) project. Australia will benefit from active continuing engagement.<br>**Action: IT-014 to invite NPC Project to actively engage with and participate in IDMP and prEN ISO 11238 joint work (primarily being run through ISO/TC 215/WG 6).** |
| Need for Australian experts to review Security & Privacy DAM | There are some issues with the current draft of the Security and Privacy DAM that warrant review and comment by Australian experts, taking into account existing work such as ISO 22600 Privilege management and access control.<br>**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 DAM is correct and that any local requirements can be covered in the model.** |
| SOA/HSSP<br>1. CTS2 education and review | CTS 2 aims to enhance the capabilities of the initial CTS specification and extend it into domains such as terminology distribution, versioning, and classification. Now that submissions have been been received as part of the OMG RFP process, it is important that the work be reviewed to ensure that it is likely to meet Australian needs.<br>**Action: HL7 Australia, NEHTA and IT-014-02 to confer and arrange for:**<br>**(1) awareness and education activities to ensure that implementers of clinical terminology in Australia understand the implications of the work; and**<br>**(2) review of the work to ensure it meets Australian needs for terminology implementation.** |
| SOA/HSSP:<br>2. Australian feedback on IXS rejection | The SOA WG requested that feedback be sought from NEHTA on the issues that led them not use the IXS (Identity cross reference service) standard. The feedback is being sought to inform future SOA activities in this area and ensure that shortcomings in HL7/OMG process and IXS content are addressed.<br>**Action: (1) NEHTA to provide feedback to the SOA WG why the IXS standard was not used as the basis for implementing the Australian Health Identifiers Service.**<br>**Action: (2) NEHTA to develop a formal SOA capability/requirements register as part of a national eHealth Model and map those requirements to existing international work.** |

| Topic | Issue/Action/Recommendations |
|---|---|
| SOA/HSSP:<br><br>3. Australian support for CBCC and completion of HSDS RFP | Work on the Human Services Directory (HSDS) RFP, due for completion at this WGM was delayed until September due to lack of funding for Max Walker (Co-chair of CBCC) to attend this WGM. He has previously been supported by Department of Health Victoria. Completion of the HSDS work needs to be supported and this would be best done by funding Max Walker's attendance at HL7 Working group meetings.<br><br>**Action: IT-014 to investigate means of funding Max Walker's attendance at the next WGM to facilitate completion of the HSD RFP documentation.** |
| SOA/HSSP:<br><br>4. CDS (Clinical Decision Support service) | In Australia, groups such as the National Prescribing Service (NPS) and RACGP that have an interest in clinical decision support, should be made aware of the HL7 Clinical Decision Support Service project and the IHE Clinical Guidance profile based upon it.<br><br>**Action: HL7 Australia and IT-014 to raise awareness of CDSS an seek participation among relevant groups including National Prescribing Service (NPS), RACGP, ACHI and AGPN.** |
| Need to progress publication of HL7v2.7 including gaining continued acceptance of Australian content | HL7v2.7 is important to Australia as it contains important extensions supporting collaborative care that were included to meet our requirements. Its publication has been substantially delayed due to the inability to resolve a number of conflicts arising from the v2.7 ballot. A recirculation ballot is expected to be held to advise balloters are aware of these conflicts and, hopefully, when complete allow v2.7 to be published. Australia needs to ensure that its needs are considered in this process.<br><br>**Action: HL7 Australia to coordinate with those stakeholders who may be eligible for any HL7v2.7recirculation ballot to ensure an Australian position is clear and taken.** |
| Recommendation that Australia lead revision of incorrect examples in HL7v2.7 ballot documents | Some of the published examples in the draft v2.7 documentation are incorrect and require revision. Examples are highly influential for software developers so the incorrect examples reflect badly on v2.7 and should be attended to as soon as possible. Given Australia's leadership of work on v2.7 and need for it to be published, it is proposed that IT-014-06-03 address this issue.<br><br>**Action: IT-14-06-03 to prepare corrections for the incorrect examples published in the HL7v2.7 ballot documents.** |
| Security | As there are some issues with the Security and Privacy DAM it is recommended that further review and input from Australian delegates take place to ensure it is correct and any local requirements can be covered in the model. |

# 2 INTRODUCTION

The benefits that the Australian Healthcare Community derives from Australian representation at international meetings such as this international HL7 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 May 2010 HL7 WGM included 6 delegates whose expenses were paid by the Commonwealth Department of Health and Ageing through Standards Australia and 6 others that were attending on behalf of their employer organisations, including 5 from NEHTA. A senior project manager from Standards Australia also attended the first two days as an observer. The contributions of delegates and other representatives in the Australian team were invaluable. This collaborative approach represents a very positive step in the national and public interest and allows the achievements of the delegation to be enhanced through mutual backup, support and input.

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

This report provides 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 with areas of potential concern to Australian stakeholders being highlighted for consideration of appropriate action by those stakeholders. For those who would like further information or to participate in the standards work, Information is provided on how to contact relevant Australian experts in the various areas. Many of the issues raised in this report 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 Kylie Sugar of Standards Australia (kyile.sugar@standards.org.au).

References provided in the text to wikis can be accessed with the user name wiki and password wikiwki. Access to references at HL7.com can be obtained via the members only web page of HL7 Australia.

# 3 THE WORKING GROUP MEETING INTERNATIONAL ATTENDANCE

Analysis of registrations showed that this meeting had 210 participants from 25 countries.

In all, 12 Australians attended as representatives for the duration of 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 | 5 | +1 |
| Part funding by employer: Standards Australia | 1 | +1 |
| Full funding – DOHA through Standards Australia contract | 6 | -1 |
| Part funding – DOHA through Standards Australia contract | 1 | +1 |
| Total: | 12 | +2 |

The DOHA-funded delegates were selected through an independent panel process jointly with NEHTA, DOHA, HL7 Australia and Standards Australia.

It should be noted that due to funding limitations of the delegation three current co-chairs from Australia were unable to attend this meeting. None of these co-chairs sought IT14 support prior to standing for their positions. This does not mean that their input would not be of great value to Australia's position, but that they are not endorsed by IT14 for their involvement. This situation reinforces the need for continual review of the delegate selection process and the need to identify areas of risk and need for mentoring and extending our capacity to cover all areas required when individuals are unable to attend for whatever reason.

Figure 1 indicates the investment being made by the international community to participate in, learn from and influence the development of standards at HL7. The figures shown represent attendance by country at this meeting and averaged for over the three meetings during 2009. This allows a comparison of attendances to the meeting outside the USA. The number of countries attending (25) and was slightly higher than the average of 22 countries.

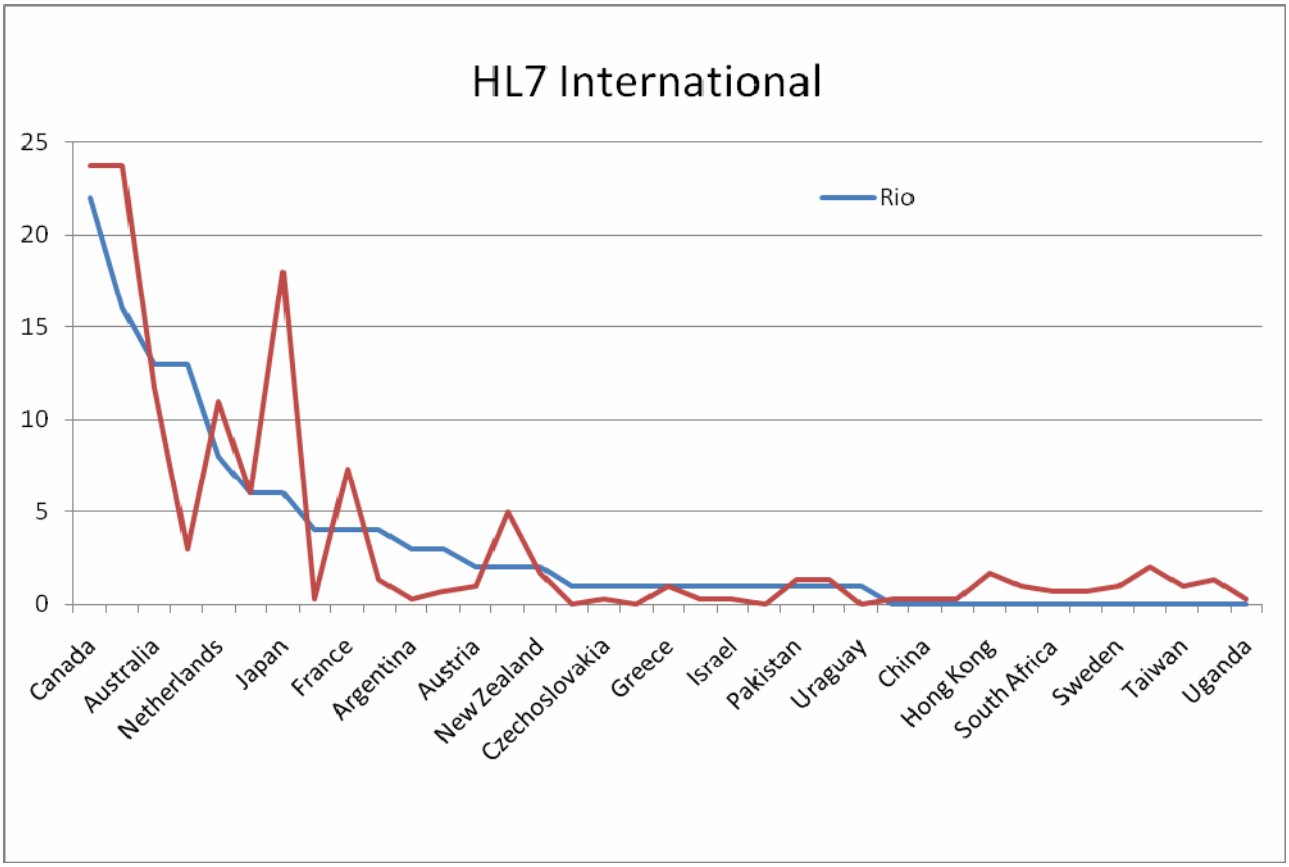



**Figure 1 International Attendees**

These international attendees are largely funded to attend by their employer, or they are funded as employees or consultants to national programs to influence HL7 developments, and return expertise to

their own country. This financial support does not negate the voluntary nature of much of the work which is done on weekends and evenings, out of work time, but does indicate the value attached to the activities by employers and national programs.

USA traditionally has the largest number of attendees at all WGMs, however their attendance is much lower where international meetings are held outside North America as many US employers (particularly State governments) are reluctant to fund attendance at offshore meetings. The proportion of attendees at the Rio meeting from outside the USA was also significantly lower to normal. Usually around 70% (n 228.3) of all WGM attendees are from the USA; however, for this meeting the percentage of attendees from the USA was 43% (n 88).

Following previous recommendations, Australian Government support for the Australian delegation has continued. There will be considerable opportunity to extend and improve knowledge and expertise in this area when Australia holds the international HL7 WGM 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 AUSTRALIAN LEADERSHIP AT HL7 INTERNATIONAL

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

| Working Group or Committee | Position | Status | Person |
|---|---|---|---|
| Structured Documents (Developers of CDA) | Interim Co-Chair | Current position | Grahame Grieve |
| Advisory Council to the Board of HL7 International | Chair (and ex-offiicio, non-voting member of Board of HL7 Int'l) | Current position | Richard Dixon Hughes |
| Architectural Review Board | Member | Current position | Andy Bond |
| | Member | Current position | Grahame Grieve |
| HL7 International Grants and Contracts Infrastructure Committee | Member | Current position | Richard Dixon Hughes |
| Organisational Relations Board Committee | Member | Current position (not in attendance at this meeting) | Klaus Veil |
| V2/v3/CDA Product Strategy Task Force | Member | Current position | Richard Dixon Hughes |
| Internationalization Task Force | Member & chair of Governance Subgroup | Current position | Richard Dixon Hughes |
| Community Based Collaborative Care Working Group | Co-Chair | Current position | Max Walker |
| Conformance Working Group | Co-Chair | Current position | Jane Gilbert |
| Modeling and Methodology Working Group | Co-Chair | Current position | Grahame Grieve |
| Patient Care Working Group | Co-Chair | Current position (not in attendance at this meeting) | Klaus Veil |
| V2.x Publishing Working Group | Co-Chair | Current position | Klaus Veil |
| Vocabulary | Co-Chair | Current position | Heather Grain |

# 5 MEETING LOGISTICS

HL7 International Working Group Meetings cover 7 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 event is a true working meeting, not a conference, with many individual groups, including those identified in Table 2 below, 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 – both those present at the meeting and those in the wider community of interest. While HL7 engagement with stakeholders in other forums is also strong (through regular, often weekly teleconferences), the ability to influence the work program, outcomes and strategic direction requires physical presence at working group meetings.

Table 2 below shows the meeting schedule for some of the larger meeting groups. Of the 63 separate working groups and committees, Board and Council meetings that occur at most HL7 meetings on 50 met at this meeting. This was largely due to some groups having insufficient members present to conduct business.

**Table 2 Meeting schedule highlighting areas of major Australian interest**

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

| | | | | | |
|---|---|---|---|---|---|
| Vocabulary | X | X | X | X | |

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 (eg vocabulary submission requirements). Shaded areas indicate groups where items of major Australian interest are being discussed. The number of concurrent sessions makes it impossible for a small delegation to effectively follow the issues and to influence change. It is noted that delegates funded by their employer, or individually to international meetings have no obligation to work with or relate information back to the Australian delegation, though some have done so in the past. It is clearly desirable that there be a cohesive Australian position. The size of the delegation and the reduction in the number of sessions held assisted in our capacity to cover the most important Australian requirements at the Rio meeting.

# 6 JANUARY 2011 HL7 WORKING GROUP MEETING - SYDNEY

## 6.1 BACKGROUND

After preparatory discussions and presentations throughout 2009, HL7 Australia submitted a proposal to the Board of HL7 International seeking to hold the international WGM for 2011 in Sydney in either January or May. 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). The Advisory Group is ongoing.

Critical success factors for a successful HL7 International WGM 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.

The proposal to hold the January 2011 WGM in Sydney was endorsed by the HL7 International Board in December 2009 subject to

(a) HL7 Australia providing at least $A100,000 in local sponsorship, to assure financial viability

(b) 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.

There are significant benefits for Australia in securing the WGM, most notably in:- 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.

## 6.2 CURRENT STATUS

Prior to the Rio meeting, HL7 Australia had secured commitments from DoHA and NEHTA that jointly provided most of the required $A100,000 in sponsorship funding. Accordingly, HL7 Australia advised HL7 International that it would be able to provide the required level of local sponsorship, subject to HL7 International being able to confirm before the end of June 2010 that the January 2011 WGM will be held in Sydney.

Discussions with HL7 International HQ staff in Rio confirmed that the venue bookings for the Florida meeting had been successfully deferred.

For several months now, Sydney has been advertised as the venue for the January 2011 on the HL7 International website for January 2011, and repeated announcements to this effect have been made.

With respect to meeting facilities in Sydney, a contract has been obtained from the Cliftons Training Facility in Sydney for the bulk of the meeting space and is under discussion but has not yet been signed.

Just prior to the Rio meeting, the Four Seasons Hotel – which was to provide the venues for the general sessions as well as accommodating the HL7 Board and staff – indicated that it was no longer available for the general sessions and could no longer to offer economical accommodation in the price range being sought by HL7 as it had secured by alternate events. A large AMWAY convention, the Sydney Ashes Test cricket match scheduled for the week before the WGM, and the Sydney Festival were reported to be putting pressure on some of the accommodation being considered by HL7.

## 6.3 PROGRESSING THE SYDNEY WGM

The emergence of these potential problems led Mark McDougall, Executive Director of HL7 International to again raise his concerns about the practicality and financial implications of holding the January 2011 WGM in Sydney (also see report of Board deliberations at section 7.2 below).

Accordingly, over the period of the Rio meeting, HL7 Australia sought a replacement venue for the general sessions. David Rowlands and Richard Dixon Hughes as senior HL7 Australia office bearers present at the Rio meeting, supported by Tina Connell-Clark from NEHTA, held several meetings with the Executive Director, his staff, the CEO (Dr Jaffe) and other key opinion leaders to reassure HL7 International about the viability of the Sydney event and the adequacy of the proposed arrangements.

During the week, a suitable replacement venue for the general sessions was located at The Establishment, a short walk from Cliftons. The Amora and/or The Grace were also identified and discussed with HL7 International as potentially suitable accommodation for the HL7 board members and HQ staff within their identified price range.

## 6.4 EVENTS IMMEDIATELY AFTER THE RIO WGM

In the week after the Rio WGM, the Finance Committee and the Executive Committee of HL7 International reviewed the financial outcome of the Rio WGM, which will make a significant loss having been poorly attended. To avoid further losses to HL7 International, the Executive Committee proposed a circulating resolution to the Board of HL7 International that, for all future WGMs held outside North America (including the proposed Sydney meeting), the responsibility for governance and financial outcome (profit/loss) be with the local HL7 Affiliate in the host country. After significant debate, this motion was passed. The Board of HL7 Australia therefore had to consider whether or not it was prepared to accept holding the proposed January 2011 WGM in Sydney on these revised terms.

Following discussion with cornerstone sponsors, NEHTA and DoHA and a review of the potential costs and its financial position, the Board of HL7 Australia resolved to accept the revised offer subject to HL7 Australia having ultimate control over expenditure and costs of the event. This has now been formalised by exchange of letters between HL7 Australia and HL7 International.

It is therefore a priority for HL7 Australia to work with HL7 International (who will continue to provide their WGM management expertise) to finalise cost effective venue and accommodation arrangements, establish a local group to oversee management of the event, see that HL7 Australia's interests are protected and to increase efforts to secure further funding opportunities to complement existing sponsorships. ]

## 6.5 ISSUES AND NEXT STEPS

Among those that regularly attend HL7 WGMs, enthusiasm for the proposed January 2011 WGM in Sydney is high and this may have inadvertently affected attendance at Rio. It appears that some delegates could not get time/permission to do two overseas meetings only 7 months apart and have opted for Sydney. Consequently, HL7 Australia believes that the relatively low attendance in Rio does not necessarily imply a low attendance in Sydney. Most Co-chairs have indicated they will be able to attend. A number of groups are actively planning co-located events though HL7 Australia has decided to not bid for the IHIC conference, which is often held immediately prior to the international working group meetings (in fact, some in HL7 HQ have formed the view that co-locating an IHIC conference with an international WGM may be adversely affecting attendance at the WGM itself.

Further meetings of the HL7 Australia Advisory Group will be convened in the near future to develop approaches for dealing with a series of issues that will affect the overall success of the Sydney WGM. These include:

- Financial viability. HL7 International was further stressed financially by the Rio WGM. Relatively low attendance in Rio (around 200 participants) resulted in a significant net loss. It is critical that the cost structure for Sydney be kept low and that participant and sponsorship revenues are further encouraged.
- Sponsorships. HL7 International needed to confirm in writing that the WGM will be taking place, in order for HL7 Australia to secure the DoHA and NEHTA funds [Note: this occurred on 14 June as this report was being finalised]. HL7 Australia still needs additional sponsorship to cover the remainder of the core $A100,000 as well as potentially funding a range of satellite and networking events.
- Participation. Significant marketing needs to be undertaken in at least three dimensions. Overall participation needs to be maximised to build the revenue stream. This requires broadcast marketing in arenas where likely participants will congregate and through channels they consume. Individuals critical to progressing standardisation need to be identified and individualised marketing strategies initiated. Fourteen working groups did not meet in Rio, and some others struggled for quorum and/or sufficient knowledge and expertise to enable effective meeting outcomes. And marketing strategies also need to highlight HL7's international profile.
- Partner events, pre- and post-WGM tours/options etc will also be appropriate to encouraging attendance, and a program will need to be developed.
- Participant accommodation. A variety of suitable venues (covering a range of costs/styles but readily accessible to the WGM venues) need to be supplied to HL7 International in the very near future, so that intending participants can secure accommodation at reasonable prices.
- Associated education and training will take two forms – (a) that delivered routinely in WGMs (i.e. tutorials); and (b) satellite events arranged by HL7 Australia.
- A fundamental background issue is HL7 International's inherent conservatism about the style of meeting. WGMs usually occur at a venue that is large enough to accommodate general sessions, 30+ parallel meetings and accommodate substantial numbers of participants; general sessions are usually held over breakfast, in banquet style; etc. However, this style of meeting would not be financially viable in Sydney, and an alternate approach will be taken. Considerable reassurance will need to continue to be provided to HL7 international staff and opinion leaders that this approach will be viable.

  **Action: It is proposed that meetings of the HL7 Advisory Committee convened as soon as possible to address these issues.**

## 6.6 EDUCATION PROGRAM FOR SYDNEY 2011 WGM

The educational requirements for the meeting in Sydney in January, 2011 need to be reviewed to assist the Advisory Group determine which tutorials will be required for the Australian audience, and which tutors (including Australians) are best equipped to deliver these.

The Advisory Group will also need to determine higher level (master class) and out-of-Sydney needs, in order to ensure that global experts attending the WGM are persuaded to stay on to address these needs.

There is a need for a coordinated approach to encourage suitable attendance at proposed new web based sessions, and to conduct an evaluation of these tools to either directly support Australia's requirements, or to be used to assist in the development of material for Australia.

Heather Grain has suggested that a small team be formed to assist in this task including some with HL7 implementation experience and standards development experience and an educator with experience in course development and delivery in Australia and competency development competency.

Heather Grain is reviewing the current content available and she and Tina Connell-Clark are reviewing competency requirements and assessment processes.

To assist in this endeavour, HL7 International's Education Committee will need to provide information on the content, learning objectives and target audiences for its existing material.

**Action: HL7 Australia form a group to review educational requirements for the meeting in Sydney in January, 2011.**

# 7 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).

## 7.1 INTERNATIONALIZATION AND THE ITF

In addressing the International Council, the Board, the Internationalization Task Force (ITF) and the general sessions, Dr Bob Dolin, the Chair of HL7 International, indicated his view that this WGM should particularly focus on how HL7 can realise "internationalization" – a strategic direction that promises 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. These challenges are being considered with the assistance of the ITF, which was established by the Board at the January 2010 WGM in Phoenix.

### 7.1.1 Internationalization Task Force (ITF)

The ITF is examining long-term strategic issues associated with HL7 International becoming an organisation that within 2-5 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 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

The work is 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 subgroups meet by teleconference and are in the process of defining their scope, objectives, and the issues and problems to be addressed with a view to discussing the issues in more depth at the Board retreat in late July.

A summary of progress and issues was also discussed at the Affiliate Chairs forum. If 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).

### 7.1.2 EU office

The HL7 Europe office is now operational (as an outpost of HL7 HQ). The legal charter allowing HL7 International to operate as a European organisation and participate in EU initiatives remains in development.

The approach being pursued is to have HL7 International as currently constituted also registered as a legal entity in Belgium, which may require some changes to the Bylaws of HL7 International. Current issues surround identification of a European to serve as a "legal proxy" for the purposes of the HL7 Bylaws and further clarification of terms and conditions.

At a practical level, the relationship between the HL7 Europe office and the local Affiliates in Europe needs to be worked through, possibly by introduction of some form of advisory structure comprising the chairs of the European Affiliates.

An HL7 EU website will also be set up.

## 7.2 WORKING GROUP MEETINGS OUTSIDE NORTH AMERICA

The recommendations of a Board Task Force formed to assess International WGMs were received and considered at some length by the HL7 Board and are already having a significant impact on planning for the January 2011 WGM in Sydney. In brief, key observations and outcomes during the Board's consideration of the issues included:

- The Board noting that HL7 is struggling to balance three key priorities with respect to WGMs, namely that WGMs must:
  - (1) be financially viable
  - (2) be productive, and
  - (3) engage the international community.
- Those proposing to hold a WGM outside North America need to have real "skin in the game" – either through a significant up-front financial contribution or being prepared to underwrite any losses. The IMIA business model where any profit/loss is borne by the local committee was noted.
- The local support of recent WGMs outside North America has not lived up to the initial promises, which means that financial viability and HL7 productivity have both suffered without achievement without any greater engagement with the international community.
- An organising committee is to 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.
- Arranging a WGM is an 18-month process. If there is to be a WGM outside North America in 2012, a proposal will need to have been received and approved by the Board no later than January 2011 to include a description of the organizing committee and how the hosting country will help fund the meeting.
- The failure of WGMs outside North America to attract significant additional international participation remains a concern. Treasurer Buitendijk is looking at how WGMs can be better spread among regions to encourage greater participation.
- The task force considered possible root causes of low attendance may have included: - holding meetings that are not close to a high concentration of HL7 members; the challenges of ensuring co-chair participation and cost – but no interventions have been proven to work yet.
- Marketing – has everything possible been done to promote WGMs? And, as to cost, are they being run as economically as possible to encourage attendance or as a money-making venture?
- Co-chair participation is essential – there needs to be an expectation that at least one active co-chair will be available to keep the momentum up within each work group.

- Proximity in time to other meetings may also be a factor – the near-debacle of scheduling the May 2011 HL7 WGM and the ISO/TC215 meeting in the same week has emphasised the need for greater communication and cooperation between the SDOs active in health informatics. HL7 has already suggested that the schedule be coordinated through the Joint Initiative Council (JIC).
- Cost to US delegates (who are the majority of those attending WGMs) is a major factor that reduces attendance at WGMs outside North America.
- Questions were raised about the possibility of HL7 having to schedule additional out-of-session face-to-face meetings to address increased work coming out of current US-Government initiatives and whether this would impact the level of US attendance at meetings outside North America. Dolin and Quinn noted that the present demand appears to be for use case development and implementation guides, rather than additional standards.

## 7.3 HL7 ROADMAP AND BUSINESS MODEL

The Roadmap Taskforce (led by Bob Dolin, Chair) has revised the Strategic Initiatives for 2010. SMART objectives[1] are being assigned to these initiatives, and preliminary mapping of milestones to the revised initiatives will be undertaken by HQ staff.

The Roadmap initiatives are described in Attachment 1. There appears to have been little action since the January meeting on this front, and no decisions were required from the Board at this WGM.

A facilitated day of discussion at the annual HL7 Board retreat in late July will focus on the HL7 business model, where the organisation should be in 5 years; where the money will come from; what venues should be pursued for revenue steams; and, how HL7 can ensure that it is pursuing its strategic objectives and roadmap.

## 7.4 V2/V3/CDA TASK FORCE

The v2/v3/CDA Task Force (TF) was established at the Atlanta plenary meeting to deal with a range of organizational concerns relating to the uptake and use of HL7 standards and future product strategy including:

- While V3 has been successful, it has not been as widely adopted as expected - particularly for messaging applications in the USA (when compared with Canada, the UK and some European countries).
- HL7 currently supports 3 exchange methods – V2, V3, CDA – but these do not draw on common data types, vocabulary, and semantic models.
- V2 and V3 are facing challenges in meeting the industry need for cross-institution and national interoperability.
- There is an industry shift from message based to service based interoperability.

Dr Stan Huff (Intermountain Healthcare) is chair of the Task Force (TF) and is being assisted by a consultant/facilitator, Virginia Riehl. Stan Huff reported on the TF's activities to both the Board and the general membership. Richard Dixon Hughes and Grahame Grieve are appointed members of this Task force. In summary, the TF 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, and
- Recommending actions and a plan.

The first major activity completed by the TF was to produce a problem statement which was refined through a process of discussions with TF members, senior HL7 office bearers, the TSC and several key experts. An interview protocol and series of questions was then developed to assist in discussion of the issues and a list of interviewees was compiled.

There are over 50 people being interviewed and about half of the interviews had been completed by the time of the May 2010 WGM in Rio. Australians included in the interview process have included Andy Bond (NEHTA), Max Walker (Victoria Health) and Michael Legg (HISA/ pathology messaging) – with Klaus Veil also to be interviewed.

[1] Note. SMART objectives have metrics that are Specific, Measurable, Actionable, Relevant, and Timely.

At the request of NZ delegates present in Rio, Richard Dixon Hughes arranged for two NZ representatives to be added to the consultation schedule.

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 remain to be resolved. Dr Huff indicated that one part of the solution may be for HL7 to develop a standard intermediate format for clinical information models and terminology binding to/from which other types of related artefacts may be compiled.

The need for clarity and resolution of the relative positioning of HL7 V2 and V3 grows more acute. This has been thrown into sharp focus by the continuing omission of V3 messaging from the "Meaningful Use" documents which set the agenda for the USA eHealth initiatives.

As the consultation and information gathering exercise comes to a conclusion, the next steps are expected to be:

| Activities | Timeframe |
|---|---|
| Complete interviews and summarize outcomes<br>Review interview results with TF<br>Review interview results with Board | May/June |
| Prepare draft plan and recommendations<br>Review plan and recommendations with TF<br>Get ArB and TSC input on implications<br>Determine Task Force recommendations<br>Present to Board | June/July – for detailed consideration at annual Board retreat in late July |
| Progressive communication and discussion of outcomes, recommendations and plans with membership and key stakeholders | September Plenary and WGM |

Previous issues with respect to governance and scope of this TF and its relationship to other HL7 groups such as the TSC and ArB have now been resolved and its scope has now been better defined.

Given the potential strategic impact of this TF's work and potential for confusion with current product strategies, the Board has approved a documented communications plan and plan for reviewing recommendations. In converging on approaches meeting the needs of some groups in HL7, there is a risk that important feedback on strategic requirements across other aspects of the product range (e.g. v2) might be lost or overlooked.

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

## 7.5 HL7 FINANCIAL POSITION

Hans Buitendijk, HL7 Treasurer, reported on the HL7 finances. The results for the 2009 (now audited) and projected results for the 2010 calendar years many be summarised as follows:

| 2009 – Last Year | Budget | Actual |
|---|---|---|
| Revenues | $3,689,785 | $3,901,746 |
| Expenses | $4,807,603 | $4,380,244 |
| Net income (Loss) | ($ 1,117,818) | ($ 478,498) |
| Reserves | $2,958,612 | $3,540,606 |
| Months | 7.5 | 9.9 |

| 2010 – This Year | Budget | Forecast |
|---|---|---|
| Reserves in $ | $3,639,445 | $3,509,861 |
| Reserves in Months | $4,451,034 | $4,400,798 |
| Net income (Loss) | -$ 811,589 | -$ 890,937 |
| Reserves in $ | $2,729,017 | $2,649,669 |
| Reserves in Months | 7.36 | 7.23 |

Significant points noted included:

- Intel's donation of an executive position to provide a CEO for HL7 International will come to an end on 31 July this year, after which HL7 will be faced with carrying the costs of its CEO.
- The May 2010 WGM in Rio is heading for a record loss of over $150,000. HL7 cannot continue to underwrite international WGMs to this level.
- The Finance Committee of the Board has had to review expenditures and is proposing cuts (including staff) to balance the budget going forward. If no action is taken and current trends continue, HL7 International would exhaust its reserves some time in 2013.
- In the absence of additional revenue sources (which are nevertheless being actively pursued) the aim is to cut expenditure to a level needed to sustain reserves near current levels.
- The previously budgeted Director of Marketing position will not be filled.

## 7.6 OUTREACH

### 7.6.1 US OFFICE OF THE NATIONAL COORDINATOR (ONC)

Stimulus funding to accelerate HIT spending has provided leverage opportunities for HL7. A financial proposal has been put to the Office of the National Coordinator/DHHS. Meetings with key stakeholders (NLM, NIST, and ONC) have been held and minor adjustments made per their recommendations.

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

- ARRA (HITECH) funds: these stimulus funds are intended to address near-term objectives but may require some form of competitive contracting for HL7 (which may still prove to be a barrier), and
- Funds for long-term objectives tied to a sustainable business model – potentially as part of on-going CMMS program funding.

A proposal to license HL7 IP for nation-wide use in the USA has been under consideration for some time and will be finalised by about mid June for further discussion with the Department of Health and Human Services and the ONC. The potential impact of national licensing on membership and membership revenues is one of the factors behind the current focus on HL7 business models.

ONC is in the process of evaluating its first 3 RFPs for various types of eHealth standards related activity. As these required a pre-approved contractor for administrative management, HL7 International was not able to bid directly but has been approached to join bids by several of the 9 eligible contractors. Several more RFPs have since been released. HL7 is expected to be a grant recipient under the RFP, although the amount and duration is unclear. More information about these RFPs is most easily obtained following the links from the following blog site:
http://geekdoctor.blogspot.com/2010/06/onc-standards-rfps.html

### 7.6.2 NIST AND OTHER US-GOVERNMENT AGENCIES

Productive discussions have been held with NIST (National Institute of Standards and Technology) about HL7 managing a substantial fund related to development of conformance and compliance testing. These funds should be awarded soon but the question is whether they will all pass through or provide some revenue for HL7 itself.

Overall, diverse opportunities to drive new revenue are being pursued including from FDA, NIST, the National Cancer Institute (NCI) the Centre for Disease Control (CDC) and Department of Defence. However, these are all grant-based and do not address HL7's need to maintain a sustainable business

model. Contract work is of limited benefit to HL7, if it cannot leverage existing capabilities and has to incur significant extra costs to deliver.

### 7.6.3 MARKETING

An updated Marketing Plan has been approved and there has been significant reporting of HL7 in the US media. HIMSS 2010 was a very successful event for HL7.

A new marketing campaign - "HL7 Can Help!" – was successfully introduced.

### 7.6.4 IHE OUTREACH

A one-day meeting was held in January with the objective of improving cross-organization communication. The outcomes comprised joint commitment to:

- Development and piloting of a single deliverable for CCD, using existing HL7 and IHE content
- Development of a Standards & Implementation "life cycle" concept (and white paper)
- Definition of an Implementation Guide development process, and
- Definition of the organizational governance necessary to produce unified, consistent, unambiguous implementations.

### 7.6.5 EUROPEAN PROJECTS

HL7 is monitoring and, as opportunities arise, engaging with the projects involving eHealth activities in Europe, with the following being noted:

- epSOS – This initiative has finalised its commitment to use CDA in its pilot project for pan-EU ePrescribing. The Board is considering a suggestion that epSOS be given complimentary access to HL7 IP for use in the pilot.
- Argos project – This is a high-level EU-US project to coordinate HIT, including standards. The US management contract has been awarded to AMIA.
- SEGHOVIA – This initiative is supporting the European eHealth Governance Initiative and action. HL7 is one of some 40 organisations invited to join this initiative starting in June 1. With a budget of €500k and timeline of 36 months, its objective is to integrate eHealth into EU health policy.

### 7.6.6 CLINICAL RESEARCH INITIATIVES

A range of clinical research activities are underway or being established. Examples include:

- The BioIT Alliance – a nascent "standards implementation" initiative, supported by IBM, Microsoft, HP, Accelrys, and big pharma. This is a collaborative effort between HL7 and CDISC, rather than any intent to create new standards.
- CTSA Data Standards & Interoperability Group – the vision is for coordination of CTSA-wide standards development, with primary focus on secondary use.
- HANYS Initiative – the vision is to leverage secondary use of healthcare data for clinical trials (both recruitment and trial design). This is currently limited to New York State (NY HIE) and big pharma.

### 7.6.7 CONTINUING MEDICAL EDUCATION (CME)

HL7 will offer CME through the American College of Physicians for WORKING GROUP meetings in 2010-11. There is no intention in 2010 to extend the CME scheme for non-US events, but perhaps Australian CME options could be considered in respect of Sydney '11.

### 7.6.8 ANNUAL REPORT

The first annual report produced by HL7 International is being finalised for publication in June 2010. It will be released in both printed and electronic form and will cover:

- Report from the Leadership
- Technology Achievements
- HL7 Ballot results
- Conference and Workshops reports
- Financial Statement
- HL7 International achievements
- New International members
- Work Group Achievement, and
- Contact Information.

## 7.7 POLICY ADVISORY COMMITTEE

The HL7 Policy Advisory Committee (chaired by Don Mon of AHIMA) has developed position statements in response to the U.S. Meaningful Use discussions, Standards and Certification and ONC Certification (they are available at http://www.hl7.org/newsroom/index.cfm).

It has also developed a response to the EU's request for consultation on a collaborative effort between the European Commission (EC) and Europe's National Standards Organizations (NSO) to reform their standards setting process—via which standards will be aligned with laws and European Directives so that standards can be quickly produced to support the implementation of a law.

The Policy Advisory Committee is also working on the following internal projects:

- Development of mission/charter statement, and
- Development of committee-specific decision making practices (DMPs).

# 8 CTO REPORT

The following is a summary of the CTO reports as presented by the CTO, John Quinn, in several forums including the Board, the Co-chairs meeting and in general session for the HL7 membership.

## 8.1 TOOLING & STATIC MODEL DESIGNER (SMD)

The UK NHS sponsored the development of SMD 1.0 which is now being piloted within the NHS CfH to support design and publication of their specific HL7v3 Implementation Guides.

HL7 is adapting the SMD to include capabilities needed to support: - V3 Balloting and Publication; HL7 User developed implementation specifications for messaging; and CDA templating.

There is a requirement to import and export of various versions of the MIF, including graphical information which is viewed (HL7 Tooling and MnM WGs) as key to HL7's interoperability tool strategy. There is also a need to validate the full set of constraints that the SMD validates as part of the modelling process. While the SMD has the ability to "enable or disable" specific validation rules, HL7 needs to confirm which ones are essential to the model design process needed to produce specifications with models that are not as tightly constrained as those used in implementation guides.

The Shared Artefact Repository Requirements will follow once SMD modifications and import/export requirements are fully agreed.

The XML processing project is in process and initial work should be completed by end of June.

The V3 Generator remains to be specified. Canada Health Infoway and HL7 International are both looking at the Generator to see if there are any joint interests that could be leveraged by cooperative activity.

Tooling projects are on or under budget but some are running a couple of months behind schedule.

An OHT Board meeting is expected in June but not yet scheduled. The OHT Architecture Project has a Value Proposition Survey that is being tested with the HL7 Tooling WG & the ArB. The intent is to progress the survey via those groups and then bring the results to HL7's CEO & CTO.

## 8.2 SERVICES AWARE INTEROPERABILITY FRAMEWORK (SAIF)

The Architecture Review Board recommended and TSC approved a name change from SAEF to SAIF (aligning with terminology used within the US Government).

ONC has been developing an Interoperability Framework for the Nationwide Health Information Network (NHIN). This framework was presented at the March, 2010 ONC HIT Standards Committee Meeting in Washington DC and includes HL7 SAIF as the services harmonisation component for.

The National Cancer Institute (NCI) has moved aggressively forward with development of a full Services Enterprise Architecture based on SAIF.

Significant progress has been made on further documentation development. Three of six documents/sets are now available for peer review:

- SAIF Introduction
- Enterprise Conformance and Compliance Framework, and
- Behavioural Framework.

The Governance Framework, Information Framework and Implementation Guides are yet to come.

The ArB has sponsored an entry on Wikipedia to give wider access to information on SAIF, the link is: http://en.wikipedia.org/wiki/HL7_Services_Aware_Interoperability_Framework

Further comments on the consideration of SAIF at the ArB are reported in section 23 below.

## 8.3 HL7 QUALITY PLAN

There has been a muted response from WGs and TSC in response to feedback on the proposals for development of a quality plan. TSC is considering how this should be progressed – noting a need to coordinate with recommendations of the v2/v3/CDA Task Force.

# 9 INTERNATIONAL COUNCIL AND AFFILIATES

Meetings of the International Council and the Affiliate Chairs in Rio occupied over a day and a half of Affiliate Chair time, a significant part of which was spent in considering implications of possible new operating models relevant to a truly international organisation and the implications of these changes for the existing Affiliates driven by the activities of the Board's Internationalization Task Force (discussed further at section 7.1.1 above).

During the plenary meeting of the International Council on the Sunday brief updates were given by each country outlining activities in their respective countries. These updates are summarised in Appendix B to this report.

Since the previous WGM, HL7 Norway has been admitted as a new affiliate and a petition to form a new affiliate has been received from Puerto Rico.

Other pertinent highlights included:

- **Changes to Affiliate Agreements**. These agreements specify the rights and responsibilities of national Affiliates, and will require re-thinking in the 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 by HL7 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 draft expected from HQ in the next month or, after HL7 receives feedback from their attorneys.

Affiliate reporting arrangements to HL7 Headquarters are currently reasonably onerous, and a balance needs to be found between accountability and practicality;

**Action: HL7 Australia to review Australian requirements and consider proposed changes to the Affiliate agreement.**

- **Use of Intellectual Property (IP)**. There were several substantial discussions about IP issues at this WGM, and HL7 Australia needs to be clear on its current usage of HL7 IP, its obligations under the Affiliate Agreement and its requirements in respect of IP so as to ensure they are adequately reflected in the Task Force's recommendations, new Affiliate Agreements, etc.

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

- **Non North American meetings**. The International Affiliate chairs were consulted on a range of proposals and options for enhancing the viability of international meetings. Under some o0f the options being considered, there is a risk that meetings in the Asia-Pacific region may be scheduled very infrequently, and creative thinking may be required to ensure balanced global representation. The consideration of policy surrounding WGMs outside North America by the Board of HL7 International is reported more fully in section 7.2 above.

- **Affiliate input on technical issues**. While the International Council has a representative to promote Affiliate interests at the TSC (Ravi Natarajan from UK NHS CfH), there is no organised communication pathway by which technical input from Affiliates can be fed into HL7 decision-making processes at the level of the TSC. Technical communication within the Affiliate community needs to be enhanced, and an arrangement to network Affiliate technical leads will be trialled in the short term for review at the next WGM.

  **Action: HL7 Australia to identify and nominate a technical lead to be the communication channel between HL7 Australia, the Affiliate community and the TSC on HL7 technical issues.**

- **The passing of the late Dr Joachim Dudeck** (HL7 Germany) on 31 March 2010 was noted by way of tributes and an opportunity for remembrance at the International Council, the Board and the Wednesday General Session. Prof Dudeck was a former chair of HL7 Germany, a dedicated leader and teacher of health informatics in Germany and was instrumental in encouraging HL7 to establish the IHIC conferences and to hold WGMs outside North America.

# 10 BEHAVIOURAL FRAMEWORK PROJECT

The behavioural framework project is a joint effort between the Architecture Board and the Orders and Observations Work Group. The project is seeking a new way forward for standardising the behavioural side of HL7 specifications – who says what and when. HL7 standards must be understandable from a business stakeholder point of view, and amenable to implementation in either messages or services, or, in some contexts, by a freeform exchange of documents.

While we recognise that services are implemented by messages, and messages implement services, the general design philosophies of "services" (SOA) and "messages" differ, in terms of granularity, technology, and how much of the trading partner agreements are implicit or explicit. Because HL7 has not had a single rigorous approach to describing the behavioural model, the SOA approach and the messaging approach have actually gone ahead and described solutions that work differently from a business point of view, and neither solution has been particular well matched to real world business problems (or, at least, the suitability has been difficult to ascertain).

A document is under preparation which describes the business interactions for pathology laboratories; this document will form the basis for future HL7 specifications in the key area of allied clinical reporting. As such, it needs to reflect current Australian legislation and business practices through the diagnostic services sector. This document has had significant Australian contributions (first draft written in Australia), but further work will be required to ensure that our requirements are met. The document will be published for public comment in the next few months. The NEHTA Diagnostic Services Reference Group is working on related and complementary documents; hopefully these will be open for public comment in a matching time frame.

The progress of this work is critical to enabling HL7 and its stakeholders to convert the apparent value of their specifications, knowledge, methodology and community into real deliverable value; as such, it has attracted a degree of interest from a number of significant stakeholders. Unfortunately, however, it has not attracted any substantial support, and so is progressing slowly at this time.

# 11 CLINICAL STATEMENT WORK GROUP

The Clinical Statement Pattern (CSP) is an HL7v3 DMIM which is used within the Patient Care, Structured Documents and Orders and Observations domains to express rich clinical content. It has been developed over more than 3 years and allows nearly any clinical statement to be encoded in its rich, recursive structure.

It passed ballot as a DSTU but did not have a specific "home" or owner within HL7. This led to the formation of the Clinical Statement Work Group (WG) at the January 2009 WGM with representation from the technical and clinical content committees. Its workspace can be found at: http://wiki.hl7.org/index.php?title=Clinical_Statement_Harmonization_Project

This was the fifth face-to-face meeting of this work group. With the scope of the Clinical Statement having been clarified at the last WGM, the WG is concentrating on attempting to simplify areas that are amenable to common representation. This is a difficult process and requires significant cross-domain knowledge of potentially common elements such as CMETs for which there is not yet any common centralized repository. Implementation simplification whilst not compromising functionality is proving difficult. However a number of promising areas have been identified for further work. It is hoped that any simplifications will then allow development of tools to support the enhanced Clinical Statement in a more rapid timeframe.

Proposed changes to the CSP and relationship between CSP and the Care Statement topic within the Care Provision domain (managed by the Patient Care (PC) Work Group) was discussed at some length in joint session between CS WG and PC WG. This and related topics being progressed by PC WG are reported (with recommended actions) in section 19.4 below.

# 12 COMMON TERMINOLOGY SERVICE 2 (CTS2)

CTS 2 will be a commonly accepted standard for terminology services that enhances the capabilities of the initial CTS specification for sub-setting and mapping, and extends the specification into domains such as terminology distribution, versioning, and classification.

The CTS 2 work in HL7 has produced a "Request for Proposal" (RFP) for common terminology services which was issued in September 2009 under the standardization processes of the Object Management Group (OMG). Information on the project is available by following links from the HSSP wiki: http://hssp.wikispaces.com/cts2.

The RFP is available from the OMG website: http://www.omg.org/cgi-bin/doc?ad/2009-9-17.

The major elements being sought through the RFP are:

- Being capable of: "query, authoring and management of functional terminologies in a distributed environment"
- Having MDA-capable platform independent model (PIM) – MDA = Model Document architecture. Should be expressed in UML – [but it appears this may not be possible – submitter using Z notation]
- Including a platform-specific model in the form of a Web service endpoint (WSDL with SOAP/HTML binding)
- Defining explicit operations that support all mandatory capabilities)
- Interface specifications that support complex terminologies e.g. SNOMED CT, RxNORM
- Supporting the ISO 11179.3 R2 Clause 10 notion of a conceptual domain and support the following functions: List conceptual domain, Return conceptual domain, create conceptual domain, maintain conceptual domain
- Conforming implementations that implement at least one CTS2 profile
- Supporting vocabulary requirements in the HL7 MIF (Message Implementation Framework)
- Being not limited to the healthcare domain – Boeing and Car manufacturers have expressed interest, and
- Preference given to submissions using SoaML to specify the service.

CTS2 proposals were received at OMG in May 2010 and the October meeting will undertake work on updates and further additions. Three letters of intent have been received and two detailed submissions

were received (from ii4sm/Visumpoint and from Mayo) and are being worked on. The Mayo Clinic is currently building a Terminology Service based on the CTS2 specification.

These submissions have different approaches but it is hoped that the two organisations that responded to the RFP will merge their efforts and create a single response, which is a preferred model for OMG.

For CTS2, new Supporter and Reviewer roles in OMG have been created. Supporters are additional to submitters and do not need to be OMG members. Supporters agree to perform timely and regular review of artefacts when requested and have access to all Submitter documents. Reviewers review artefacts when requested and all HL7 members are automatically eligible to be reviewers.

Considerable discussion took place at this WGM around managing expectations of what CTS2 will deliver. Some HL7 members had expressed the view that a terminology service must provide support for the HL7 International ballot publication process and terminology bindings. However, this had been explicitly excluded from the CTS2 scope. Some additional requirements have also been identified since the completion of the CTS2 DSTU. These include functionality to return fully populated XML for all HL7 V3 (and possibly V2) datatypes so that not only is the canonical name and code returned, but also the terminology type, version etc. It was determined that ArB will create a high level service blueprint document, showing the services that HL7 has or will require. This document has to come back to SOA as a new service for data type resolution. This will allow terminology elements to be packaged, for example, in HL7 data types.

Based on discussions with ArB and SOA it was recommended that Vocab WG have a firm hand in the submission management process. HL7 technically doesn't have a way of forcing its way into the submission process. Vocabulary WG will appoint liaisons to OMG who will be responsible for working with the submitter teams to ensure that HL7-specific requirements are reflected in the RFP responses in an appropriate manner.

For example: submitters may develop a more abstract set of data types that may correlate to the HL7 data types but may not be an exact reflection of them. The submitters might want to keep the customer base large and may provide an interface to different data types. It would be the liaisons' responsibility to understand and undertake a detailed review of the submissions. They may provide suggestions to HL7 that would go forward to John Quinn to be officially communication to OMG. Following this correct procedure has advantages in keeping the technical management within HL7 informed of issues and presenting recommendations that have the backing of HL7 as an organisation. Vocab WG will also contribute by involvement in the HSSP project with its goal of continuously improvement.

The main concern in adopting this approach is that the submitter teams are not obliged to accept HL7 input, although it is considered likely that they will. Another concern is finding resources to understand, and review the document. This is going to require a significant effort and it will be difficult to find the right people with the requisite understanding of terminology, modelling and data types.

**Action: HL7 Australia, NEHTA and IT-014-02 to confer and arrange for: (1) awareness and education activities to ensure that implementers of clinical terminology in Australia understand the implications of the work; and (2) review of the work to ensure it meets Australian needs for terminology implementation.**

# 13 COMMUNITY BASED COLLABORATIVE CARE (CBCC)

Dr David Rowed (Australia) has recently been elected as an interim co-chair of this WG and, although new to the post, he was the only CBCC co-chair present at the Rio meeting. Max Walker from the Victorian Department of Health is one of the permanent co-chairs but, on this occasion was not funded to attend the WGM.

The permanent co-chairs of the CBCC are leading the main activities being conducted by the WG but as none of them were present at this WGM, only a little discussion or progression of CBCC activities could take place. As the only CBCC co-chair attending this WGM David Rowed's main aim was to ensure continuity of CBCC WG operations and deal with any issues which arose.

Over recent years, work within CBCC WG devolved into two quite different streams of activity:

- Managing the range of information and workflows required for health care delivery in community settings – this was the original purpose of the WG, as attested to by its title, is Australia's main interest in the WG and was the reason we supported its formation.

- Managing the privacy and security of sensitive personal information relating to clients receiving health care in community settings (although this work then became more generic). This is the only aspect of interest to particular groups in the USA and was pursued for some years almost to the exclusion of the WG's main purpose (as seen by Australia) and despite there the Security WG being specifically constituted and better placed to address this scope of work within HL7.

Of considerable general interest to many delegates was the joint meeting with the Security WG at which Bernd Blobel presented current work in relation to the harmonisation of the Security and Privacy Domain Analysis Model (DAM), in particular, the pivotal role and relevance of the ISO 22600 Privilege management and access control (PMAC) standard. ISO 22600 and the Security and Privacy DAM have their foundations in the ISO 27001 Information Security Management Systems standard and, architecturally, they make no distinction between the information structures and systems functions used to manage security and those used to manage privacy; however it was acknowledged that, at a business level, these are fundamentally different concepts.

As per the ISO 22600 standard, the Security and Privacy DAM describes a privilege management infrastructure for policy based access control. During the discussion it was highlighted that Community Based Collaborative Care is a complex domain in which to implement a model such as the proposed DAM however it was also acknowledged that it was likely to be an area where the benefits of policy based access control would support the necessary cross enterprise information sharing necessary to allow a collaborative care environment. The fallacies associated with any attempt to deal with privacy as a separate issue without regard to the existing models were noted. Berndt offered the opinion that the CBCC approach might be justified for developing use–cases while the Security WG would be a more appropriate place to manage detailed engineering perspectives and technical work in the area.

At a joint meeting of Patient Care WG and its associated WGs, CBCC reported that its regular Tuesday teleconferences would be focussing on reconciliations of comments received from balloting its CDA Implementation Guide and the joint Security-Privacy DAM. Wider participation would be welcome.

Other items of particular relevance to Australia in relation to CBCC included:

- Issues surrounding progression of HL7v2 for use in collaborative care settings which is being considered by PC WG (see report and recommendations in section 19.7 below).
- The Human Services Directory Service (HSDS) project had passed ballot under the SOA WG. This project was inspired by and is based on the Victorian DHS Human Services Directory and was managed by Max Walker.

Work on community based collaborative care is of considerable relevance to the development of eHealth in Australia and there is a need to ensure that Australian needs are addressed and progressed as part of mainstream HL7 standards work. The previous use of the CBCC WG to focus on client privacy issues (to the exclusion of other collaborative care content) has delayed this objective but with two Australian co-chairs, it is time to move the original agenda forward.

**Action: HL7 Australia, IT-014 (and subcommittees) and Australian delegations to upcoming HL7 WGMs to:**
**(1) Promote continuation of work within CBCC WG on defining the needs, workflows and information needed to support community based collaborative care delivery in Australia.**
**(2) Promote close collaboration and joint activity between CBCC, PC and CS WGs in progressing this work to meet Australian needs.**
**(3) Support Security WG having the lead role within HL7 on all matters relating to the management of security and privacy, guided by use cases from CBCC and other domains.**
**(4) Inform, engage and encourage participation from the states/territories in CBCC work which produces implementable v2 and services standards.**

# 14 ELECTRONIC HEALTH RECORD (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 provide users or certified systems with 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.

## 14.1 SUMMARY OF EHR ACTIVITIES

As usual, EHR Work Group had a full program, although attendance was considerably lower than at meetings in the US. EHR WG reviewed its work program at the WGM, with progress across the following range of activities being carried out under, or in conjunction with EHR WG being noted:

- **EHR-S FM Release 2 (R2)**

  The current main task for the EHR WG is production of new EHR-S FM R2 reconciling experiences from the EHR-S R1.1 (now also ISO/HL7 10781) and its application across a range of functional profiles and incorporating material from other sources. (Refer to section 24.1 of the report on the January 2010 WGM for a complete list of the 18 principal sources being reconciled to produce R2).

  The EHR WG allocated a total of 8 quarters (2 days) to EHR-S FM R2 work at this WGM and the latest schedule is reported in section 14.2 below.

- **Personal Health Record Systems Functional Model (PHR-S FM)**

  Currently published as a DSTU (with a functional profile also having been published), work has commenced on upgrading this specification to normative status within HL7.

  This activity is being managed by the subsidiary PHR WG led by John Ritter, Don Mon, Gary Dickinson and Lorraine Doo. The PHR WG meets fortnightly by teleconference (around 1am/3am Thursday – Australian time).

- **EHR Interoperability Work**

  Under the leadership of Gary Dickenson (assisted by Gora Datta), the subsidiary EHR Interoperability WG has been progressing a range of activities associated with the workflow processes surrounding the use of electronic health records, their integrity, completeness and trustworthiness of electronic health records.

  HL7 took a policy decision to reflect relevant core requirements of the previous EHR Interoperability Model DSTU in R2 of the EHR-S FM; however, Gary Dickenson, as the chief proponent of this earlier work, controversially submitted much of the same material as part of an ISO new work item on "Standards Convergence to promote EHR Interoperability" which Australia voted against earlier this year (discussed further in the report on the ISO/TC215 meeting in ISO).

  Activities reported by the EHR Interoperability WG are summarised in section 14.3 below.

- **Proposal to develop Data Profiles.**

  Dr Steve Hufnagel proposed that EHR WG start work on the development of data profiles to complement the functional profiles used for certification against the EHR-S FM. More information on this controversial proposal is given in section 14.5 below.

- **Ambulatory Oncology Functional Profile.** This is being actively progressed by Helen Stevens as part of her NCI work via weekly teleconference at 1 pm US-ET Thursdays (3am Fridays AEST).

- **EHR-S FM Functional Profile (FP) for Canada**

  Sasha Bojicic reported on Canada Health Infoway progress in developing the Canadian functional profile as part of the broader Canadian EHR Blueprint 2015 project. The Blueprint 2015 functional profile defines (system) functional capabilities required for realization of collaborative health care delivery among various clinical applications and EHR systems. It leverages HL7 EHR-S FM as a vehicle to provide consistent rendition of the functional capabilities to support selected BP 2015 clinical themes.

  The Blueprint 2015 FP is used as a reference point for the numerous clinical systems that integrate with EHR systems to indicate purpose and relevance of functional features and capabilities to clinical practice. In developing the FP some additional functions and clarifications appear to be

required and closer alignment of the Blueprint functional model and the HL7 EHR-S FM specification will be pursued.

The wider Blueprint 2015 project also emphasises formalism and methodologies to consistently articulate architecture assets and alignment with HL7 SAIF, specifically:

- TOGAF ADM is used to select appropriate architecture artefacts for Preliminary, Business, Information and System architecture
- Business process modeling (BPMN) is used to model clinical scenarios
- Service oriented methodologies and techniques are used to articulate definition of service contracts, governance and information models, and
- Blueprint 2015 will be an early adopter of SAIF (Alpha project) and will adopt and adapt SAIF as its interoperability framework, focusing on definition of the functional capabilities implemented via service interfaces.

At its weekly teleconferences, EHR WG has already commenced its review of enhancements for inclusion in R2 arising from Canada Health Infoway's work on Blueprint 2015.

- **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) The team continues to express gratitude for information on the recording of births and deaths in Victoria, which was supplied last year to give the team an international perspective. The main problem being tackled at present is the differences between the various states in the US and the challenge of achieving greater automation, cleaner records and reduced functional duplication by collecting data once and using it in legal/regulatory, statistical and healthcare delivery contexts.

- **Public Health.** The activities of public health stakeholders in reviewing their use and requirements for the EHR-S FM, and potentially a future PH-EHR-S FM are reported in section 14.4 below.
- **Enhancements to the Emergency Services profile.** These were brought forward by Peter Park of the (US) Military Health System for discussion/inclusion in R2 and their consideration was expected to be completed by the end of June.
- **Diabetes Data Strategy** – as reported by the EHR Interoperability WG in section 14.3 below
- **Use Case Alignment with EHR System Functional Model R2** (derived from ONC/AHIC/HITSP Use Cases) – as reported by the EHR Interoperability WG in section 14.3 below.
- **Completed functional profiles**. The following are the EHR-S Functional Profiles that were completed and published some years ago:
  - Behavioural Health (Jim Kretz)
  - Child Health (Joy Kuhl, Andrew Spooner)
  - Clinical Research (Mitra Rocca), and
  - Long Term Care (Sue Mitchell).
- **Other functional profiles**, currently being progressed (but not elsewhere reported in Rio):
  - Dentistry (Mark Diehl, Pat Van Dyke)
  - Emergency Care (Steve Hufnagel, Peter Park)
  - Pharmacy/Pharmacist (Sue Thompson), and
  - Standalone Electronic Prescribing (Sue Thompson).
- **EHR WG specifications progressing through ISO/TC215 and JIC as international standards**

  The timetable for updating ISO 10781 (EHR-S FM) to align with HL7 ballots on R2, and whether there should or should not be an ISO CD (Committee Draft) ballot in parallel with initial HL7 ballots will be determined after the June SWAT meeting. The matter of how to progress this as a joint work item will need to be considered at the JIC.

  Development of an ISO NWIP for adoption of the PHR-S FM is understood to be at preliminary work item stage in ISO/TC215/WG8. The PHR WG co-chairs were tasked with building out a calendar of work and posting it on the EHR wiki.

  The proposal being promoted by the EHR Interoperability WG for a new international standard on "standards convergence for EHR interoperability" had not passed NP ballot as an international standard as originally proposed and is now to be re-balloted for progression to a technical report.

The EHR WG also addressed:

- **US Government work on EHR System Design Reference Model (EHR-SD RM)** also known as the Healthcare SOA Reference Architecture (H-SOA-RA) V 2.0. This was a joint meeting with the Government Projects WG at which the relationship of the H-SOA-RA to various HL7 architectural artefacts including SAIF and the EHR-S FM was discussed and the use of these approaches in the development of an immunization management application for use with USAF personnel was discussed. The material on the Immunization pilot is discussed in several other parts of this report and further information is available on:
  - EHR-SD RM (and H-SOA-RA) at http://hssp.wikispaces.com/Reference+Architecture, and
  - The presentation material and its application in the immunization case study: http://hssp.wikispaces.com/file/view/Constructing+a+Future+State+EHR+Reference+Architecture+20100515-H.ppt.
- **e-Health in Brazil** - see section 14.6 below.
- **Genomics in relation to EHR & PHR** – as a "birds of a feather" session led by John Ritter.

## 14.2 PROGRESSION OF EHR-S FM RELEASE 2

Originally, work on EHR-S FM R2 was being pushed for completion and ballot in March 2010 but this ambitions 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 as follows

| Date | Activities |
|---|---|
| 9-11 June 2010 | Face-to-face OOS working session in Chicago |
| 15 June | Review the proposed schedule. During the Work Group Conference Call, announce/Request all other components to be considered in R2 |
| 29 June | Word Format/Translation to XML discussion finalized |
| 1 August | Closing of new items for R2 consideration (bring in VR, Pharmacy, ISO documents, other |
| 15 August | Harmonization spreadsheet updated to include all profiles and new work outside of profiles |
| 30/31 August | Face to Face: Chicago |
| 28 September | Harmonization complete and approved by Work Group |
| 1-10 October | Restructuring of chapters |
| 24 October | Notice of Intent to ballot due |
| 31 October | Notice to HL7 of proposed content |
| 2 November | Word document finalized. Review done/voted on by Work Group. Moved to publications |
| 2 – 20 November | Publications cleans up documents |
| 21 November | Final content /documents to HL7 for ballot cycle. To include XML. |
| 24 November to 3 January 2011 | Ballot |
| 4-7 January 2011 | Publications amalgamate and circulate ballot comments |
| 8 January 2011 | Ballot reconciliation |

## 14.3 ACTIVITIES OF INTEROPERABILITY WG

Gary Dickinson reported on the following from the perspective of the EHR Interoperability WG:

- **Proposal to ISO TC215 to develop ISO 16223 – Standards convergence to promote EHR Interoperability**. At its May 2010 plenary Rio de Janeiro, Brazil (the previous week) ISO TC215 approved a Preliminary Work Item to develop and ballot a New Work Item Proposal for an ISO Technical Report on this topic. [ RDH: this revised approach of producing a technical report addresses Australian concerns about standardizing such a nebulous concept. The technical report will help align any further requirements for standards in this area.]
- **HL7 EHR-S Functional Model R2**. At the May 2009 HL7 WGM in Kyoto EHR WG agreed to incorporate the EHR Interoperability Model and the EHR Lifecycle Models into Release 2 of the EHR-S FM. The EHR Interoperability WG is monitoring the development of R2 in relation to the Kyoto decision and has posted the strategy for achieving this and proposed R2 Inserts onto the EHR Interoperability WG Wiki.
- **RM-ES Profile to EHRS FM R**2. EHR Interoperability WG is tracking work on incorporating the RM-ES Functional Profile into EHR-S FM R2, ensuring that the Action + Action Record paradigm is explicitly included in R2 as per the EHR Interoperability Model and EHR Lifecycle Model.
- **EHR Record Meta-Data**. Discussions are underway between RM-ES Project, EHR Interoperability WG and Structured Documents WG with the aim of aligning EHR record meta-data between the EHR Interoperability Model, the EHR Lifecycle Model, RM-ES Profile and CDA R3 and applying the RM-ES use cases to ensure that EHR-S FM R2 and CDA R3 metadata are compatible.
- **CDA Release 3**. Some 2 to 3 years ago an exercise was undertaken to map the requirements of the EHR Interoperability Model (EHR-IM) DSTU against the attributes of a HL7v3 CDA R2 document. CDA R2 was capable of being used in ways that supported most of the 54 specific requirements imposed by EHR-IM; however, 5 residual EHR/IM could not be addressed by the published CDA R2 standard but were deferred for further consideration in the development of CDA R3, which is now underway. The requirements are set out in documents available through the EHR Interoperability WG wiki.
    - Result of mapping EHR Interoperability Model requirements to CDA R2 Attributes, and
    - Reference profile for EHR Interoperability DSTU, published Feb 2008 (as detailed in the Implementation Guide for CDA R2).

  Specific proposals have been posted to the CDA R3 Wiki with activity focussed on potential incorporation of the material in v3 “Medical Records” messages. Calvin Beebe is the lead on this item for Structured Documents WG and Gary Dickinson is the EHR Interoperability lead.
- **Use case alignment**. A review of accepted HL7 use cases for is underway for alignment with EHR-S FM R2, with the aim of producing specific recommendations for their alignment with EHR-S FM R2 and associated EHR Interoperability requirements. The work is planned over several yeas: - in year 1, Biosurveillance, Consumer Empowerment, Lab Results Reporting; in year 2, Quality Reporting; and, in year 3: Remote Monitoring.

  Project leads - Gora Datta, Kim Salamone, Sherry Selover.
- **Paper/Electronic – Legal Record Continuity**. The aim of this work is to identify the legal characteristics of the paper record and show how their continuity in electronic form. Issues to be addressed include: continuity over the record lifespan, methods of replication for paper and electronic records and methods of content verification. Status: Gary Dickinson is preparing a draft of relevant material for a project.
- **HL7 SAIF**. The objective for EHR Interoperability WG is to contribute in its area of expertise to the Alpha project bringing the EHR-S FM and PHR-S FM into the HL7 Services-Aware Interoperability Framework (SAIF). This project is a collaborative effort by the TSC, ArB, EHR WG and EHR Interoperability WG. The EHR Interoperability WG proposes to develop an integration plan addressing appropriate requirements from the EHR-S FM, PHR-S FM, EHR Interoperability Model and the EHR Lifecycle Model – with a view to showing the relationship between actions and events in the real world and how these should be captured within EHR systems (via process services) and reflected in the EHR record (via record services).
- **Quality reporting to support ARRA 2011 requirements for “Meaningful Use”**. This project arises from the needs of the US EHR Incentive Program for quality and performance measurement and reporting. It is is proposed that an alignment analysis be used to show coverage and gaps between the ARRA EHR content requirements for quality reporting and the functions provided in

the EHR-S FM and PHR-S FM and the relevant requirements of the EHR Interoperability Model and the EHR Lifecycle Models. The next step is to review collect, capture, filter, analyse and report on the requirements for each proposed measure, then identify gaps in process and information that need to be addressed by relevant standards. Project leads - Kim Salamone and Gora Datta.

- **HL7 Diabetes Use Case**. 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. Current status: Use case templates and examples offered to Diabetes Team and discussed on several team calls. The next steps involve building out the use case scenarios, events and actions using the template and associating specific data (elements, templates) with each action. Project leads: Don Mon, PhD (EHR WG), Crystal Kallem (Clinical Interoperability Council), Pat Van Dyke (EHR WG) and Gary Dickinson (EHR Interoperability WG)

More information is available from the EHR Interoperability WG wiki at:
http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG

## 14.4 PUBLIC HEALTH EHR REVIEW

Under the leadership of Anna Orlova and the Public Health Data Standards Consortium (PHDSC), a major review is being undertaken by a PH-EHR Task Force to re-evaluate the HL7 EHR-S FM from various public health perspectives.

This follows an earlier review some 6 years ago, which led to a series of enhancements to the HL7 EHR-S FM and better engagement between HL7 and the public health community through activities such as their participation in the Public Health and Emergency Response (PHER) WG and the HL7/ONC/EHR Biosurveillance Use Case Alignment Project.

Public Health has also been involved in the national HIT standardization efforts through HITSP, IHE and other initiatives. Looking to the future, it is clear that the ARRA criteria for “Meaningful use of EHR-S” will lead to more extensive interaction with, and greater use of, public health information systems. Adoption of systems for public health applications such as immunization registries and disease surveillance will result in much greater emphasis on EHR systems and standards in public health, where any level of standardization would be a bonus.

The Task Force's work was supported by a contract between PHDSC and CDC/NCHS (National Center for Health Statistics) to *"Conduct re-evaluation of HL7 EHR-S FM Release 1.1 to identify necessary functionality for public health reporting and information sharing across clinical EHR-S and public health information systems"*. The recommendations made by the PHDSC Task Force include:

1. Incorporate revisions identified by the Task Force members into the HL7 EHR FM Release 2 ballot (primarily in the Direct Care chapter).
2. Add 16 new conformance criteria as extensions to the EHR-S FM.
3. Consider the development of a Public Health Functional Profile as a basic approach for identifying certification criteria for standards-based HIT products.
4. Work with HL7 EHR WG on defining a new specification entitled "Data Profile" as a supporting document to the Functional Profile that will define standardized data set(s) for information exchanges (for more on this see section 14.5 below – the recommendation raises many issues about data set compatibility and governance within HL7 and more widely).
5. Additional work is needed to better define the need for an independent HL7 Public Health Functional Model that will define functions for non-clinical data sources, e.g., environmental and socio-economic data.

   [RDH – this is also a controversial area. EHR WG is concerned at the prospect of having various groups working on different functional models that, over time, may duplicate, overlap or provide inconsistent interpretation of existing EHR-S FM functional requirements. Nevertheless, there appears to be a need and logical justification in the public health area and the approach being suggested by the Task Force seems to address the core needs while minimising problems].
6. Next steps (1). For 2010, continue current project working with HL7 EHR Working Group on the comment reconciliation for the EHR-S FM Release 2 ballot

7. Next steps (2). In 2010-2011, conduct a pilot project in collaboration with HL7 EHR WG and PHER WG to develop a methodology for using Functional Profiles and Data Profiles to establish certification criteria for standards-based HIT products.
8. Next steps (3). Work with Early Hearing Detection and Intervention program on defining an approach for setting certification criteria with support from CDC.

For more information see:

- PHDSC web-site: http://www.phdsc.org/health_info/ehr-task-force.asp, and
- PHDSC project wiki: http://wiki.phdsc.org/index.php/EHR-PH_Project2010 PHDSC EHR-PH Task Force.

## 14.5 PROPOSED PROJECT ON DATA PROFILES

Based on work with key US Government agencies, a group including Dr Steve Hufnagel is proposing that EHR WG start work on the development of data profiles to complement the functional profiles used for certification against the EHR-S FM.

This is a controversial proposal for EHR WG that, if accepted, would take the WG into the area of defining EHR content – traditionally the role of domain groups within HL7 and ISO and potentially at odds with more structured approaches such as ISO13606, openEHR and HL7v3.

Nevertheless, the need for rigorous requirements on information content (i.e. data profiles) in areas like public health to accompany the existing functional models has strong support from some US Government agencies and many other users of HL7 standards. As an organisation, HL7 has struggled with notions of "minimum data sets" and "clinical data elements" but now needs to have a strategy for addressing the needs for data profiles arising from the ARRA (HITECH) initiative if it is to retain its relevance. Key questions for HL7 are not whether it supports "data profiles" but, rather:

1. Whether it takes a leadership role in defining, governing and managing the content of the many data sets themselves (or just the structures) – and, if so:
   (a) Whether it does so on its own, or in collaboration with other SDOs, professional and regulatory bodies?
   (b) Whether EHR WG is the appropriate place within HL7 for this function to be managed?
2. If not, whether HL7 actively seeks to recognise, collaborates with and/or works with other groups (having the responsibilities in relevant realm) to perform these functions,

To progress the work, Dr Hufnagel has volunteered to do the scope statement for the project. He has suggested deriving a data model from the EHR-S FM and then building on the data model to create a profile in the form of an information model with specific data elements. Issues discussed included:

- How does this vary from the RIM? A: It is proposed as another level of fidelity. The RIM is a higher level of abstraction. It can be compared with the approach already used with CCD where there are data modules and then data elements associated with the modules.
- The conceptual data model would be at the EHRS-FM level and the profiles would be based on the information model derived for each use case interaction – but also having the higher level connections that maintain context.
- The use cases will include actions that relate to the FM but Dr Hufnagel proposes this as a self standing model---not integrated into the FM. The development of a prototype is proposed to investigate the extent to which it stands alone or is integrated into the FM.
- It was suggested that a small number of people would pre-populate the model from what HITSP has already done within its published data architecture.

For an idea of how Dr Hufnagel may see these models coming together, refer to the following references previously cited in relation to the joint session with (US) Government Projects:

- EHR-SD RM (and H-SOA-RA) at http://hssp.wikispaces.com/Reference+Architecture
- Application in an immunization case study: http://hssp.wikispaces.com/file/view/Constructing+a+Future+State+EHR+Reference+Architecture+20100515-H.ppt

It is important that HL7 has a strategy and approaches for meeting such needs in ways that are compatible with its other products and necessary national and local variations in the resulting data profiles.

**Action: IT-014-09 to carefully review proposed scope of HL7 EHR project on data profiles with a view to commenting on overlaps with work on other HL7 information artefacts, ISO18308, ISO 13606, open EHR and national reporting regimes in Australia.**

## 14.6 E-HEALTH IN BRAZIL

Jussara Macedo Pinho Rötsch, National Coordinator of the Subcommittee for Standards and Interoperability, provided a presentation on e-health in Brazil in which the following were discussed.

The Brazilian health system has been through a decade of significant improvements but still faces a range of problems in its: - inability to record clinical information and share health information or notifications across provider enterprises; over-utilization of health diagnostic and testing services (largely due to missing data); inaccurate information for reimbursement and an inability to use health data for decision support, clinical research

While there level of adoption of EHR (clinical information systems and ICT standards is still low, the Government is aware that many problems can be solved or improved by more effective health IT infrastructure. So, since 2007, Brazilian experts have been participating of SDO meetings, to (among other things) observe other national e-health programs, which have aimed to address similar problems to those being faced by Brazil. They observed the following lessons learned:

- There is a high cost in adopting multiple standards that were not designed as a coherent whole.
- There is a high cost in standards that do not allow modeling of clinical content, process and terminology independently of the particular deployment technology (e.g. messaging).

Brazil is therefore adopting an approach based on the concept of a single self-consistent base of specifications, including information models, service models and content models, in other words, an e-health knowledge platform, the components of which are:

1. service models, which can be deployed in a service-oriented architecture environment, including: information, knowledge, event/ notification, health resource, business workflow, auditing and messaging services
2. standard information models to enable physical communication of identity, demographic, EHR and all related administrative and clinical information
3. a knowledge modeling approach delivering formal models of health information content
4. standardized approach to terminology – encompassing both international and local Brazilian terminologies for clinical and administrative use – with a common maintenance architecture supporting the creation, management and deployment of terminology Refsets
5. an openly specified query methodology and language that is independent of physical database schemas

6 information privacy model, and

7. security facilities, including user authentication and authorization and auditing.

Specific standards and technologies selected for these purposes include:

- openEHR information model, knowledge models including archetypes (ISO 13606-2), templates, and methodology for knowledge model management,
- openEHR service models for EHR, vEHR
- IHE specifications for PIX, PDQ and HL7/OMG EIS
- HL7/OMG CTS 2 terminology service specification for terminology services architecture
- Specific terminologies (for today) include: WHO ICD-x and WONCA (including ICPC), HL7 LOINC, Brazilian terminologies and vocabularies (including those maintained by ANS, ANVISA, professional associations and others for clinical and reimbursement purposes), and
- For the future - IHTSDO terminologies and tools, including SNOMED CT.

At the centre of the approach is a knowledge enterprise bus that will enable integration and secure sharing of health information and notifications within the enterprise, between health provider

enterprises, and from enterprises to other agencies including jurisdictional data centres and private health plans. The design of the knowledge bus has the following features:

- The content and workflows it handles will be defined by archetypes, templates and other knowledge models, along with terminology.
- Capable of generating messages and EHR Extracts based on templates and archetypes.
- Within the enterprise, will include services for identity, EHR, demographics, and notifications.

# 15 IMPLEMENTATION/CONFORMANCE (IC)

The Implementation/Conformance (IC) Work Group has been grappling for some time with the difficulties of how to achieve an integrated approach to conformance across all HL7 standards. A proposal was developed and put to the Technical Steering Committee (TSC) that recommends all new projects have a conformance plan section and a conformance/implementation facilitator.

If the proposal is accepted by TSC there will need to be an implementation/conformance facilitators outreach meeting at future WGMs; however, there is little enthusiasm for the concept from the Foundation and Technology Steering Division (FTSD).

The following are among matters reviewed and discussed by the IC WG;

- **Editing of v2.7 (chapter 2B)**. General concern was expressed at the poor rate of progress in editing this material to reflect previous agreed actions and this, as well as backwards compatibility issues, was holding up publication of this standard. The main issue appears to be lack of volunteer time and with the reduction that has occurred in personnel at NIST they have not been able to provide the usual level of support.

  The XPN datatype and possible technical correction in v2.7 are being discussed with InM.
- **v2.8 proposals**. No updates were presented and no progress made.
- **Common template and style guide for HL7 implementation guides**. Rob Snelick (NIST) introduced a proposed project aimed at providing definitive guidance on how to write implementation guides. His proposal reflects the fact that many HL7 implementation guides are being written in HL7 and by IHE, CDC, NCI and other organizations. Each has their own style, terminology and interpretation of conformance - restricting the potential to facilitate their production and interpretation by the use of tooling (such as MWB or tools from the UK NHS or the NIST testing infrastructure project) in. Specific points to be addressed in the project proposal include:

  1. Implementation guides should be based on a template (common style).
  2. Explicit conformance requirements need to be embedded directly into the specification or as a supplement in ways that can be automatically processed (i.e. pulled out) by tooling.
  3. Need to standardize on a common format to allow for the automated tooling. This way any tool could be used to extract the conformance requirements.
  4. Need to standardize structure and content of the conformance section so the conformance is interpreted in the same way across implementation guides.
  5. Various conformance requirements and validation processes need to be explicitly stated.

  If approved, the approach would be piloted for v2 with application to other standards to follow. The next step is to prepare a formal project proposal to be submitted for approval as an HL7 project (which will be done by Rob Snelick).
- **RCnL: new conformance codes for sender/receiver** - this issue was tabled for the next meeting (as Lloyd Mackenzie was unable to be present to discuss the topic).

## 15.1 CONFORMANCE AND "MEANINGFUL USE" – ROLE OF NIST

As part of the Obama recovery program (ARRA), NIST (National Institute of Standards and Technology) has been tasked with developing Conformance, Compliance and Accreditation (CCA) testing infrastructure and tools to enable testing for “Meaningful Use” to support incentive payments to health care providers that make meaningful use of EHR technology as defined within the ARRA (HITECH) legislation.

Requirements for “Meaningful Use” will be progressively ramped up in 2011, 2013 and 2015. For 2011 most requirements will simply be inspection testing with more rigorous criteria to apply from 2013.

NIST put forward their intentions for testing HL7v2.5 messaging for both ambulatory and inpatient care. Their criteria leverage existing HL7 compliance criteria but define a more comprehensive conformity assessment scheme with no optionality in HL7v2 segments. Requirements for CDAr2 use will be constrained to “receive and render” for 2011 with future criteria extending to “persist and parse”. It was felt that true Meaningful Use cannot be determined without use of structured text but there are significant issues in requiring RIM-based structure to be mandatory by 2011.

Specific profiles are developed for meaningful use testing; however, given the simple criteria in the IFR (Interim Final Rule) derivation of conformance requirements from these criteria has proven problematic for NIST. This aspect is elaborated further in section 15.2 below.

NIST is to develop the testing process, build development testing tools and produce interoperability testing tools. These developments will be made available in the public domain. Whilst funding for this infrastructure was provided last year and RFP’s have been issued these are still in National Contracts office almost one year later due to administrative issues. Up to $US5 million per year is to be spent over the next five years to a total of $US22 million.

NIST’s concept of operation is an integrated portal for all testing including V2, V3, XDS and DICOM integrated under a single web service paradigm which can be accessed by other agencies and potential international communities. It will include validation services, as well as automated generation of messages/documents with test data. NIST will also provide “test agents” (simulators) to provide actors to interact with the system under test with a test harness controlling execution of the test.

Test case management especially versioning is proving difficult. There will be a sophisticated test case management system (for HL7 V2 initially) which will be integrated via a scenario manager. Another group within NIST is developing a test case development tool whose XML output can be input to the test engine.

Initially NIST will concentrate on isolated system testing (to support IHE pre-Connectathon testing) and will use IHE Connectathons for peer to peer testing.

Value set content testing will be provided against standards based value sets but also against scenario required values (usually a constraint on the standards based value set).

NIST already supports an implementation of the IHE patient identity manager (PIX/PDQ) which implements five actors from the Profile.

The Office of the National Coordinator (ONC) has significantly revised its approach to accreditation. The previous roles of HITSP and CCHIT have been eliminated. In the short term ONC will appoint accredited testing laboratories and certification organizations but in the long term there will be formal accreditation of testing labs and accreditation organizations. The US Department of Health and Human Services will maintain a list of accredited products online.

Further information on testing procedures and methodology (current and proposed) can be obtained from:

- www.healthcare.nist.gov/testing_infrastructure
- www.healthcare.nist.gov/use_testing

RFPs for building the infrastructure will be released on www.fbo.gov (fedbizops) but will be restricted to US companies.

There is clearly an opportunity for Australian eHealth programs to leverage these capabilities and adapt them to local needs.

**Action: Australian eHealth programs should consider partnering with NIST in developing test tools rather doing so independently.**

## 15.2 MEANINGFUL USE TEST PROFILES

The difficulty of interpreting the meaningful use criteria in the IFR for use in developing test profiles for certification of a product to meet was discussed. This role is undertaken by NIST under its commission to develop test methods to ensure that vendor products are sufficient to allow "meaningful use" within the meaning of the legislation.

With respect to HL7, the IFR stipulates 5 criteria which require use of HL7 but they are very general and do not include compliance with implementation guides. For V2 messaging it is using either V2.3 or V2.5.1. Where a given vocabulary is required it is stated. On the V2 side they have a set of test data eg: for immunisation. NIST are seeking feedback on whether they are representative set of test data. NIST have established what an expected result should be and the checking process is about confirming that required data elements are populated. For example a CDX code is required for immunisation and other areas.

They are preparing an abbreviated profile for meaningful use. Requirements can also be included in the test data. Requirements are ranked:

- Required absolutely
- Required – implied intent, and
- Certification bodies - you should be sending this to create a conformant message.

The V2 model for vocab is tables of enumerated values.

There is nothing likely to be measured by the Meaningful Use using V3 and there is no CDA R3 at the moment, the V3 vocabulary model is a very different beast.

Identification of which code set goes with which field in which transaction artefact and making sure they are all appropriately enumerated and providing this to industry to support implementation and conformance testing.

Checking includes confirming that value sets are appropriately populated. Eg: if you are sending some SNOMED CT codes for specimen types you can populate these in table 70 specimen type and the code system is HL70070 or you can populated the code as SNOMED CT. In CE data types – everything is optional. In meaningful use you have to use items 1 and 3.

Vocabulary also discussed this issue with respect to vocabulary conformance and gave NIST guidance on the vocabulary requirements for conformance, particularly in the use of code system specifications and data types.

## 15.3 JOINT MEETING WITH ARB

### 15.3.1 IMPLEMENTATION AND CONFORMANCE

The Conformance/Compliance elements of SAIF are specified in the Enterprise Conformance Compliance Framework (ECCF) document. At the meeting, the ArB asked IC WG to take charge of developing the HL7 ECCF implementation guide that specifies how to populate the ECCF matrix in support of business, static, dynamic, and deployment viewpoints. Key requirements will cover content, representation and placement.

The National Cancer Institute (NCI) and USA DoD have each done an implementation guide for their domains. The DoD document is available in draft from the SOA wiki and the NCI work was expected to be released a few weeks after the WGM.

It was noted that commencement of this work will only be possible once the SAIF and ECCF has passed ballot which it is hoped will be at the next WGM. An HL7 ECCF implementation guide will need to deal with the requirement for conformance at different levels from abstract model to platform specific implementation (required for “plug and play”).

The ECCF vocabulary is compliant with IS0 17000 and this will need to be maintained in an implementation guide.

Comments on the latest ECCF which was released the week before the Rio WGM (available from the HL7 ArB website) should be forwarded to the ArB by the next WGM.

There was also general concern that the ECCF (the conformance section of SAIF) was not receiving sufficiently wide review due to lack of understating of SAIF and time pressures.

## 15.4 JOINT MEETING WITH VOCABULARY

The joint meeting of IC and Vocabulary covered a range of topics, including:

- **Identification of terminology set/version**.

  The issue as to how a terminology set and specific version should be referenced in standards and conformance testing tools received considerable discussion. The consensus was that a random OID (from a nominated root) should be assigned to each revision of a terminology set. A separate table would need to be added to the standard, listing the versions of terminology sets and tables and their associated OIDs.

- **ISO work item on terminology conformance measurement**

  A presentation was given on the ISO work item on terminology conformance measurement, which has an intended audience of decision makers and administrators. This work was seen to be useful and that there is a need to harmonize with HL7 activity. The draft will be circulated to both the Vocabulary and Implementation/Conformance working group lists along with an ISO comment form when it is available. Comments will be incorporated into the ISO process.

- **Syntax for Vocabulary Binding (in Implementation Guides)** – as discussed in section 15.5 below.

- **Refinement Constraints and Localization (RCnL)**. Beverly Knight will provide the first wording for a new section on terminology usage to be added to the RCnL document.

## 15.5 SYNTAX FOR VOCABULARY BINDING IN IMPLEMENTATION GUIDES

A new scope statement is to be developed to specify the syntax for representing vocabulary bindings in implementation guides. This work item is to be led by Implementation/ Conformance (primary sponsor), Vocabulary (co-sponsor) with other interested parties including Structured Documents and MnM.

Currently, implementation guides have to provide some kind of binding of the static model to the vocabulary used. As there is no exact guidance how it should be specified, different implementation guides differ on that point.

The intent of the project is to specify a human readable syntax which covers all necessary information and provides a universal way to specify it. All (future) implementation guides are to follow the specifications laid out in this guide.

The current normative section will be revised and additional material added.

Project intent – The intent of this work is to provide guidance for associating value sets, (implementable terminology) to v2 coded elements and data type properties, defining syntax and style for representation in implementation guides to define vocabulary conformance. This work is to align with Core Principles work and assist implementation of the concepts expressed in that document.

The section will be informative and will be added to the "refinement and localization" section of the ballot. Remaining tasks include:

- Project scope statement to be revisited and changed to reflect comments received
- Project scope statement to be sent back to steering division
- Project participants to schedule calls to draft an outline
- Leverage existing material and enhance where needed
- Conference calls to prepare draft for discussion at Sep 2010 WGM, and
- Targeting ballot for Jan or May.

# 16 IMPLEMENTATION TECHNOLOGY SPECIFICATIONS (ITS)

The ITS workgroup is currently considering a series of proposals that have arisen out of v3 implementation experience. The intention of these proposals is to change the technical basis of v3 specifications to make implementation easier and more palatable to a wider set of stakeholders. Some

of the proposals represent only minimal change, and are now close to completion, while others are still only ideas under discussion.

## 16.1 ITS R2

The first of these proposals is known as ITS R2. This is a pair of documents, one known as "ITS R2 structures", and the other is "ITS R2 data types" (but is more widely known outside HL7 as ISO 21090, "Healthcare data types"). These documents are paired together. At the most fundamental level the aim of these specifications is to "UMLise" the specifications, document all the things that are not documented in the previous R1 specifications, and change the form of the XML to make it much more regular and amenable to computerised tooling.

After about a year in final production, ISO 21090 is about to go to ISO/FDIS ballot through ISO TC215, but is effectively closed for further changes. ITS R2 was undergoing final ballot resolution at this meeting. A necessary consequence of the changes in R2 is that the specification is not backwards compatible. This is highly unwelcome to a subset of HL7 stakeholders; either they do not use implementation approaches where such UML-centric design is relevant, or they have paid the price of the existing implementations. This issue was discussed during the Monday session. It was raised that in most areas HL7 emphasis has always been to ensure backwards compatibility, although it was noted that sometimes "breaking" change is necessary.

This issue had already been discussed and resolved under previous normative ballot the Co-Chairs determined the comment to be non-persuasive.

## 16.2 ITS R1.1

In order to accommodate users who wish to adopt the new semantics of R2 without having to deal with the revised technical approach, the ITS WG also published R1.1 (both structures and data types). These have been finalised and published as informative specifications, and may be used by trading partner agreement (including in CDA R2, where some of the features are starting to be used).

## 16.3 NEW ITS APPROACHES

The existing XML structures in ITS (both R1 and R2 versions) are an uncomfortable compromise between a regular XML form in which all structures are represented in the same way, and one in which enough information is present to allow XML Schemas to validate that the models conform to the rules in the detailed models (RMIMs etc). This is an uncomfortable compromise for several reasons:

- The structures are regular, but not the same. While they are obviously alike, they have different schemas, and XML serialization engines must treat them all differently (actually, few organisations have the skill base to modify the behaviour of the XML engines, though it can be done for a few of them).
- The structures are not sufficiently differentiated by the RMIMs to be usefully more specific.
- The validation is still far from complete. More complete validation services are available (Eclipse Instance Editor, Alschuler Associates, and the NIST validation service), and these provide far more useful validation.
- Validation is not very useful in production anyway.

As a consequence, the existing XML ITS has been a source of contention – it makes everyone equally unhappy. There are really two kinds of users:

1. The kind of user that writes v3/CDA 1 or 2 interfaces. These people are ill-served by the current XML ITS: they must encounter something that it represents consistency they are not interested in, and they must pay the price of the complexity it brings - but for no benefit to themselves.
2. The kind of user that maintains many interfaces – perhaps hundreds. Usually they have many trading partners. These users want consistency, but don't get enough of it from the XML ITS. They are prepared to invest in infrastructure in order to leverage v3/CDA.

There is growing interest in HL7 in pursuing a split solution to this problem instead of the existing one size fits all approach. For the first users, the ITS workgroup would like a new approach to XML that generates specific XML that is simple and easy to use – this is known variously as "µITS" or "Green CDA". For the second set of users, the ITS workgroup is preparing a direct RIM serialization

specification. As it is possible to transform between the two approaches, both parties should be much more able to implement V3.

The RIM ITS is the easier to bring forwards, as it involves the lesser amount of work. The draft specification underwent first ballot prior to the WGM, and ballot reconciliation was done on Tuesday. While it passed ballot, a number of necessary substantiative changes were made, and the specification will be reballoted again in the next cycle, where it is expected to pass.

While the Green CDA/µITS work has attracted a great deal of interest, including by some significant industry figures, it is still early days; there is no clear agreement about how specific a context is required before this approach becomes useful – while still representing a manageable amount of work by a (necessary, apparently) knowledgeable HL7 analyst, and representing an improvement in value for money without HL7 becoming a software solutions developer, a task for which it is not well suited.

A related and possibly useful approach in this space is Robert Worden's work relating to an agreed specification for a mapping grammar, though this may end up being more suitable for a platform SDO such as OMG in the long term.

Note that this split approach is conceptually equivalent to that currently being taken by openEHR, with a single general serialization for archetyped data, and the use of templates to produce specific XML forms for particular uses. HL7 may wish to be informed by the openEHR approach – but it would fall to Australia to bring this forward.

NEHTA is following all these changes on behalf of Australia with keen interest and noted that:

- The discussion is effectively about the completeness of RIM and the RIM ITS in supporting all possible exchanges of static and dynamic health models.
- The proposals now being considered, in effect, create a new distributed healthcare language and object runtime; a complex task already provided by many existing distributed object environments. [Which raises the question - why duplicate?]

# 17 MODELLING AND METHODOLOGY (MNM)

MnM had a quiet meeting with some key contributors being absent.

On Monday and Tuesday MnM was primarily undertaking ballot reconciliation, mostly in regards to the MIF (Model Interchange Format) 2.1. Some key points discussed included:

- There are over 30 complex types for describing annotations and there is a need to have some sequence and order to each annotation. As such it was discussed that a future MIF release will incorporate the XML Schema 2.0 standard to better handle these structures.
- At present any enumeration change requires a new MIF release. To counter this, enumerations will be split into 2 sets, one to be managed in the MIF and the other more volatile set to be handled through HL7 Vocabulary Harmonisation and published in their releases.
- The issue was raised that if the MIF is to be a metamodel it should contain a metamodel. It was discussed that all previous attempts to develop a metamodel had failed as the underlying structures are still in a state of flux leading to continual rework in maintaining both logical and physical models. Nevetheless, it was agreed that once the components of the MIF are more static then it may be a valid activity to develop both physical and logical models if the resourcing exists.
- MnM also considered some questions driven by RIM-based application architectures, specifically in relation to how RIM models may be queried – what attributes and associations are safe to ignore. This work will ultimately meet other work in Clinical Decision Support, on vMR, and in the eMeasure specification – potentially leading HL7 onto a new path towards a meta-language for clinical query and rule making, but much water must pass under the bridge first.

# 18 PATIENT ADMINISTRATION

Work in the Patient Administration domain is currently being heavily influenced by needs and activity in Australia, Canada and The Netherlands in the areas of patient/client and provider registries. The group is looking at mapping the Australian service model for the Health And Community Services Directory to the relevant HL7 DMIM.

# 19 PATIENT CARE (PC)

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. It was the original sponsor of the Community Based Collaborative Care (CBCC) Work Group which was formed at the request of Australia in response to Standards Australia's and HL7 Australia's gap analysis. 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 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.

Although the bulk of the current message development work is in Version 3, the analyses, use cases, methodologies and representations developed, together with the Detailed Clinical Model Project, are of importance regardless of the implementations used in different messaging, document and health record applications and their deployments across the world.

In the Version 3 Ballots, Care Provision is a major topic, with standards being Draft Standards for Trial Use (DSTU) and other ballot sections being informative.

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

In association with HL7 HQ we recently reviewed all of our work, identifying specific projects and clarifying their stages of development and timelines. This was important given the extent of our work, the resources required and member expectations. Projects were then classified according to their development status and mapped to a three year plan. It will now be much easier for us all to have a clear picture of the projects, especially those with which we may not be directly involved.

There was no ballot item produced by PC WG at the Rio meeting, with the time being used to discuss a number of topics that may shape the direction and activities of the work group.

Elections were held and Dr Stephen Chu of Australia was elected to the co-chair position vacated by Kevin Coonan from the USA. Klaus Veil of Australia is also a co-chair but was not allocated funding to attend the meeting. With 2 co-chairs from Australia, one from The Netherlands and one from UK this is now a totally internationally-chaired WG. The international nature of the WG was also illustrated by the attendance being essentially as strong as when meetings are held in the US which is not the case for many other WGs.

## 19.1 ALLERGY & INTOLERANCE AND ADVERSE REACTION TOPICS

The Allergy/Intolerance and the Adverse Reaction (Informative) topics within v3 Care Provision are still work in progress, but in the future they will be combined under a new project, to be scoped as a type of *Condition*.

The "Allergy & Intolerance" topic has been in Draft Standard for Trial Use (DSTU) R2 status since September 2009. PC WG plans to seek extension approval on its DSTU status after the Rio meeting (likely to be in June 2010), with plan to go for normative ballot in September 2012. The content of this topic (i.e. static and dynamic models, use cases, storyboards, etc) will need to be reviewed for any required updates prior to initiating normative ballot.

The "Adverse Reaction" topic has been in informative draft since 2007. The plan is to take it to DSTU ballot. This will require a new project scope and investigation of harmonization requirements with Patient Safety and Pharmacy Workgroups.

Definitions of the concepts "Allergy & Intolerance" and "Adverse Reaction" also need to be reviewed.

These topics have high relevance to NEHTA clinical data group requirements. Active engagement and contributions from Australia are essential. The potential interest of HL7 Australia, IT-014, IT-014-02,

IT-014-06-06 and IHE Australia were all noted and Australian involvement should also be coordinated with the activities on related functional topics at ISO – being led by Heather Grain, Nicholas Oughtbridge and Rikard Lovstrom.

**Action: Stephen Chu, David Rowed and Heather Grain to review proposed HL7 work on the Allergy/ Intolerance and Adverse Reaction topics and make recommendations to IT-014, its subcommittees and HL7 Australia on how all Australian interests should be informed of, engaged in and encouraged to participate in this work.**

## 19.2 HEALTH CONCERN TOPIC AND PROBLEM/DIAGNOSIS

The Health Concern topic covers all communications related to health concerns (eg problems) for a particular patient and includes EHR request updates, queries etc. The topic has been in DSTU status since September 2009. The contents of this topic now need to be reviewed and approval sought for and extension of the DSTU while material is prepared for normative ballot. The plan is to advance this topic to normative ballot in September 2012.

Work that commenced on modelling of Problem and Diagnosis will be incorporated into this project and will need to be reviewed to determine how the models may be integrated into the "health concern" topic.

OpenEHR is currently developing archetypes for Problem and Diagnosis and PC WG will attempt harmonisation with that work. Again potential underpinning definitional incompatibilities are already apparent here and these need to be addressed up-front.

"Concern Tracking" is currently modelled as a separate Care Structure CMET and is at DSTU stage until next year when it is anticipated it will, after reconciliation, become a major topic in its own right, for re-ballot -- hopefully normative

Australian delegates David Rowed and Stephen Chu suggest that definitions of these concepts should also be reviewed. The need for better concept definitions has caused difficulties in this work and has been a key driver for the Patient Care Glossary project.

As with allergies, intolerance and adverse reactions (discussed in section 19.1 above) these topics also have high relevance to NEHTA clinical data group requirements and have similar needs for coordination with other IT-014 and ISO activities.

**Action: Stephen Chu, David Rowed and Heather Grain to review proposed HL7 work on the Health Concern topic, Problem/Diagnosis and Concern Tracking and make recommendations to IT-014, its subcommittees and HL7 Australia on how all Australian interests should be informed of, engaged in and encouraged to participate in this work.**

## 19.3 CARE PLAN TOPIC

PC WG is now concentrating on completing the drafting of the Care Plan topic ready for ballot. This is an extensive and difficult area of clinical representation and communication, building on previous more compartmentalised work by PC WG.

The Care Plan project covers active patient-focussed condition management by collaborating care providers and includes care coordination, goal setting and monitoring, and condition tracking together with documentation of unmet goals.

The PC WG Care Plan documentation has been in draft form since 2007. It had little attention until the January 2010 WGM in Phoenix when work recommenced and it has been ongoing via teleconferences since that meeting. Experts from Australia, Canada, US and Netherlands will continue the work over coming months with the aim of going to DSTU ballot in the September 2011 cycle and then normative in September 2013.

The activity has strong support from Australian members given its importance in collaborative care communications and referral. It has particular relevance to Australia in primary care and allied health where the HIC is funding team-based care planning processes via the MBS. IHE Australia is also working on Care Plan profiles and document exchange.

PC WG also reviewed the IHE approach to care planning which is more focussed around the process for document exchange than the detailed modelling of the Care Plan content - which is what Patient Care needs.

Dr David Rowed has agreed to produce Primary Care use cases for Care Planning and other PC WG members will develop Nursing use cases. It is hoped to combine this work with the Chronic Disease Management Profile currently being developed by IHE Australia (led by Jon Hilton) in conjunction with IHE International.

Given Australia's interests and experience in collaborative care and collaborative care standards, NEHTA, the states/territories, health professional organisations, IHE Australia, IT-014 (particularly IT-014-06-06) and other groups working on collaborative care, CDA, and discharge referral should be strongly encouraged to commit resources and become involved with this Care Plan work which needs a lead in Australia.

**Action: Stephen Chu, David Rowed and IT-014-0-06 to make recommendations to IT-014, its subcommittees, HL7 Australia and IHE Australia on how the wide range of Australian interests should be informed of, engaged in and encouraged to participate in the HL7 Care Plan project work.**

## 19.4 CARE STATEMENT TOPIC AND CLINICAL STATEMENT PATTERN (CSP)

The Care Statement topic has been the core part of the Care Provision DSTU R1 since 2007. It is the original “Clinical Statement” component of the Care Provision Domain, and provided the basis of what has since become the “clinical statement pattern” (CSP). Since then, CSP has undergone several iterations of change and, as a minimum, the content of the Care Statement topic needs to be reviewed and made consistent with CSP and structures defined for the emerging "Health Concern" topic.

Given that CSP now exists, the need for Care Statement to continue as a separate artefact is being seriously questioned in light of the capabilities of the Clinical Statement artefact. The counter-argument is that Care Statement is controlled by PC WG, has a broader scope and is more closely tailored to Care Provision requirements (without any compromise to address the needs of Structured Documents and/or O&O); however, such an argument runs contrary to the rationale for the CSP.

If retained as a separate artefact, the Care Statement topic would need to go to normative ballot by 2011 and the current project schedule is geared to ensuring that this deadline can be met. PC WG has agreed to work on these issues in association with the CS WG with the aim of resolving them for final decisions at the next WGM in September 2010

A joint session of the PC and CS WGs at the WGM considered these questions and decided to review the purpose of the Clinical Statement Pattern (CSP) but not its definition and revise CSP models. These revisions will make the CSP simpler while allowing users to add complexity when needed; that is, the CSP won’t be a “maximal” pattern/design.

The CSP is important because it attempts to standardise the expression of clinical content across both CDA and messaging/communication implementations. Australian interests were instrumental in the establishment of a separate shared Clinical Statement stream and would traditionally support a stronger role for CSP going forward (in preference to separate models in each domain/technology).

The definition is not changing as it would be too hard at this stage to precisely define any lower level of detail for the CSP. The CSP model will be the definition of the detail. Simplification will partly come from disallowing more than one depth/order of participation except where it is always needed. The question of at stubs vs. incomplete models, and analogies to CMETS will also be revisited.

Work on the Care Statement topic and CSP has high relevance to NEHTA clinical data group requirements and active engagement and contributions from Australia are considered essential. Like Health Concern, Allergy/Intolerance and Adverse reaction, there is a need for Australian input to be coordinated with other IT-014 and ISO activities.

**Action: Stephen Chu, David Rowed and Heather Grain to review and consult with Australian stakeholders about the preferred Australian position on the purposes and direction of work on the Care Statement topic and Clinical Statement Pattern (and related CDA classes) and make recommendations to IT-014, its subcommittees and HL7 Australia on how Australian interests should be informed of, engaged in and encouraged to participate in this work, where relevant.**

## 19.5 CLINICAL DOCUMENT TOPIC

The Clinical Document topic was discussed in joint session of PC WG and Structured Documents WG, which has overall responsibility within HL7 for Clinical Document Architecture (CDA).

The Clinical Document topic provides a set of transactions that allow for the capture and maintenance of simple CDA documents used for referrals, discharge or care summaries and textual observations such as family history, social history, etc.

It proposes an architecture where discrete data (coded observations, conditions, allergies, medications, etc.) are captured and maintained via transaction-based messages independently of the CDA documents, thereby limiting the content, role, function and utility of CDA documents.

The Clinical Document topic was created to meet Canadian requirements to send CDA documents in Care Provision messages that support referral, discharge, etc but there is significant confusion about the different roles of CDA documents and Clinical Document transactions.

Patient Care WG voted to remove the Clinical Document topic from the current ballot and send it back to Canada for clarification of scope and purposes. A new topic/project proposal will need to be created if Canada after revaluation decides that this topic is required.

## 19.6 DETAILED CLINICAL MODEL (DCM)

Discussion of progress with DCM was held in joint session with Orders & Observation (OO), and addressed the following different aspects of the work:

- ISO 13972 project on DCM quality requirements – William Goossen reported that the modelling part of the proposed standard attracted serious criticisms at ISO/TC 215 and hence had been removed from the project for the present. The work is now proceeding with a focus on defining a quality matrix and criteria for the processes of capturing, representing, storing, transforming and managing DCMs independent of implementation technology or architecture.
- DCM for medical device project – aims at developing DCMs for clinical data coming out of medical devices. This project has been approved by the Patient Care and Medical Devices WGs.

  The work involves creation of Domain Analysis Model (DAM) for DCM and DAM for clinical data generated by medical devices. The DAMs will be used to guide the DCM development. The Netherlands use Sparx Enterprise Architect (EA) to create UML diagrams of DCM which are then converted to XML.

With respect to other ongoing activity in HL7 on DCM (notably the DCM pilot projects), it was suggested that (a) project proposal on DCM work should be created for a joint HL7/ISO activity and submitted for vetting by JIC (Joint Initiative Council); and (b) (Orders & Observations) OO should investigate how a platform independent DCM can/should be transformed into HL7 templates for use, e.g. with Clinical Statement.

OO has expressed a need to review and comment on DCMs that are developed.

The HL7 project is being re-scoped by PC WG in preparation for informative ballot. The importance and risks of PC undertaking this project have previously been reported, particularly noting its significance in relation to the ISO work, the lack of both tooling and the need for much greater clinician understanding, and involvement in authoring, review, and broad acceptance. This has been evidenced by the unacceptably slow (by order of magnitude - less than 20 concepts after several years) rate of production of instance models. The separation of work between ISO and HL7 has been reviewed in both SDOs with HL7 supposedly being more focussed on instances and ISO on DCM quality.

There are a range of DCM projects at various formative stages within HL7. Australian experts are currently involved in DCM work at ISO but there is also a need for wider local engagement and consideration of proposed DCM activity at HL7 PC WG to ensure that its scopemeets 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 engage more widely on DCM work and actively contribute to PC WG discussions on development of DCMs in HL7.**

## 19.7 HL7 VERSION 2 IN CLINICAL COMMUNICATIONS

This remains a key area for Australia where HL7 Version 2 (v2) is used as the standard for referral including discharge referral and is the currently implementable form of collaborative care communications as laid out in AS 4700 Implementation Guides managed by IT-014-06-06. As a consequence, Australia has taken the lead internationally on the development of v2 messages for clinical communications, working via PC and CBCC WGs in HL7. Much resource has gone into this from Standards Australia, DOHA, GPCG, and state jurisdictions.

To progress this work internationally, Australian representatives proposed defining a formal HL7 project for approval by PC WG and the TSC – with leads from IT-014-06-06 and HL7 Australia. The proposal is still in draft but the prime requirement is the ongoing support and maintenance of Chapters 11 and 12 of the HL7v2 standard and their messages for Referral and Collaborative Care, to include handling requests for enhancements to v2.x for clinical and community care communications (including transfer of clinical responsibility) as well as new non-V2 aware payload structures, such as Archetyped Data, CDA etc.

At the May meeting, David Rowed canvassed opinions on how this project ought to be scoped and whether a specific project was indeed required. The alternative is keeping v2 maintenance as a core general responsibility of PC (an approach not previously favoured by one of the co-chairs).

Frank Oemig of HL7 Germany has in the past been very critical of (and is seeking reversal) of some of Australia's more radical v2 solutions and was present during discussion of this item.

The overall outcome was that v2 maintenance does not require PC WG to mount a specific project; however, having a project would facilitate provision of specific HL7 resources (secretarial, meeting rooms etc). The consensus within PC WG was that, at this stage, a separate project for v2 maintenance is not required but it could be justified, if specific significant requests for changes come forward. Similarly, preparing for version 2.8 would also not justify a project without such requests coming forward.

Frank Oemig reminded PC WG of the problem (initiated by himself) of the lack of "legitimacy" of HL7v2.7 (mainly to do with a lack of backwards compatibility). While Frank seems to effectively have an "injunction" out on v2.6, v2.7 and, indeed, any v2.8 Ch 11, 12 submissions, the prospects for progressing significant further work in this area is hazy. Under these circumstances, the idea of elevating Australian work on carriage of archetyped data in v2 to a project at HL7 would, at this stage, be both premature and problematic.

The best way of contributing Australian input and expertise to HL7's global consideration of clinical communications issues needs to be identified taking into account the above developments and other projects within the HL7 PC, CBCC, OO and CDA WGs. Australian stakeholders should consider whether to propose a separate project on Collaborative Care Workflows as a possible area in its own right through the PC WG.

> **Action: IT-014-06-06 and HL7 Australia to examine how to best progress requirements for Clinical Communications in HL7v2 over and above Ch 11 and 12 maintenance starting with clarification of constraints on document, archetyped data , documents and workflow, and responsibility indicators in v2 Clinical Messaging.**

There is also a need for an Australia position on how to use of CDA for reporting and communicating clinical orders, requests, and intents and reconcile potential conflict of moods in the clinical statement part of CDA with sender receiver responsibilities specified by the implied dynamic model of a surrounding v2 message (or transport layer). This should be done with input from experts the HL7 Patient Care, OO and Structured Documents WGs, be consistent with the purpose of CDA and address the significance (or otherwise) of HL7's deliberate exclusion of a control wrapper for CDA.

> **Action: IT-014-06, IT-014-06-06 and NEHTA to review, seek clarification and form a consistent Australian position on use of CDA for reporting and communicating clinical orders, requests, and intents within v2 messages.**

## 19.8 PATIENT CARE PAYLOAD FOR PRIMARY CARE SOA INTEROPERABILITY

This project, sought by Australia has been accepted by SOA which is overseeing it as a Patient Care WG activity.

It seeks to define how a clinician or health care facility can define its applications as collaborating services and how these interact. The use-case put forward from Australia was the DOHA-funded, and RACGP-endorsed, IBM GP Computing System Functional Specifications. As this was the main use case, SOA wanted the project scope to be limited to primary care but PC could expand on this.

At the meeting, Thomas Kuhn, Systems Architect for American College of Physicians came forward to enthusiastically support the project and be involved, stating that his organisation urgently recognises the need for this approach in order for systems to be able to comply with the US 'Meaningful Use' criteria.

Galen Mulrooney, of US Veterans Affairs. and co-chair of Services Oriented Architecture advised the WG that US VA now recognise an urgency for this approach as they fear 'Meaningful Use' requirements will effectively impose it, and if not done properly, non-standards based ad hoc implementations could proliferate.

This work needs to be done through PC WG where interested US groups are more likely to engage with and accelerate the process.

**Action: HL7 Australia in collaboration with IT-014, the RACGP and relevant standards bodies seeks DOHA/NEHTA funding for a project to review the IBM GPCS, update requirements as appropriate, and organise it into a services-based framework and a consistent scope for adoption as part of the approved HL7 project being progressed by the HL7 PC and SOA WGs.**

## 19.9 PATIENT CARE VOCABULARY AND GLOSSARY PROJECT

This is a project in initiation stage, pushed recently by Australia, and needed to cover concepts taken for granted during modelling of care provision where different interpretations arise during project development and impede progress. We have taken advice from Heather Grain co-chair of Vocabulary regarding this and working in conjunction with the ISO server-based project and the HL7 International SDO Glossary project being developed by Heather through the Vocabulary WG.

We have agreement that we will focus on concepts as they arise in ongoing and new work, notably Problem, Diagnosis, Care Plan, Health Asset, Referral, Discharge Summary, Discharge Referral, Allergy, Intolerance, and Adverse Reactions.

Work has commenced via the PC Wiki and we will co-ordinate with the Vocab committee and other WGs. The scope will be developed in parallel with this early work. We will need to work out how this fits in with existing HL7 work and how we manage variances from other groups.

**Action: IT-014 and its subcommittees and HL7 Australia collaborate with Australian clinical and terminology groups to work toward greater consistency for the concepts needed within the Patient Care domain.**

## 19.10 OTHER PC WG ISSUES AND ACTIVITY

### 19.10.1 LIMITATIONS OF ACCESS TO PC MATERIALS BETWEEN DSTU AND INFORMATIVE BALLOTS

A problem has been identified in which products disappear from ballot documents, and therefore from public view and general access, once they have passed DSTU but are not put into a subsequent ballot, for example: if ongoing work after reconciliation delays normative ballot or repeat DSTU inclusion. There needs to be some type of "Passed DSTU Holding Area" in the ballot documentation.

PC WG is taking this up with the v3 and v2 publishing teams.

### 19.10.2 ASSESSMENT SCALES

This activity aims to provide standard templates and models for use in all forms of assessment scales (Barthel, Glasgow, APGAR etc) which can be used in messaging and documents. The team is currently refining it from first-round DSTU reconciliation and preparing it for another DSTU.

A caution regarding copyright ownership of many scales was raised at the meeting. This has not impeded generic development, but may impact on use case publication and jurisdictional deployments for some scales (notably Barthel).

### 19.10.3 OTHER ON-GOING PROJECTS

Other V3 Care Provision projects which are proceeding on course and have not undergone significant changes include the following:

- DSTUs (Draft Standards for Trial Use) due to conclude their two-year test periods in 2011:
  - Care Provision DMIM
  - Care Record, Care Record Query, Care Transfer Topics
  - Care Structures, and
  - Vitals Observations Topic.

In addition:

- The Professional Service topic is about to be published as DSTU for first review in 2012.
- Patient Care is collaborating with CDS WG on Order Sets; however, CDS WG didn't meet at the May 2010 WGM.
- Patient care is collaborating with EHR WG on a diabetes project being led by EHR but with strong support from Netherlands and William Goossen (The Netherlands) as PC Co-chair.

# 20 PATIENT SAFETY

## 20.1 GS1 STANDARDS AND PATIENT IDENTIFICATION

A presentation was given by John Pearce of GS1 regarding their effort in developing unique patient and provider identification methods using an identifier created using their GSRN (Global Service Relation Number) format. The standard they have developed has been recently supported by ISO/TC 215 at its meeting also held in Brazil the week before the HL7 WGM.

The key purpose of the GS1 standard is not to replace local identifiers but to complement and assist data collection and interoperability by providing a standard mechanism of converting an identifier into a reusable object by other systems and devices. For example a patient identifier contained in the GSRN format can be mapped directly into a GS1 Data Matrix barcode for use on a patient label or wristband.

All GSRNs are 18-digit numbers, and defined by the application identifier 8018. They then utilise a GS1 company prefix number and the local identifier to construct the full number. Finally a check digit suffix ensures data integrity. For example, in the NHS, a GSRN can be constructed using NHS CfH prefix 5050898 and a patient's ten digit NHS number as follows: (8018)505089845055771041.

There are a number of concerns with wide scale-adoption of the GSRN in the NHS at this point in time for patient and provider identification:

- Systems probably cannot handle 18-digit patient identifiers.
- All patients do not have known NHS numbers.
- Hospitals have their own PAS systems that identify each patient-admission.
- Back-up, human-readable information is required on wristbands.
- GS1-128 bar code is too wide at smallest x-dimension of 0.25 mm, 52.25 mm for wristbands.

The Patient Safety WG highlighted the need for such a standard across the industry and felt that this work needed to be incorporated into the HL7 scope. It was however felt that the more appropriate WG would be the Patient Administration, Medical Device or EHR groups.

**Action: IT-014 to:**
**(1) investigate and report on the need to adopt the GS1 GSRN Patient and Provider Identification standard for the representation of unique identifiers; and**
**(2) monitor HL7 activities to see the uptake of this standard particularly in areas such as medical devices or structured patient labelling.**

## 20.2 PHARMACOVIGILANCE

The office of Pharmacovigilance at the NHS proposed a new work item for Patient Safety in regards to the reporting of information from Pharmaceutical companies to regulatory authorities in regards to Risk Management plans for registered products.

Currently there is very poor reporting of updates to regulators of Risk Management plans as new information regarding the products becomes available to the manufacturers. This reporting is often manual and difficult to collate leading to significant lag times in the publication and transfer of knowledge to users of the products.

The Patient Safety WG agreed that this was an area of concern and asked that the NHS and other EMEA members put forward a formal proposal on the scope and nature of work to be covered.

A second future work item was also proposed to create a standard for the Periodic Safety Update Report to be developed into a structured document. Currently submissions received to regulators are largely static file (PDF) submissions. The file is submitted initially at licensing and in an ongoing basis over a number of years as further information pertaining to the product is available.

In the EU there are currently moves to strengthen the legislation around the reporting of patient safety information in relation to medication and medical devices and the ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) is currently considering to review the specification and there is a chance this could include the provision of a structured electronic format. Therefore it is an opportune time for HL7 to look to develop a specification which can be adopted as the standard structured document format.

The Patient Safety WG agreed that this work item is also of interest and will take up the discussion with the Structured Document WG.

Measures to manage and standardize reporting of hazards associated with medicines and for preventing harm to patients are relevant to Australia and therefore developments in this area should be monitored.

**Action: IT-014 to monitor developments in the area of standards for the reporting of new information about hazards associated with medicines and for preventing harm to patients.**

# 21 PHARMACY WORK GROUP

The activities of the Pharmacy Work Group at the May 2010 WGM included discussions on and review of a number of interesting topics.

**May 2010 Ballot**. In this ballot, Pharmacy WG had re-balloted topics and models that did not pass the January 2010 ballot:

- Common Product Model (joint reconciliation meeting with OO, Patient Safety, RCRIM, and PHER)
- V3 Pharmacy CMETs, Release 10
- V3 Pharmacy; Medication Dispense and Supply Event, Release 1, and
- V3 Pharmacy; Medication Statement, Release 1.

Negative comments were discussed and ballot reconciliation began. Comments and resolution details are to be published in the reconciliation spreadsheets.

## 21.1 PHARMACY V2.7 INFUSION SEGMENT

The Pharmacy/Treatment segment has been used to support general infusion orders. However, it lacks the specific parameters to support more complex infusion orders such as analgesia infusion with bolus patient controlled analgesia delivery or syringe driven multi-ingredient infusion. A proposal to add an optional infusion order segment (RXV) has been submitted. The proposal is discussed at a joint Pharmacy-OO meeting.

The proposal is supported and the proposed segment will be added to the following message types:

| MESSAGE | EVENT | DESCRIPTION |
|---|---|---|
| OMP | O09 | Order Message |

| | | |
|---|---|---|
| RDE | O11 | Encoded Order |
| RDS | O13 | Dispense Message |
| RGV | O15 | Give Message |

## 21.2 COMPOSITE ORDER MODEL

Joint discussions occurred with Orders & Observations (OO) relating to the Composite Order Model – produced by merging and harmonising the Laboratory and Medication Order Models from OO and Pharmacy. The harmonization processes involve:

- the consolidation of common information components (i.e. HL7 RIM classes) that are common to both domains
- the generalization of information components that are similar in both domains, and
- elimination of information components that are completely specific to each domain.

The Composite Order Model can be used by each domain to develop domain specific messages. Each domain can extend the model to meet its additional requirements by adding standardized domain specific information components. The harmonization principles and outcomes were agreed upon at the joint meeting. Patrick Lloyd (OO co-chair) will finalize the harmonized model.

Implication – The harmonized modelling and extension mechanisms are a useful approach for NEHTA to consider in its development and refinement of its clinical information specifications, especially the "Core Information Components" for discharge summary and referral.

**Action: NEHTA to consider the approaches used to develop a harmonized model for the extensible composite Pharmacy/Medication order and to extend it for domain specialisation – as potentially applicable to development and refinement of NEHTA clinical information specifications, especially the "Core Information Components" for discharge summary and referral.**

## 21.3 ADMINISTRATION OF MEDICINAL SUBSTANCE (AFMS)

HL7 has a value set for specifying the routes of administration of medicinal products. The value set does not cover other parameters required to describe administration of medications, e.g. site and methods. Canada has taken on the responsibility to produce an AfMS value set. The AfMS status was briefly reviewed at the meeting.

It is revealed that IHTSDO and other entities also have produced similar value sets and the need for harmonization of the various value sets was discussed. It is proposed that

- inputs sought from Julie James (vocabulary facilitator) on the status of AfMS
- a harmonization proposal to be developed to deprecate the current "route of administration" value set
- Jean Duteau (one of the co-chairs) to explore the need for new Concept Domains as part of integrating the 'Method' attribute into the domain models and associated refined models, and
- input from HL7 sought on any new Vocabulary processes for dealing with HL7 Value Sets.

Implication – this is a useful and important work item which will impact on information model and terminology development for electronic prescription and medication administration recording.

**Action: Australia (with NEHTA lead) should monitor the progress and participate in project arising from the AfMS work item.**

## 21.4 DOSE SYNTAX

A New Work Item Proposal has been initiated in ISO and initial work has led to development of a draft dose syntax abstract model that contains a set of classes and attributes to support dose instruction description. This model is based on an earlier document produced by Julie James for NHS.

It is suggested that the dose syntax abstract model and dose instruction may become a joint initiative project involving ISO, HL7 and IHTSDO. It is unclear whether ISO intends this NWIP to be a TS

(technical specification) or an IS (international standards). ISO appears to favour an IS approach. Garry Cruickshank (one of the co-chair) has been requested to follow up with ISO (Ian Shepherd) on this matter. It is agreed that HL7 needs to consider and determine how to engage, and be more proactive in the joint initiative.

Pharmacy WG is interested in further developing this document. Pharmacy would recommend to John Quinn (HL7 CTO) that this work should be done under the auspices of the JIC, perhaps with HL7 leading this initiative. Garry Cruickshank will take on the responsibility to discuss this project with John Quinn.

Dose syntax is a highly complex and difficult topic in the medication order model from which Australia can learn while also contributing. Australia/NEHTA should monitor the progress and participate in project arising from this work item.

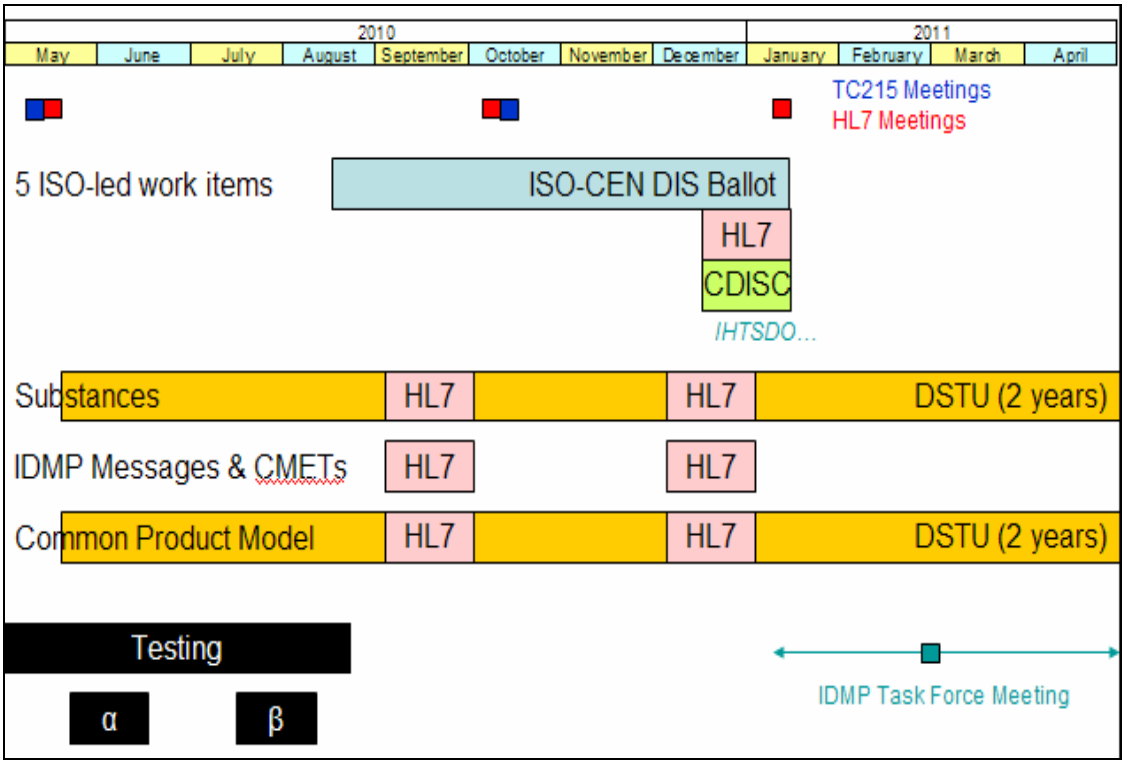
**Action: Australia (with NEHTA lead) to monitor progress and participate in project arising from the ISO Dose Syntax work item, particularly if it is endorsed as a joint work item with HL7 and CEN through JIC.**

## 21.5 IDENTIFICATION OF MEDICINAL PRODUCT (IDMP)

Tim Buxton presented an overview of the current status of the IDMP items which are joint items between ISO/TC 215, CEN/TC 251 and HL7:

- Approval for a five month DIS ballot for the 5 IDMP standards
- Will be a parallel ballot in HL7 (a month at the end) and CDISC (GS1 will not ballot)
- Within HL7 the Substances have been modelled and discussed and are now DSTU (2 years), and
- Within HL7 the Common Product Model has been modelled and discussed and are now DSTU (2 years).

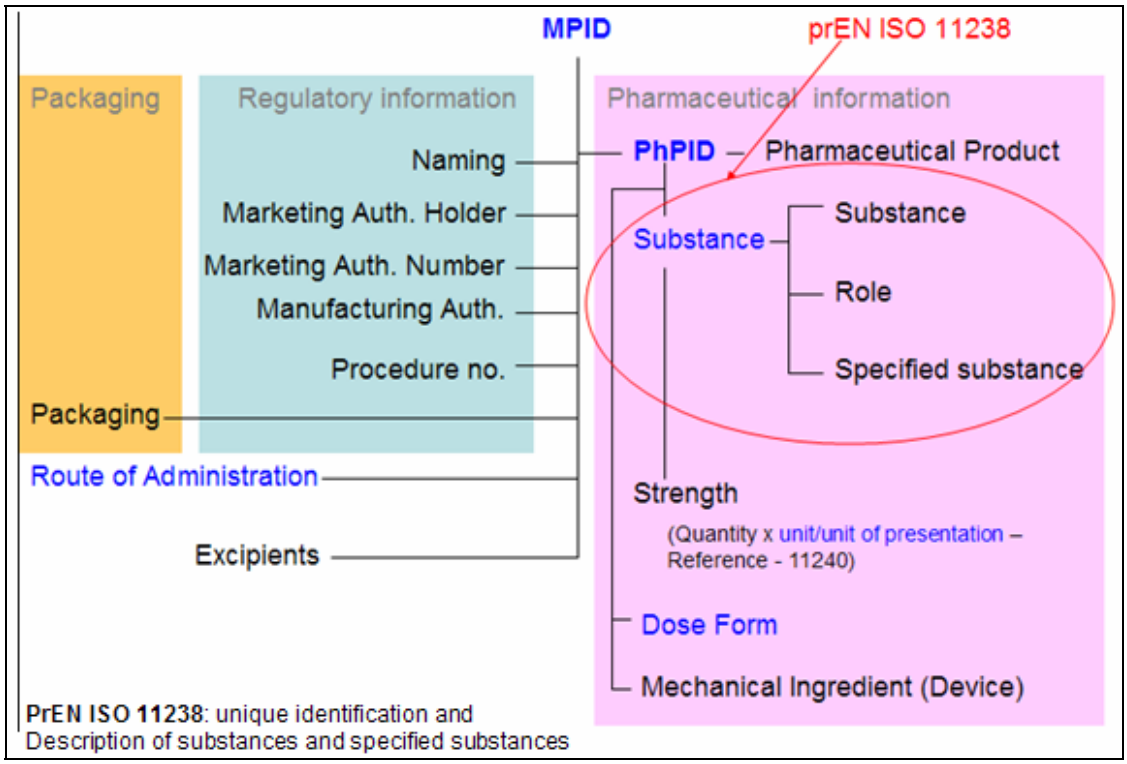
IDMP Timelines:




There are significant discussions on the distinction between IDMP and Pharmacy's Common Product Model (CPM).

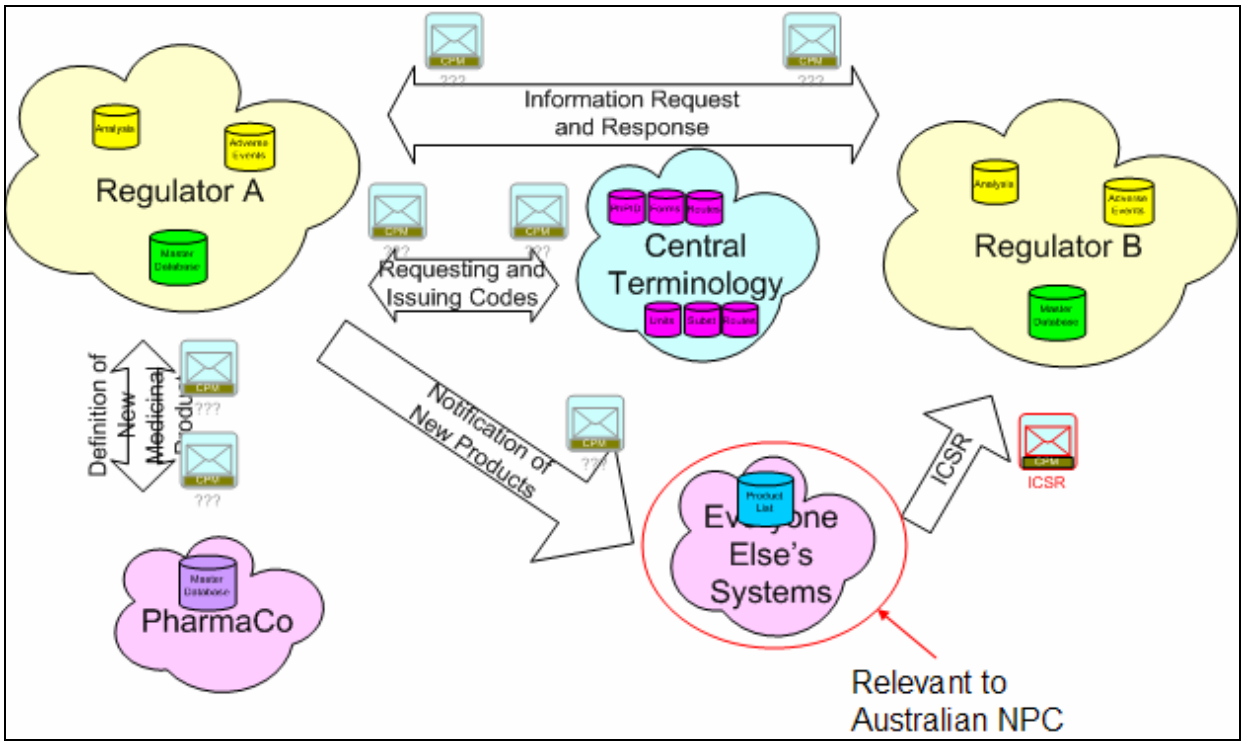
CPM can carry all the relationship, characteristics, etc but it is somewhat more difficult to understand (at a much more abstract level than IDMP). IDMP tries to present the material in a more easily understood view.

The IDMP Model:




There are also some discussions on how CPM would be able to conduct the contents from IDMP from one source to a target as required in different communication processes that IDMP is intended to support.

IDMP Supported Processes:




Pharmacy WG produced V3 Identification of Medicinal Products topics and models which are published in the May 2010 ballot package document:

- Story board
- Trigger events, Interactions, and
- Creation and Maintenance Messages, R1.

Comments were discussed at a Pharmacy WG and IDMP ballot reconciliation session. Suggestions have been made to develop a number of IDMP CMETs which are proper constraints (flavors) of CPM (R_Product CMET). This would allow an enforceable terminology value set binding as opposed to what an implementation guide based on the CPM would provide. Concern has been expressed that this would add extra complexity and time to getting IDMP implemented.

Implication – The Identification of Medicinal Product (IDMP) and prEN ISO 11238 (Data structure and elements for unique identification and description of substances and specified substances) have relevance and utility to Australia's NPC (national product catalogue) project. Australia will benefit from active continuing engagement.

**Action: IT-014 to invite NPC Project to actively engage with and participate in IDMP and prEN ISO 11238 joint work (primarily being run through ISO/TC 215/WG 6).**

## 21.6 CDA IMPLEMENTATION GUIDE FOR EU X-BORDER PRESCRIPTION

A presentation (by Catherine Chronaki) at the International Affiliate Council meeting on European HL7 Interoperability included a report on an EU cross-border prescription project. Preparation is underway for project scope statement for ballot on a CDA implementation guide.

Sponsoring organizations include: HL7 Hellas, HL7 Italy, HL7 Finland, HL7 Spain, HL7 Germany, HL7 Spain, HL7 Austria and HL7 Czech Republic.

HL7 UK plans to bring this topic to the attention of its Board.

- EPSOS is a project in the EU is trying to come up with a method to share information across boundaries, including an e-prescribing methodology/ standard.
- There is an HL7 Project Proposal coming forward to create a CDA R2 Implementation Guide for European Cross-Border e-prescriptions.
- There is a question whether HL7 Pharmacy WG would be interested in participating in the project.
- This might 'force' the Pharmacy WG to bridge the gap between the message model approach and the CDA approach.

- They plan to standardize content but not workflow (no dynamic model).

A question was raised on whether this work is to support an actual order (e-prescribing → sending prescriptions for fulfilment) or about reporting information on e-prescriptions (medication statement). OO has made a statement that CDA cannot be used to send orders, this will be clarified.

Implication – This activity is highly relevant to CDA implementation of electronic prescription and dispense records communication projects in Australia. Stephen Chu has initiated follow-up email communications with epSOS team members and coordinator to access detailed information.

# 22 PUBLIC HEALTH EMERGENCY RESPONSE (PHER)

Public Health Emergency Response WG had a small representation at this meeting and there was little new work or resolution specifically discussed. Of primary interest was the joint session with the EHR WG on the collaborative work between the HSSP, PHER and EHR WG's for the "The Practical Guide for SOA in Health Care Volume II: Immunization Management Case Study".

Within the US there is a large legacy in V2.3 messaging for Immunisation (with more recent implementations using V2.5). Policy issues however prevent there being interoperability in messaging using V2 messages. As such there was a need to develop a common information model to underlie all Immunisation Messaging with the extensibility to all for local policy requirements. There was also an overall requirement to provide a specification that followed a robust methodology to ensure that requirements from a business, information and technological perspective were considered.

As such the "Practical Guide" contains a full SOA implementation guide, which shows by example what it means to do "standards-based" SOA development of a capability. It has been developed as an HL7 SAIF (Services Aware Interoperability Framework) Alpha Project, which demonstrates the SAIF ECCF (Enterprise Conformance and Compliance Framework (ECCF) used to document the Immunization Management Capability (IMC) exchange architecture, Interoperability Specifications and Conformance Criteria.

The document delivers an IMC prototype demonstrating how the EHR-SD RM (EHR System Design Reference Model) can be used to build a baseline architectural specification for an acquisition, development or certification program. A copy of the document can be found here: http://hssp.wikispaces.com/file/view/Practical+Guide+for+SOA+in+Healthcare+Volume+II+Immunization+Management+Case+Study.pdf

In other discussions for the PHER WG it was raised that the PHER WG will not have any ballot material this cycle between this meeting and the following WG meeting in Cambridge. In this period however it is planned to publish a reference architecture practical guide and also for the revised Immunisation DAM to be uploaded to the HL7 SVN site (GForge).

Teleconference Times – It was also raised that the current teleconference times were not suitable for members, it was proposed to move them to Friday 1PM (US EST), however we raised the issue that for any Australian participation this time equated to early Saturday morning and was not suitable. Following discussion with members of the WG a more suitable time of 4pm Thursday (US EST) was agreed upon, this allows for any interested Australian participants to dial in early Friday mornings.

# 23 SAIF PROJECT

The following points were noted from discussion of SAIF at the ArB.

- As noted elsewhere in this report, Dr Steve Hufnagel has used the SAIF in a use case for "Practical Guide to SOA in Healthcare Volume II: Immunization Management Capability". This is the first time a significant piece of work has looked to marry SAIF in with an architecture development approach like the TOGAF ADM. A core element of work has been population of the ECCF matrix. There has been some confusion as to the relationship between ECCF viewpoints and traceability both across and down the ECCF matrix.
- Several HL7 stalwarts have provided review comments on SAIF. In general there were far fewer issues with the ECCF than the Behavioural Framework (BF). A reworking of the BF is required to more completely position it relative to the layers of the MDA stack as well as defining it's relationship to ODP viewpoints.

- As the SAIF is populated through experience and discussions, questions are now emerging as to how the varying products and philosophies of HL7 can co-exist within a common framework. This is, by nature, the value of the SAIF in that it requires decisions to be made as to how conceptual, logical, and platform models of different artefacts can relate. Key to these modelling decisions will be the selection of the RIM as a potential logical model alongside the likes of an HL7v2 logical information model, each related to a common conceptual information model.
- The first version of the Governance Framework (GF) and Information Framework (IF) are expected within the next few months. These will require bedding down the relationship between these frameworks and the viewpoints described within the ECCF. Currently the Behavioural Framework covers portions of the Enterprise and Computation viewpoints. It should be the case that the IF, at least, should be more aligned to the Information viewpoint. While the GF will concentrate on governance, it too will need to include more information on the language and artefacts expected to be defined within the Enterprise viewpoint.
- The existing SAIF Alpha projects are struggling to create significant headway in the use of SAIF. Steve Hufnagel's use case is probably the exception to this analysis. The issue now is the harvesting and feedback of what has happened within the SAIF Alpha projects. This is a significant piece of work to begin the harmonisation process across these different experiences.
- The SOA/HSSP group and the ArB have agreed to work more closely together moving forward. Regular teleconferences and working group meetings sessions will be organised to ensure the work of the SOA group is incorporated into the SAIF and enterprise architecture work of HL7. Andy Bond has agreed to provide a liaison role between the groups.
- Following TSC meetings, the SAIF will look to be more inclusive of contribution from speciality groups within HL7. For instance, the Implementation & Conformance will become the primary contributor to the ECCF. The ArB will provide more of an editorial/coordination role rather than sole author.

# 24 SECURITY WORKING GROUP

## 24.1 GLOBAL INITIATIVES IN E-HEALTH SECURITY

An overview was given by different affiliates as to any significant bodies of work currently underway that had significant impact on Information Security in relation to health information.

Europe currently has a cross border trial of data sharing across health services across 12 countries, with a second phase in 2011 to involve all EU countries. The sharing of information is complicated by multiple patient and provider identifiers and also multiple methods of authentication across the countries. As such, they are looking to trial the IHE Authentication profile between Germany and France during the project. In addition to identification and authentication issues they also still have no agreed mechanism for encryption.

Germany is currently reviewing the powers of the Ombudsmen who monitor Data Protection. The Data Protection Ombudsmen are regulated by the German Society for Security and Data Protection who is involved in the current EU cross border data sharing trial and they are working on a trust relationship model with accredited partners to be able to participate in data sharing with foreign countries.

Japan is currently engaged in large-scale Government funded projects on community based care which has a requirement that information security (and other information exchange requirements) must be based on international standards.

Australia mentioned current legislation regarding the Healthcare Identifiers and also the Security and Privacy framework that is in the scope of work at NEHTA.

## 24.2 SECURITY AND PRIVACY DOMAIN ANALYSIS MODEL (DAM) AND ONTOLOGY

The combined Privacy and Security Policy DAM had ballot comments dealt with in Rio. This piece of work looks to bring together privacy and security constructs to define and use policies across various aspects of e-health including EHR. It augments a family of ISO-derived security specifications for e-health that create a comprehensive health-specific library for foundational work in e-health.

During ballot reconciliation some logical inconsistencies were identified in the metamodel presented and a simplification of the specialisation of classes was proposed to make the model easier to navigate and understand but also more flexible for real world use. Further revision and review of the Security and Privacy DAM is required before it can be presented as normative.

The Security WG presented the draft Security and Privacy DAM in joint sessions with other WGs at this meeting (in particular, see report of discussion at CBCC in section 13 above).

There are some issues with the current draft of the Security and Privacy DAM that warrant review and comment by Australian experts, taking into account existing work such as ISO 22600 Privilege management and access control.

**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 DAM is correct and that any local requirements can be covered in the model.**

As part of the work on security policy, a new project has been approved to define a Security and Privacy Ontology. The work derives from the Policy DAM work currently in train and will define a comprehensive vocabulary for the definition of policies as well as their enforcement, management and use within decision support.

### 24.3 SERVICES, SECURITY AND THE PASS PROJECT

The most mature of the SAIF alpha projects is PASS (Privacy, Audit, Security Service). It is anticipated that this work will form the basis of a new HSSP project in the near future.

The Privacy and Security Domain Analysis Model (DAM) (discussed in the preceding section) forms the centrepiece of this activity.

The completed model would be a useful input to NEHTA's work on security services as it is not US biased and it does not reference the HL7 Reference Information Model (RIM) but is instead based on HL7/ISO datatypes. Hence it is applicable to all international jurisdictions. The US Federal Government is developing a Federal Health Information Model in which the security is modelled based on the PASS DAM.

## 25 SERVICE ORIENTED ARCHITECTURE (SOA) & HSSP

Within HL7, SOA is the work group charged with providing a service-oriented architecture view of the HL7 world. In addition, SOA provides service-oriented input and expertise to HL7 committees and other work groups.

The Health Services Specification Project (HSSP) has been a major part of that work (in collaboration with OMG), ensuring that specifications have implementation experience prior to being moved to full HL7 standards. For further information about HSSP and current SOA work see the HSSP wiki: http://hssp.wikispaces.com.

Most of the SOA documents referenced in this report can be found on the HSSP wiki.

Galen Mulroney (US DVA) was re-elected as Co-Chair and Ann Wrightson (UK NHS) was confirmed as the first non-US Co-chair following her interim appointment at the previous WGM.

There were significantly reduced numbers attending the SOA Committee at this meeting and the other two Co-chairs Ken Rubin and Don Jorgenson, were unexpected apologies.

Joint meetings were held at this WGM between the SOA Committee and Security, Vocabulary, the Architecture Review Board (ArB) and Patient Administration Committees.

The SOA Mission statement and SWOT analysis were updated, confirmed and posted to the HL7 Web site (see: http://www.hl7.org/Special/committees/soa/index.cfm)

A new project concept was introduced by Ann Wrightson which would result in a set of RIM platform services being produced for RIMBAA. The theory is that introducing an independent service layer at the RIM would allow for more portability of applications between different RIM implementations and, also, for support of virtual, potentially distributed, RIM infrastructure.

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

For the first time in 2 years, the CEO of OMG, Richard Soley, did not attend the HL7 WGM.

## 25.1 STATUS OF HSSP/SOA PROJECTS

### 25.1.1 IDENTITY CROSS REFERENCE SERVICE (IXS)

IXS (formerly the Entity Identity Service – EIS) - passed its final normative ballot in September 2009 and has now been published. The UK NHS, The Netherlands, Canada Infoway and the European Community are considering implementations. This work is consistent with the functional requirements included in both existing Australian and ISO health informatics Identification standards documents,

It appears that Australia will not be using this Standard for its Health Identity Services to be launched on July 1, 2010, although it is unclear why that is the case, as the standard appears to provide all required functionality.

The SOA WG requested that feedback be sought from NEHTA on the issues that led Australia not to use the IXS standard. The feedback is being sought to inform future SOA activities in this area and ensure that shortcomings in HL7/OMG process and IXS content are addressed.

**Action: NEHTA to provide feedback to the SOA WG why the IXS standard was not used as the basis for implementing the Australian Health Identifiers Service.**

**Action: NEHTA to develop a formal SOA capability/requirements register as part of a national eHealth Model and map those requirements to existing international work.**

### 25.1.2 HUMAN SERVICES DIRECTORY SERVICE (HSDS)

The work on this service (also referred to as Health Care Provider & Services Directory Service - HCPDS) is being led by Max Walker from Department of Health Victoria. This work has slowed due to lack of funding for him to attend this WGM. He is normally supported by the Department.

A completed DSTU was submitted to ballot prior to the January WGM and all comments were satisfactorily resolved during the previous Working Group meeting.

A delta analysis was performed by the Patient Administration WG which confirmed that it encompassed most of their requirements. The major challenge remaining was to incorporate their existing Data Analysis Models (DAM) and HL7 V3 messages into the service specification.

This project currently has a near complete RFP but finalization of that step, originally scheduled for this WGM, will now need to wait until the next WGM in September despite it previously having been anticipated that an RFP could be completed and issued rapidly.

Whilst some progress had been made on developing the RFP through teleconferences since the last meeting, this had slowed once it became clear that Max Walker would not be funded to attend the current WGM. It is now hoped that the RFP can be completed by August for approval at the next WGM.

The Human Services Directory Project needs to be supported and this would be best done by funding Max Walker's attendance at HL7 Working group meetings.

**Action: IT-014 to investigate means of funding Max Walker's attendance at the next WGM to facilitate completion of the HSD RFP documentation.**

### 25.1.3 COMMON TERMINOLOGY SERVICE 2 (CTS2)

The CTS2 RFP was distributed in September 2009; however, responses have been delayed and will now close on June 1. There appear to be at least 3 responses in preparation.

The CTS 2 project is being progressed jointly with the Vocab WG, with more detailed information on progress and recommended actions being reported in section 12 above.

### 25.1.4 CLINICAL DECISION SUPPORT SERVICE (CDSS)

Having been completed as a DSTU in January 2009 and despite some initial delays in formation of the OMG Task Force, the CDSS project is now progressing well with the OMG RFP expected to be completed by the HL7 WGM in September.

Considerable interest has been expressed in this service by a wide range of groups within HL7 who wish to see application of CDS in their domain. The flexibility of the service design should enable implementation in many domains including some outside Health.

In addition this service has been specified as the basis of the IHE Clinical Guidance Profile.

In Australia, groups such as the National Prescribing Service (NPS) and RACGP that have an interest in clinical decision support, should be made aware of the HL7 Clinical Decision Support Service project and the IHE Clinical Guidance profile based upon it.

**Action: HL7 Australia and IT-014 to raise awareness of CDSS an seek participation among relevant groups including National Prescribing Service (NPS), RACGP, ACHI and AGPN.**

## 25.2 SOA JOINT MEETING WITH THE ARB

In a joint meeting with the Architecture Review Board (ArB) it was clarified that the SOA Committee would continue to perform the role of moving the services oriented agenda at HL7 forward in consultation with other working group committees. The ArB would in future be principally involved with issues of governance and overall strategy rather than specific projects.

Further clarification of the evolution in the Service Aware Interoperability Framework (SAIF) was provided by Charlie Mead which outlined that SAIF is an architectural design paradigm for distributed computing which delivers the following benefits:

- Intrinisic interoperability
- Supports Interoperability vs integration
- Increased federation
- Common endpoint and local governance
- Increased business technology alignment
- Linear degree of difficulty for change
- increased vendor neutrality
- Increased ROI
- Increased organisational agility, and
- Reduced IT footprint.

SOA challenges include increased design complexity, need for design standards, top-down delivery requirements, counter agile (contract-first) design/delivery and more complex governance requirements.

A need for an HL7 Service Inventory and Service Blueprint has been identified by the ArB. This was a lesson that had been learnt over the last year at the USA National Cancer Institute (NCI). It was noted that SOA is an architectural design paradigm for distributed computing which does not necessarily have anything to do with Windows or web Services. Hence a “Service inventory” is actually a function/capability inventory which describes components and needs static (informational) and functional capability descriptors.

It is planned that the ArB will define the inventory content and the SOA Committee will oversee its population and maintenance principally by contributions from HL7 content committees such as Patient Care and Patient Admin. The initial starting point for this work could be “service decomposition” of HL7 EHR Functional Model (EHR-FM) following on from the USA DVA work on an immunization service which utilized the EHR-FM

It was agreed that HSSP will become a just one path to service implementation flowing from an HL7 DSTU and alternative processes (such as that at the Mayo Clinic with CTS2) are already in process. The SOA Committee would need to track these alternative implementation pathways and gather feedback for input to the ballot process.

The book by Thomas Erl, “Principles of service design” is recommended reading for those interested in further understanding of SOA and its underlying principles

This meeting represented a welcome increase in collaboration between the ArB and SOA Committees and in future there will be an ArB / SOA standing joint meeting Wednesday Q1 at WGMs as well as two joint teleconferences between WGMs.

Andy Bond and Anne Wrightson will informally provide liaison between the Committees though this should be formalized at the next WGM.

### 25.3 THE PRACTICAL GUIDE FOR SOA IN HEALTHCARE

This completed document (Parts 1 and 2) can be accessed at:
http://hssp.wikispaces.com/practicalguide

This document has now been significantly enhanced with a draft but near complete implementation guide for an immunization service. It documents the HSSP process and the Service Development Framework (SDF) used by HSSP. It is a remarkably accessible document and recommended reading.

The document has been revised to include information learnt from the first full HSSP cycle and to incorporate the relationship with HL7's Service Aware Interoperability Framework (SAIF). It contains more detail about how a platform independent service can be developed into a particular service instance implementation including how to specify conformance criteria, service behaviour and shared terminology. It has been extended to include analysis of HITSP, HSSP, HL7 SAIF, US Federal Enterprise Architecture, and other industry reference sources to elaborate a mature healthcare SOA Reference Architecture.

Addition of an Implementation guide for an Immunization service has significantly enhanced the Practical Guide to SOA Vol II.

The implementation developed uses the IXS (former EIS), RLUS and CTS2 services and demonstrates the use of HL7 services in an EHR environment.

This work was carried out at the US DVA and of particular note is the conclusion:

One of the most difficult challenges facing healthcare organizations making IT investments today comes from deciding whether to go all-in with a particular vendor, or whether to self-integrate components from multiple vendors. The appeal of the single-vendor solution is strong – no finger-pointing, out-of-the-box integration, [US-based] EHR certification via the Certification Commission for Healthcare IT (**CCHIT**), and so on. This is contrasted with seemingly increased risk and work involved in a multi-vendor solution involving integration. A multi-vendor SOA solution can offer compelling best-of-breed options; where, a SOA promotes an easier integration and alignment across suppliers into a cohesive, testable and certifiable architecture. We demonstrated an approach that can build and present consistent Interoperability Specifications (IS) and conformance criteria for both best-of-suite and best-of-breed components and their exchange architecture. Having these ISs, exchange architectures, certification criteria and associated business cases is the appropriate due diligence needed to help justify a best-of-suite vs. best-of-breed decision.

## 26 STRUCTURED DOCUMENTS WORKING GROUP

Many regular contributors to the Structured Documents committee were absent, so the committee had a fairly quiet meeting. Key focuses:

- Green CDA. The group met with ITS; see the report under ITS. Note that we agreed that the CCD specification is not sufficiently profiled to be useful implementation basis for green CDA itself – some additional profiling will be required, though there is no consensus on where that might come from.
- CDA R3 – a little progress on some proposals. Most of this work is proceeding on teleconferences.
- Implementation Guides. A number of implementation guides are making their way through the ballot process, but none are directly relevant to Australia.

## 27 V2.7 PUBLICATION

Publication of HL7 V2.7 has been substantially delayed due to the inability to date to resolve a number of conflicts of expert opinion arising from the V2.7 ballot.

Significant progress has been made in separating out editorial issues from substantive content issues, and in reducing the number of those outstanding substantive content issues to about seven, all of which are in the Financial Management, Patient Administration, Orders and Observations or Infrastructure and Messaging domains.

The remaining issues of concern include:

- Inconsistencies between chapters (between usage of data types between the Financial Management and Orders and Observations domains), and
- Differing interpretations of the (potential) usage of specific fields and associated differing interpretations of the potential consequences for both consistent future application by software developers and for backwards compatibility.

These seven outstanding issues have been referred back to the Financial Management and Patient Administration working groups, though the latter has already adjudged the ballot comments to be non-persuasive.

Persuasive higher level technical advice within HL7 does not appear to be forthcoming. The Architecture Review Board, which in the past may have assisted resolution of issues such as these, is now pre-occupied with SAIF issues and is not addressing V2, while clear and decisive direction has not been forthcoming from the CTO.

It now seems highly likely that a recirculation ballot (i.e. a ballot closed to all but the original balloters) will be held, to ensure that the balloters are aware of these conflicts and that their new ballots are sufficiently informed of the issues. This will further delay the publication of V2.7. However, V2.7 is important to Australia because of developments therein in relation to Collaborative Care messaging.

**Action: HL7 Australia to coordinate with those stakeholders who may be eligible for any recirculation ballot to ensure an Australian position is clear and taken.**

During discussion of these issues in the Patient Administration working group, it was acknowledged that a number of the published examples are incorrect and require revision – which has not yet occurred. Since software developers may be at least in part guided by these examples (and some committee members suggested that the examples may in fact be highly influential), their correction should perhaps be attended to before further expansion is undertaken in V2.8. It is proposed that IT-14-6-3 address this issue.

**Action: IT-14-06-03 to prepare corrections for the incorrect examples published in the HL7v2.7 ballot documents.**

# 28 VOCABULARY

## 28.1 HARMONISATION MEETING AND MEETING PROCESSES

On the HL7 web page there is a site for harmonization meetings. This page gives an overview of the purpose of harmonization meetings. There is a desire to improve and streamline the process and the consistency of all proposals brought forward for harmonisation.

The web site is to be updated to provide improved submission forms and procedure documentation.

The information requirements will be reviewed and identified but must at least include detailed rationale and instructions for:

- harmonization process
- templates for submission
- harmonization requirements, including rules for harmonization of different artifacts
- Timelines for each stage, and
- responsibilities of submitters and the harmonization committee.

There are issues of attendance at Harmonisation. A new minimum requirement for attendance has been suggested that will ensure all relevant parties are available to discuss each proposal and its implications. Representatives will be requested from: MnM; Vocabulary, Structured Documents, International Council; DESD; SSDSD; and, proponent work groups.

Quorum was identified according to the risk inherent in their absence. If the representatives of MnM, Vocabulary, International Council and the proponent WG are not present you can't vote. A minimum of 6 people must be present and each individual can represent only one of the groups.

## 28.2 UNIVERSAL BINDINGS

A point of contact for the International Council is needed to take any recommendations from harmonization approval for any non structural vocabulary to be submitted to the International Council to be advisory and tell us that it has been approved internationally. The International Council will be contacted regarding this requirement.

Where universal vocabularies are put forward to harmonization there is a need for international review and agreement. A process needs to be established by which a review and acceptance / comment from the international community can be managed prior to acceptance of these vocabularies at harmonization. There is a potential project for the International Council to identify appropriate process, including consideration of whether agreement is achieved before or as part of the harmonization process.

Alternatives:

- This could be the presence of an international representative at harmonization processes
- It could be a balloting process, and
- Manage as a process through the International Council.

## 28.3 CHANGE REQUESTS FOR SNOMED CT

This project is to draft a policy statement for endorsement by the Board on submitting HL7 proposed content change requests for SNOMED-CT to IHTSDO. A number of issues have been identified and the feeling of the meeting was sought to support development of an outline of the draft policy including:

- The process for identification of changes or additions required to SNOMED CT.
- Who within HL7 can request a submission to IHTSDO?
- Who in HL7 makes the submissions to IHTSDO?
- How is it determined that a given request is valid for submission?
- Licensing arrangements and IP. A request to IHTSDO will be made through the JIC to manage IP issues related to terminology content.

The discussion document on this topic is available at:
http://wiki.hl7.org/index.php?title=HL7_proposed_content_change_requests_for_SNOMED-CT_to_IHTSDO

## 28.4 INTEGRATING THE HEALTH ENTERPRISE (IHE) - VOCABULARY

Presentation by Charles Parisot on IHE value set communication issues.

Sharing value sets profile was published in 2008 by IT infrastructure domain of IHE International

It specifies a transaction to retrieve value sets from a value set repository Actor by a Value Set Consumer Actor. There is an OID and I get a bunch of CD data types and I get all the members of the value sets – this is actually sharing a value set expansion – the instantiated instance of a value set which includes the OID and the content.

There is a need to distinguish between the persisted construct of a value set definition, and the point in time coded values. It is important to understand the difference as this influences the metadata to be sent and the actual data sent. The value set definition has a version as does the instantiation of values. Both are required. This is not the process currently used in IHE. There is much more information needed to accurately confirm the instantiation and the metadata relevant to a value set at a point in time than what is available through the current profile.

IHE is only taking flat value sets at the moment, as these are easy. These still require metadata to support utility. Using the CD there is the code, code system, a display name; however, IHE are proposing using multiple CD statements to handle multiple display names – this breaks the current rules as alternative representations of the same concept are not permitted. The problem is that IHE want to be able to handle multiple language code system distributions, rather than a specific instance. During discussion, it was noted that:

- Value sets were not built to support display requirements of the implementation requirements.
- The use cases are sound and reasonable but the process is not yet covered adequately in HL7.

- This was considered relevant to but out of scope for MnM, the value set machinery is well defined, the method of implementation (which is where this problem sits) sits with MnM.
- Vocabulary would not endorse system behaviour where a system receiving a CD instance containing translations infers a mapping of those concepts.

Metadata to describe SS were briefly discussed. The potential for an extension to SVS was presented – this is going to public comment with a 1 month public comment period. IHE are eager to engage and use Vocabulary Working Group to provide comments on the utility of their approach.

There was concern that this overlaps with CTS2 to some extent. CTS2 defines an application, but includes service definitions for messaging over the wire. This existing work makes some of the IHE work counter-productive. The vocabulary workgroup should review this during teleconferences

## 28.5 CORE PRINCIPLES COMMENT DISPOSITION

Considerable time was spent at this meeting on ballot comment disposition. The details are not provided here but will be available in the next ballot cycle at which point it is hoped the Vocabulary components of core principles will be sufficiently robust to pass ballot.

## 28.6 CONFORMANCE ON POST-COORDINATION

When the concept you are representing is represented with a post coordinated expression (for example, those that can be constructed using SNOMED CT). The requirement is to be able to determine whether a given code value is conformant to the specification. There is also a need to be able to evaluate artefacts that make up the conformant statement.

The issue is how to grapple with defining conformance when someone has to represent concepts in HL7 models that have to use post coordination to represent them.

David Markwell has developed some standards in this area. Lloyd McKenzie indicated the MIF has post-coordination conformance situation:

When you specify a set of value set content (a set of code) and you identify the qualifiers allowed with a given value set. Specify zero to many qualifier relationships, the conformance, required, optional or not permitted, minimum multiplicity, and maximum multiplicity, a flag for post-coordination preference. In the circumstance where you could do pre or post which do you prefer?

There is a *MIF* model of post-coordination but it has not yet been used.

The meeting discussed the need for consistent conformance of post-coordinated concepts. It was agreed that this would be a new work item and that a Project Scope Statement for Vocabulary Working Group project "conformance of post coordination representation" be prepared. .

This work would be a partner to core principles. The audience is the technical person (as it will lead them to the relevant information in the MIF documentation) and provide examples.

The non technical person making decisions on what can and cannot be included in a value set and how terminologies are implemented in their systems.

It should include a list of the formalisms we have, and what does a person type in to represent post-coordination to be conformant and machine processed and safely shared.

Simplest case:

A small number of concepts with 1 to many ways of representing it with post coordination. (you can have condition qualified by body site, body site with morphological condition).

The requirement is to:

Provide the ability for limited use of post-coordination to use a post coordination in a user interface and in the wire and consider that it is a flat value set where some are both. Simple use case a post-coordinated coding (write in the enumerated extensional value set definition – you put in the exact expression you want sent. This is consistent with allowing transmission and consistent use.

## 28.7 HL7 MANAGEMENT PROCESSES FOR VOCABULARY AND IP ISSUES (RELATES TO SNOMED-CT AND LOINC)

Chair: Beverly Knight

Scribe: Heather Grain

Pharmacy are planning to deprecate route of administration code system and use SNOMED-CT instead. There is a need to be able to make an initial assessment as to whether a code is clinical or administrative, or structural. Administrative functions should not be use SNOMED-CT concepts.

It is proposed that everything under act code should be SNOMED-CT, LOINC or other relevant representations. There is a need to identify the scope of value sets (nearly 2,000 of them) that need to be managed by HL7 it is estimated that 25% are candidates to be deprecated and use other terminologies such as SNOMED-CT .

Policy: That a policy be adopted that we will not accept context bindings to be registered where the target vocabulary is one of the value sets which should no longer be represented using HL7 vocabulary.

In order to implement this policy there must be an assessment of each value set at harmonization and progressively identify those value sets which need to be deprecated. We identify one by one the sets that are like this and we review one by one at harmonization and if we find any we undertake to get them changed in the models

It is acknowledged that each case will need to assess what RIM or Model changes will be necessary to support this change.

An effort should be made that the things that HL7 should be deprecated, but due to the consequential changes the vocabulary working group does not have volunteer cycles to complete the task completely – though they are prepared to identify priority value sets. Reviews will also occur at harmonization. There will need to be input from the domain experts to evaluate and identify solutions.

The preferred definition for deprecated is:

A specification that should be avoided as it no longer has a meaningful purpose or has been replaced by a better method or concept.

The details of this definition can already be found at www.skmtglossary.org an open web site for accessing and accessing health informatics standards based terms and standards.

Harmonization will not allow people to build code systems on deprecated value sets without significant issues.

## 28.8 GLOSSARY

Heather Grain presented a demonstration of the online glossary. The features include the ability to search for by a number of filters including: by document, by organization.

It was agreed that terms with harmonization proposals will be sent to the list for consideration and recommendations.

Heather reported that procedures are in place within ISO for glossary term management and harmonization. These have been explained and accepted by the executive of TC215 (which includes all country Head of Delegations and all Convenors and Vice Convenors). WG3, WG4 and WG1 have been actively working with the glossary. It is intended that all documents that come through for ballot in the next round will be thoroughly vetted to make sure that they have complied with glossary requirements. It was also reported that these working groups have identified that the workload savings of being able to find and use existing relevant definitions have been real and that it is currently revenue neutral i.e. it takes as much time to check the glossary before balloting and where necessary undertake harmonization, as it used to do to hunt for or create new definitions. Woody Beeler requested that ISO secretariat be requested to confirm that all ISO WGs understand the new processes required of them by the SKMT glossary procedure. He also expressed considerable concern regarding the HL7 workload and control processes. These were acknowledged and were represented as relevant reasons to develop a trial process before formal commitment. The issues raised by Woody Beeler did not receive active support within the meeting but will be addressed in order to reduce the risk to the project with HL7.

An update scope statement has been prepared, and active support has been confirmed with other HL7 working groups.

## 28.9 IHTSDO WORKBENCH

Ross explained that this project is to produce and evaluate a technical map from HL7 MIF vocabulary to the IHTSDO workbench model. It is a pilot project. There are no resources available.

Ideally this is work that needs to be done in manageable chunks and an opportunity to find some relevant documentation to support the process.

# APPENDIX A – ROADMAP 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.

# APPENDIX B - HL7 AROUND THE WORLD

A summary of HL7 Affiliate issues and priorities from the 25 countries in attendance is as follows.

## HL7 ARGENTINA

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

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

A series of training courses have been held or are planned for 2010, including at the Argentinean Congress of Health Informatics; HL7 Argentina participated in IHIC; and Spanish version tutorials are being conducted at this WGM (HL7 Argentina is providing 3 speakers and Spanish materials).

HL7 Argentina will also be proving certification testing in Buenos Aires in July 2010, for CDA R2, the RIM and V2.

## HL7 AUSTRALIA

HL7 Australia's strategic plan 2010-12 (available at http://www.hl7.org.au/) was presented. Key initiatives include more systematic education and training; an "ambassador" program; continued support for standardization; support for certification; a review of online capabilities; greater collaboration with Affiliates in NZ and the Asia-Pacific; building the membership base and visibility of the organisation; and improving governance.

Highlights of recent health reforms (funding system and governance changes; resourcing) and major developments regarding e-health (national identifiers; personally controlled EHRs) were also reported.

International Council members were reminded about the January 2011 WGM in Sydney.

## HL7 AUSTRIA

HL7 Austria has established 3 Technical Committees, on Version 2.x, Version 3 and Terminology. Its recent activities include the Annual Member Meeting and Conference (April 2010); and establishment of an OID-Portal (Registry and Repository) for the Austrian Health Care System.

HL7 Austria collaborates with the Austrian Standards Institute, IHE, GS1 and ProRec. It is engaged in projects with the Ministry of Health and the ELGA Company.

ELGA is to be the Austrian personal health record. It contains relevant health related data and information referring to a precisely identified person. These data and information originate from different health service providers and from the patient himself/herself, and are stored in one or several different information systems (a virtual health record), in compliance with data protection rules.

Highlights of Austria's e-health roadmap include:

- 2005 - "eHealth initiative" with 150 national experts in 6 groups
- 2006 - Feasibility study for a nationwide EHR
- 2007 - Masterplan, Architecture, selection of standards
- 2008 - Start of development of CDA implementation guides
- 2009 - Warning system for drug interactions (released by pharmacies); National critical incidents reporting system
- 2010 - "ELGA Company" created, responsible for EHR implementation, and

- Near future - Legal Basis: "ELGA Law"; roll out of ELGA basic functions (Technical infrastructure): Master Patient Index, Healthcare Provider Index, Registry.

HL7 Austria also cooperates with other German speaking affiliates (Germany and Switzerland) and they jointly publish a journal – "HL7 Mitteilungen".

## HL7 BOSNIA AND HERZEGOVINA

E-health is not well advanced in Bosnia and Herzegovina. Currently, a typical user of healthcare digital databases will struggle with data storage. It is common for individual IT subsystems of a single healthcare institution to be incompatible, let alone between institutions and divisions. Outside the hospital campus, the only exchangeable data will be conventional administrative data. There is a lack of strategy for standards implementation.

Accordingly, HL7 Bosnia and Herzegovina was established in 2010. Its mission is to advocate for and raise awareness on the necessity to implement HL7 standards in healthcare - to allow data exchange between healthcare institutions and their communication with appropriate government health authorities. The organization will take establish basic systems for the implementation of proposed standards.

HL7 Bosnia and Herzegovina is currently seeking Affiliate status.

## HL7 BRAZIL

HL7 Brazil is hosting this WG and hosted IHIC 2010 (which featured HL7 v2.x and 3.0 messages; CDA; Imaging, Diagnostics and DICOM; use of HL7 in IHE profiles; terminologies, ontologies and coding systems; and the use of HL7 standards in conjunction with others from ASTM, ISO and CEN.

HL7 Brazil's key activities include and OID Registry, the HL7 Brazil Newsletter, an HL7 website and a series of HL7 Systems Projects:

- SIGA SAUDE - SMS-SP: An HL7V.3 Laboratory Integration System (orders, results) handling 2.7 million exams per month (CDA based).
- TISS: Brazilian National Health Electronic Data Interchange in the Private Health Insurance Market.
- TUSS: Unique Terminology for Complementary Health.

HL7 Brazil is also engaged in a University based learning program and conducts an e-learning course in Portuguese.

HL7 Brazil collaborates with HL7 Argentina, HL7 Uruguay, HL7 Chile, HL7 Colombia, HL7 Mexico and HL7 Venezuela under a joint HL7 Latin America Board.

## HL7 CANADA

The Infoway Standards Collaborative continues to develop, maintain and integrate pan-Canadian message & terminology specifications. A delta-release of various pan-Canadian specifications (based on HL7 v3) took place in March 2010.

The Collaborative recently held its Spring Partnership meeting. These semi-annual meetings of HL7 Canada also include ISO and IHTSDO Constituencies. Ten domain-based Working Groups meet in-person over 3 days, deliberating messaging, terminology and related health informatics standards. The meetings attracted 200+ stakeholders. See http://www.infoway-inforoute.ca/lang-en/standards-collaborative/partnership.

## HL7 CHILE

In August 2009 the SIDRA Project (Clinical Information and integrated Systems for Healthcare Network) commenced. There are now projects in 16 of the 24 Chilean Regional Health Services.

The new Chilean government (March 2010) intends to develop a Digital Agenda 2.0, with a focus on standards.

Two workshops are planned for 2010 - Standards for HealthCare without Paper in Chile, (June) and Standards for better quality healthcare (September).

## HL7 CROATIA

HL7 Croatia has a strong connection with the Croatian Society for Medical Informatics, the flagship organization for medical IT experts and also has and liaison with many European projects and initiatives.

HL7v3 is the standard of choice and there is strong commitment to it by the national eHealth infrastructure. However, a key issue is lack of resources for knowledge sharing and awareness-raising.

Croatia's e-health program is 7 years into development and production (see http://www.cezih.hr/). Its current status can be summarized as:

- All GP's (cca 2300) are connected to a central network using different dedicated solutions that are certified by the Croatian Institute for Health Insurance (CIHI)
- The system is operated a by dedicated department at CIHI, and connects to public health authorities and pharmacies
- Coverage includes most important administrative and medical processes
- ePrescription and eReferal are starting parallel operation in 2 (out of 21) counties. Coverage will be gradually increased during 2010. Nationwide launch is expected on 1st January 2011
- All specialist PHC offices (dentistry, gynaecology, paediatrics and school medicine) are to be connected until by January 2011
- eReferral (incl. Discharge Letter) to specialist care is expected to be in full operation by 1st January 2011, and
- Communication is fully facilitated using HL7v3 messaging.

An e-health conference is to be held in Zagreb in September, organised by HL7 Croatia, the Croatian Society for Medical Informatics and the Slovenian Medical Informatics Association. This will feature presentations and workshops on HL7, IHE, EUROREC/PROREC, the epSOS project; with contributions from industry, Government and not for profit organizations.

## HL7 FINLAND

HL7 Finland Affiliate was founded in 1995). The first implementation projects of HL7 version 2.3 began in 1998 and V 2.3 messages are still in quite heavy routine use. The first CDA implementations (R1) began in 2003. Some insurance companies use CDA R1 to transfer health care related information.

In 2005 CDA R2 was selected as a national standard by Ministry of Health and Social Affairs. Implementation guidelines and other papers have been published in a Document archive (see front-page of www.hl7.fi ). Implementation guides for many new domains (CDA R2 body) are ready now (but still need some quality checking). These include updates on eReferral and discharge and purchased services. Latest approved specifications include medication, imaging consultation and exchange of pdf documents.

HL7 Finland actively supports national projects such as IHE, Laboratory, Document, Common Services and the Continua Health Alliance.

A National ePrescription Center is now operational and joining organizations (hospitals, health centers, pharmacies) are in implementation, testing and contract phases. A national project support office is in operation and HL7 V3 Web Services profile, HL7 V3 Medical records and CDA R2 implementation guides are stable.

National e-health architecture is based on a centralized repository service for both the ePrescriptions and eArchive. The solution employs service-oriented principles and synchronous web service interfaces to transfer HL7 V3 messages. The HL7 Web services transport profile has been applied. The transferred data is encrypted using two-way authenticated SSL/TLS connections. All the transferred CDA R2 documents are signed with W3 Digital Signature. If third-party service providers mediate messages, Web Services Security X.509 token profile is planned to be required for the authentication of the end user organization (however not in use yet).

The National Insurance Institution (Kela) now arranges specification work for national services. HL7 Finland delivers some support services and QA. This year 2010 Kela will also provide an HL7 Help Desk, because most of the questions are related to national services.

There are also plans for implementation guides for social services messaging, following the eArchive Medical records approach but with a different (non-HL7) payload. More information can be found also on at the Kela website (www.kanta.fi).

A small interoperability demonstration using IHE profiles is being arranged for the national healthcare IT event in the end of May.

## HL7 FRANCE

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

- An IHE Connectathon was in France
- An InteropSanté plenary was held on May 11th, and
- A meeting about Terminologies was held on May 19th.

An electronic Pharmaceutical Record is currently being implemented across France.

## HL7 GERMANY

HL7 Germany places substantial emphasis on visibility at and contributions to conferences, seminars, etc. 2010 activities include:

- conHIT 2010 in Berlin
- The Hospital Information Systems Conference of the German Medical Informatics Association in Berlin
- EFMI STC 2010 in Reykjavik
- ICMCC - International Council on Medical and Care Compunetics 2010 in London (www.icmcc.org), and
- The German Medical Informatics Conference 2010 in Mannheim.

However, this strong academic orientation is now changing towards an industry focus. Accordingly, HL7 Germany intends to develop a broad spectrum of membership from vendors, health service providers, decision makers, research and development.

Recent activities include:

- Close Collaboration with IHE, HL7 and DIN in the German eHealth standards collaboration and eHealth Interoperability Forum
- Continued participation in the European epSOS project
- Continued translation of v2.5.1 and v2.6
- Production of new Implementation Guides for eNursing Summary and Diagnosis including Cancer (TNM classification), and
- Implementation guides under construction: Pathology report (together with IHE QRPH and the German association of pathologists); Cancer Registry Reporting: Workgroup established with DKG (German Cancer Association) and VHitG; and Infectious Diseases.

## HL7 GREECE

HL7 Greece's activities to date in 2010 include:

- Participation in the CALLIOPE project, which is creating a European coordination network for eHealth interoperability implementation and a European eHealth Roadmap. HL7 Greece participated in Plenary meetings in March and May 2010; and in a CALLePSO Working Group meeting (a joint working group with EPSOS, a large scale EU pilot on ePrescription/Patient Summary) in February 2010.
- Participation in the Digital Health Group, jointly with the Athens Medical Society. This started in March 2010 with equitable participation of the HIT and Health Professional communities in Greece. It comprises a multidisciplinary approach focusing on establishing a common language and promoting awareness, education and training.

- The EHRQTN Information Day, which focused on Certification of EHRs (jointly with EuroREC).

Future priorities for 2010 include a General Assembly in June and a Conference in Winter.

## HL7 HONG KONG

HL7 Hong Kong was inaugurated in October 2009. Its establishment is recognized as one of the most important milestones in unifying e-health development in Hong Kong. Priorities for 2010 include:

- Instructor-led Training – to infuse the IT sector with fundamental HL7 knowledge. Over 100 professionals will be trained on V2, V3 or CDA; and over 200 professionals will be trained on HL7 adoption and practical applications of EHR standards in Hong Kong.
- A Membership Drive - HL7 Hong Kong membership categories comprise Sponsor Member, Corporate Member, Individual Member and Associate Member (Individual/Organizational).

## HL7 INDIA

A new HL7 India web site was released during the First Annual General Body Meeting of HL7 India in March 2010.

HL7 India's plan for 2010 includes:

- Ensuring financial stability and independence
- A focus on education, memberships and certification for enhancing growth, including conducting HL7 examinations (version 2.6, 3.0 and CDA R2)
- Standard certification processes - creating a group (Certification body) with Indian government participation;
- Advertise meetings (like Technical committee meetings) to attract international participation from HL7 Inc and Affiliates, which can help execution of such projects
- Project Planning for creating standard IHE and EHR profiles, for Indian product vendors to enable certification, and
- Planning of road shows for promoting HL7 further, with involvement of HL7 Ambassadors.

## HL7 ITALY

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

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

New Groups have been established for SOA Architecture in Healthcare and Patient Administration. Groups under discussion include Guidelines for XML Signature of a CDA document; Social care (production of a white paper); and RIM Based Application Architecture (RIMBAA).

The HL7 Italy Annual Assembly will be held in Bologna on 29 May.

## HL7 JAPAN

HL7 Japan's activities in 2010 include development of a CDA R2 Referral document and a v2.5 message for prescriptions and lab examination results, disease classifications; working with IHE on the transfer of images and with MFER for waveform; development of drug codes (HOT) and laboratory exam codes (JLAC10). These standards are supported by the Japanese Government - ".. You can use others, but you will not be awarded subsidy from the Ministry."

HL7 Japan also participated in a JAMI (Japanese Medical Institute)/Ministry roadshow (teaching Ministry HIT standards and possible applications.

The Japanese Government has created a Regional Healthcare Revitalization Fund totalling 300 billion yen, with 10-15% to be invested in HIT and awarded to 90 regions.

## HL7 NEW ZEALAND

New Zealand's first "true" CDA project (pharmacy dispensing) has gone live in pilot - a regional repository of all medication dispensing from community pharmacies available to primary and secondary care clinicians through the Sysmex eclair repository.

The Government has re-formed the Ministry of Health including establishment of a National IT Board. This will have much more national focus and central control and will be very clinically driven. It has produced a draft national plan and is working closely with the sector. There are very aggressive timeframes. The plan notes that at one point New Zealand may have been leaders in health IT, but this has plateaued in recent years. The plan emphasises standards as key to progress - HL7 v3 (CDA/CCD) in particular; specifically endorses CDA for a GP2GP project, and specifically endorses HL7 NZ as 'guardians of the standard' (in GP2GP).

GP2GP is seen as the most urgent project (medications management is a close second). The aim is to be able to transfer the entire record in a structured format. However, the project is being conducted in haste (2 weeks to develop the first draft!); there are 4 PMS vendors, all with different data models and different levels of capability; and experience is limited.

## HL7 NORWAY

HL7 Norway's Affiliate application was approved on 12 April 2010. Interim leadership is in place and is setting up budgets, establishing member dues rates, secretariat and working groups.

Work program priorities include training of a V3 expert group (10 people are in training); local and national projects; coordination of ongoing HL7 activities in Norway; harmonization of implementation guides; and collaboration with the national standardization body.

Regional HL7v3 implementation guides have already been developed for Patient Administrative and Document Administration Messages. HL7 Norway has now established a process to convert these regional implementation guides to national implementation guides in collaboration with the national standardization body.

Planned developments include:

- Extensions to Encounter Management - to support use cases related to Clinical Portals, and
- Extensions to Person Registry - to support use cases related to national service for auxilliary patient identifiers.

A National e-Health Record Project is commencing, taking an evolutionary approach starting with medication information. Discussion is underway on which standards to use for interoperability between primary and secondary health care, e.g. 13606/CEN/HL7.

## HL7 PAKISTAN

Key HL7 activities in Pakistan include:

- The HMIS Territory Healthcare Level Project – deploying HL7 based systems at three public hospitals in Lahore and Islamabad.
- Development of a Training System for Laparoscopic and Robotic Surgery using HL7 for communication.
- The eHAP Conference, supported by the Pakistan eHealth Association and featuring an HL7 Tutorial and Papers.
- The IEEE FIT Conference, organized by Comsat Institute. This featured tutorials on HL7 V3 Modeling and HL7 V3 Implementation challenges.

A Semantic Systems Research Group (SSRG) has been established, with 42 PhD, Master and Undergraduate Students. Its projects include:

- Database to RIM Mapping Tool - semi automation about 30-40% of relational schema to the RIM
- Semantic Process Interoperability- SHIP Project - Based on interaction ontology from HL7 and Semantic WS platform WSMO
- HL7 v2 to HL7 v3 Convertor – an ontological approach to overcome behavioral aspects of HL7 v2 and v3, and

- HL7 Services on Cloud Infrastructure - exposing existing solutions on the cloud to reduce costs and IT insensitivity in non-IT organizations.

HL7 Adoption is increasing across the public and private sectors, and localization will be needed for region-specific data contents.

## HL7 RUSSIA

Current priorities include:

- HL7 version 2.5 and CDA Release 2 - Being ISO standards, these may become the Russian national standards in 2011. HL7 Russia is promoting them to TC 468 "Health Informatics" of GOST R.
- HL7 Version 3 if the Russian Ministry of Healthcare buy Oracle Healthcare Transaction Base licenses for RHIOs.
- Inter-regional eClaims – These are associated with mandatory Medical Insurance, and are based on V2.6 Chapter 16, E01/E10 Events. Z-segments will carry digitally signed human-readable documents.

## HL7 SINGAPORE

HL7 Singapore is revamping its website to include a content management system. In the future, event registration and payment capabilities will be added. Core activities include:

- A Standards Sharing and Networking Event (June 2010).
- Introduction of eLearning (Q3 2010) - Internet based, tutor monitored, self study, with one cycle every 6 months. The first cycle will cover Module 1: Introduction to healthcare interoperability, vocabularies, UML, XML and Module 2: HL7 V2.X.
- Future offerings will include HL7 V3, HL7 CDA R2 and HL7 certification.

Singapore's e-health directions include a National Electronic Health Record; Population Health Management / Care Continuum; Central Clinical Data Repository (CCDR); and Clinical Documentation. The core standards to be used are HL7 V2.X, CDA, SNOMED CT and ICD10-AM.

## HL7 THE NETHERLANDS

Priority activities underway in The Netherlands include increasing membership – HL7 The Netherlands now has more than 230 members; supporting ongoing V2 in hospitals; more V3 projects, mainly NICTIZ; moving forward with a CDA Header Guide; publication of a V3 Datatypes/CMET Guide; and work on a Dutch "How to V3" guide.

Other work in progress includes the production of an HL7 v2 Implementation Guide (NEN 7504:2010 – Dutch National Standard) for Communication of blood type, as well as work on Order entry and communication, Care provision for several domains and Extension of medication management.

HL7 The Netherlands has been looking at its roles. Arguably, too much time is spent on national projects for future requirements, and not enough time on day-to-day problems which members run into.

A series of courses have been run this year, on EHR-S and the Behavioral Health Profile, HL7 version 2 and HL7 version 3. Upcoming events include:

- A thematic conference on HL7 v2, covering Communication of Civil Service Number and Identity Checks; Working with the DBC-Grouper for a new finance regime; and Scheduling and appointment lifecycles
- A special conference on Modelling Clinical Information with Stan Huff (Intermountain Healthcare)
- A meeting on Architecture in Healthcare, jointly with IHE Netherlands and the Dutch Architecture Forum, and
- The National HL7 Conference (December).

## HL7 UK

HL7 UK conducted its Annual Conference in March, entitled "Healthcare Connections – The Next Decade". There were around 25 speakers and 4 tutorials, and around 100 delegates.

Current educational activities include:

- Universities Engagement - Teaching is now completed for the first full academic year in 4 universities, and funding is approved for the next academic year. There are plans to increase number of universities, and HL7 U.K. is looking for commercial sponsors.
- Training courses for v2 and v3.

HL7 UK is updating the NHS Interoperability Toolkit (UK v2 profile) to reflect changing requirements, and planning to ballot the new version later this year.

## HL7 URUGUAY

HL7 Uruguay is holding four workshops during the year, for doctors, nurses, informaticans and technicians.

HL7 Uruguay is also working with the Health Ministry to define the basic interoperability to improve the National Health System.

## HL7 USA

The HL7 V2/V3 Strategy Task Force is continuing to assess the current situation with respect to V2 messaging, V3 messaging, CDA and SOA Interoperability. It will identify options for moving forward, make recommendations and develop a Plan by June-July this year.

Major issues in the USA include:

- Meaningful Use and ARRA incentives, and
- HL7's role and its relationship to Office of the National Coordinator, especially with respect to the standards development framework proposed by ONC and the maintenance of value sets and terminology distribution by an agency or department within the US government.