

**Final Report on the
HL7 Working Group Meeting
held in
Phoenix Arizona,
8-13 January 2006**

This Report was compiled by David Rowlands, Executive Chairman, Standards Australia's Health Informatics Technical Committee (IT-014) from material supplied by all Australian representatives at the Meeting

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Executive Summary

The first HL7 Working Group Meeting for 2006 was held in Phoenix, Arizona from 8 to 13 January. Australia was represented by seven experts, funded by the Department of Health and Ageing, DHS Victoria and NEHTA. Total attendance exceeded 575 people from 19 countries.

The HL7 organisation is currently undergoing a strategic review. Transition to "HL7 Global" with the creation of an "HL7 USA" Affiliate is envisaged. The implications for Australia will need to be identified and managed.

HL7 V3 was finally officially released in November 2005 and a major focus is now on V3 education, implementation and V2.x-to-V3 mapping. However, V3 "ballot fatigue" remains a major issue in the HL7 community. The Organizational Review Committee has made recommendations to address this, including reducing the number of ballot cycles per year. The HL7 standards development and implementation community is growing world-wide, with most Affiliates reporting membership growth and local or regional education initiatives. HL7 is also increasingly becoming part of national government programs.

Major areas of HL7 standards development activity include Services, the Electronic Health Record (EHR), Archetypes/Templates and Patient Care/Aged Care/Community Health. These align well with Australia's national e-health agenda, and Australia now co-chairs many of the relevant committees and groups, enabling substantial strategic influence.

Continuing international harmonisation is also a focal point - archetypes, templates, clinical statements, data types, General Purpose Information Components (GPICs) and Common Message Element Types (CMETs) need harmonisation, mapping and/or interrelation.

Australia is well positioned to lead international work on constraint mechanisms, transport of archetypes and harmonisation of EHR and clinical messaging standards, and is also providing direct input into the strategic positioning of both HL7 and ISO. Australian positions on many of these issues are therefore required as a matter of urgency. Development of these positions must take into account strategic directions emerging from NEHTA, and should be developed in conjunction with NEHTA.

A submission is being prepared from HL7 to the US National Library of Medicine for funding a proof of concept for creating HL7 templates for a master set of data elements and mapping these to the HL7 RIM. This work has many similarities with NEHTA's Clinical Information Initiative. There is potential for international collaboration.

It should be noted that considerable work is being undertaken in the USA on developing conformance criteria. This may also need to be factored in to Standards Australia's work plan.

Overall, sound progress was made towards the achievement of Australian objectives for international standardization, and it is recommended that Australian participation in HL7 Working Group Meetings be sustained.

1. Introduction

The first HL7 Working Group Meeting for 2006 was held in Phoenix, Arizona from 8 to 13 January.

Seven Australian representatives were present. David Rowlands, Richard Dixon-Hughes, Heath Frankel, Dick Harding and Klaus Veil represented Standards Australia, funded by the Australian Government Department of Health and Ageing. Max Walker attended with the support of the Department of Human Services, Victoria and Robert Wood with the support of the National E-Health Transition Authority (NEHTA).

International standardization objectives for 2005-06 are appended to the Funding Agreement between the Australian Government Department of Health and Ageing and Standards Australia Limited, and these guided Australia's participation.

2. International Affiliates Meeting

Seventeen countries were represented at the International Affiliates meeting, out of a total of 31 HL7 International Affiliates. Chile and Sweden have recently been accepted as Affiliates.

Updates presented included the following:

HL7 V3 – the first normative edition was released at the end of November 2005.

HL7 implementation - work is underway on V2/V3 mapping and capturing/developing best practice in migration between the two.

HL7 education – a competency framework is being developed as a precursor for development of learning objectives, curriculum and accreditation processes. A plan has been prepared to develop a professionally-produced e-learning package at an introductory level on the topic "What is HL7". It will be freely available and widely distributed. The Board is being approached to provide funding for this.

Services specification – the services group is very active and is developing four specifications (record location and retrieval services; common terminology services; entity identification services; and decision support services). An infrastructure group is working on how these are specified (methodology, templates etc). The aim is to ballot the entity identification services in the May 2006 ballot cycle; record location and retrieval and common terminology services in the September 2006 cycle; and the decision support services in January 2007. These will also be taken through the Object Management Group (OMG) processes, as these are collaborative projects. A workshop will be held in the UK on 31 January 2006 to look at this agenda in relation to the NHS program (see HL7 UK site). There is also a degree of informal collaboration and cross representation with the OASIS group.

HL7 V3 early adopters – an online HL7 artifacts register is managed by the National Institute of standards and Technology (NIST), at www.nist.gov/hl7xreg, for capturing details of contacts, projects and work products. This is operational but is being extended to provide an enhanced search capability by theme, topic and technology and to allow retrieval of all documents associated with a given project.

ISO TC215 Report (presented by the Chair of TC215) – ISO TC215 has published 24 health informatics standards and another 70 are under development. A Global Health Information Technology Summit was held in September at Hamamatsu City, Japan and presentations are available on the HIMSS website at www.himss.org/ASP/topics_FocusDynamic.asp?faid=134. A strong theme for TC215 is harmonization of standards and activities across international standards organizations. The activities the TC are being aligned with the 10 objectives of the ISO Strategic Plan 2005-10.

CEN TC251 Report – the leadership and secretariat of TC251 has shifted from Sweden to the Netherlands, with the new Chair being Mr Kees Molenaar, CIO of the Dutch Health Inspectorate. These shifts have resulted in lags in updating the TC251 website. The EN13606 Part 1 (Electronic Health Record Communication - Reference Model) ballot has closed with strong overall support, apart from Norway. An updated standard on Units of Measurement in Healthcare (EN12435) is about to be published but has already been recognized as defective and will be rapidly revised. It was particularly noted that it does not provide for compatibility with commonly used international measures that are supported by HL7.

HL7 EHR TC – a Glossary has been developed for the EHR System Functional Specification, and international input is specifically requested to ensure its widespread applicability.

Strategic Review Committee – a market segmentation survey document has been issued to assist the Committee to understand how HL7 standards are being applied in different realms. International input is requested. More detail on the Strategic Review is provided in Section 17 below.

European Union (EU) projects –

- There are 16 HL7 Affiliates in Europe, and there is a desire from HL7 for consolidated EU perspectives on key issues. Various options were canvassed.
- A key EU “umbrella” project is the Action Plan for e-health in the EU – the objective is to accelerate awareness & uptake of e-health as an enabler of improved health services and outcomes. The main areas of activity are national/regional roadmaps (by end 2005); common approaches to identification and EHR interoperability standards (by end 2006); and boosting investments in e-health, conformance testing & accreditation (by end 2007).
- The establishment of an EU e-health standards strategy group is currently being discussed. Specific EU standards development priorities include developing patient summaries, provider and patient identifiers and emergency data sets.

Realm localization – the HL7 Publishing Committee has agreed to host localized material, either for ballot or as realm specific standards. Parameters for holding and accessing realm standards on the HL7 publishing databases are currently being developed.

International Affiliates Co-Chairs election – 4 co-chairs are required, with the nomination period ending in March, online elections in April, and new co-chairs to be in place for the May (San Antonio) meeting. Current co-chairs can run again.

The May 2007 HL7 Working Group meeting is planned to be held outside the USA. Berlin was selected by majority of International Affiliates which responded to a request for selection of a preferred candidate. A detailed feasibility study is now being undertaken.

The 2006 International HL7 Interoperability Conference (IHIC), which was formerly known as the International Affiliates meeting, will be held in Koln, Germany on August 24-25. This will be contiguous with the Medical Informatics Europe (MIE) Conference, from 27th-30th in Maastricht, Netherlands.

HL7 in Latin American countries – collaboration is building within South America with a view to economical distribution of HL7 related material to Spanish speaking countries; and providing education, implementation and certification initiatives. There are currently 3 Latin American Affiliates, but a range of other countries are interested.

Organization review/ballot fatigue – the evolution of V3 specifications has been positive in terms of engagement of implementation projects and proving the V3 methodology. Negative aspects have included difficulties in seeing the big picture (reviewing the entire V3 ballot package) and ensuring consistency between domains. The Organizational Review Committee has reviewed these issues and recommended:

- Improved model design and descriptive text in ballot materials.
 - Automated ballot change tracking – this requires toolset improvement, but an interim solution can include manual document highlighting.
 - Visual presentation of ballot context status – e.g. normative/informative; ballot stage.
 - Wide distribution of ballot progression (scheduling) information.
 - Reinforcing the need for cross domain harmonization.
 - Reducing the number of ballot cycles per year – business process review of HL7 ballot cycles suggests 6 months is needed from announcement to reconciliation, so migration to 2 cycles per year is being considered.
- Membership seems evenly divided on whether it is advisable to reduce the number of ballot cycles in any year.

2.1 International Affiliate Reports

USA – the dispute with ASTM re the Continuity of Care Record (CCR) has been substantially resolved. A collaboration between HIMSS and ANSI will actively drive harmonization of health informatics standards in the USA – this is seen as one of the

key elements of interoperability. Other keys include certification (via CCHIT); development of a national privacy platform; and National Health Information Infrastructure architecture projects.

Australia – (presented by David Rowlands as Klaus Veil's arrival was delayed). HL7 Australia has conducted successful education/conference/workshop activities focusing on vocabulary, *openEHR* and constraint mechanisms. Closer and more formal collaboration between HL7 Australia and *openEHR* is being built.

Canada – HL7 Canada held a successful education summit. Options for a new health informatics standards organization are being canvassed to consolidate governance of all relevant standards activities nationally and oversee implementation of health informatics standards. HL7 Canada's membership is growing (now 300+), and its priorities include provider and patient identification, security and terminology.

France – HL7 France has translated the HL7 primer into French. A CDA group has developed its first output, prepared for the national EHR project and with support of the French software industry. Other activities include IHE, other translations, and pharmacy messaging.

Finland – is finalizing CDA Release 2 Implementation Guidelines, conducting training activities, and developing a V3 implementation guide. HL7 Finland strongly supports the Services work being undertaken by HL7/OMG services.

Germany – national telematics organization established, with substantial focus on HL7. Priorities include national e-prescription, standardized doctor reports.

Czech Republic – the main focus at this stage is awareness raising.

Japan – HL7 Japan now has 125 corporate members and 150 individuals. It has conducted seminars on her standards, "what's new in health informatics standards" and V3. It has established a SIG on CDA and prioritized work on patient referrals. New projects on ehr interoperability and identification are being established.

South Korea – 2 meetings have held, both well attended (100+) and educational in nature. Topics included CCOW, V3 and the RIM. The RIM has been translated into Korean and included in national standards documentation. V3 specifications are being developed for national discharge summary work. Approximately 30 people are certified in V2, and a Graduate School has included HL7 in its health informatics curriculum.

Netherlands – national e-health program priorities being rolled out this year include discharge summaries and GP consultation reports. All hospitals will have to implement orders and results by the end of 2006, and it is hoped that this will precipitate a move to latest available V2 (at least 2.4). A new national project on child health has been established, focusing on immunization & request was made for info about any other national e-health projects on child/youth health.

Spain – hosted an HL7 awareness session for Mediterranean countries, which was well attended. HL7 Spain is 2 years old and membership is small but growing. A Technical Committee has been established.

Taiwan – the 5th Asia-Pacific & Cross Strait HL7 Conference is to be held on 7-8 July 2006 in Taipei. Its focus will be HL7 focus is implementation.

UK – membership is stable. The Implementers Group is picking up and provides a sound feedback mechanism for HL7 standards developers. There is recognition from industry that standards are required beyond those directed by government, and they are engaging. A series of workshops is being held to advance initiatives seen as key to HL7 V3 implementation – specifically services, CDA and tooling.

Mexico – workshops have been held re awareness of standards. Mexico is looking at a national SNOMED license.

No reports were received from Belgium, Hungary or Israel.

3. International Harmonization Meeting

A working session between representatives of ISO, CEN and HL7 was held to discuss harmonization and this is expected to become a regular event at each HL7 Working Group meeting.

There are a series of topics that are being addressed in multiple standards development organizations that need to be well coordinated. These include:

- EHR architectures and requirements.
- EHR archetypes, templates, clinical statements, etc.
- Data types.
- General Purpose Information Components (GPICS) and Common Message Element Types .

Another issue is the ongoing emergence of new players, often with little explicit recognition of work in progress – a recent example is the initiative driven by IEEE in association with some bioinformatics industry players who have declared that they will work to standardize “everything from medical terminology to networking protocols so that medical records can be stored electronically and sent instantly anywhere in the world¹”.

Discussion focused mainly on the archetypes/templates issues and data types.

Since the last HL7 Working Group meetings, the HL7 Templates SIG has been looking in detail at CEN and *openEHR* archetypes. Unofficially, there seems a high degree of consensus that they could be adopted as templates subject to relatively small clarification/extensions. There was substantial discussion and a sentiment that 80-90% of the representations of clinical concepts for EHRs can be generic, while the remaining effort is in specifying the technical artifacts required for their instantiation in HL7, CEN, *openEHR*, etc. It was agreed to continue the comparison of archetypes and templates and begin to articulate the generic versus the technically specific components within the Templates SIG; and to refer questions of how the generic components could be governed to an ISO Planning meeting to be conducted later in the week. This group should also consider archetype/template registries.

¹ T.E. Bell, 15 February 2006, [Medical Records: From Clipboard o Point-and-Click](http://www.boldfish.ieee.org/u/1259/00473348), IEEE, available at www.boldfish.ieee.org/u/1259/00473348

At the Berlin ISO meeting, the decision was taken to develop a 3 part standard on data types. Part 1 will be a restatement of basic data types, but reformatted into a form more useful and standardized for healthcare. The same formats will be used for Parts 2 and 3. Part 1 has now been drafted. Parts 2 and 3 will both map to Part 1, but not necessarily to each other. Part 3 will be HL7 data types, and this can be produced quite readily. Part 2 is more problematic. It will comprise an amalgam of other data types emerging from a variety of jurisdictions and other sources, and will require significant and focused work to compile, reformat and negotiate. All three parts are needed simultaneously. All can be delivered in draft for discussion to the April 2006 ISO TC215 meeting, but only if financial resources can be provided to enable the development of Part 2.

It was agreed that issues around GPICs and CMETs should be deferred until after the templates work is progressed, since GPICs contain some of the characteristics of templates.

4. Technical Steering Committee

Motions were approved for the:

- Establishment of Anatomical Pathology SIG.
- Progression of Services "Birds of a Feather" to the "Service-Oriented Architecture SIG.
- Ballot schedule for 2006 – key dates include ballot content closure on 19 March, 23 July, 19 November for the three 2006 ballot cycles (balloting dates 26 March-29 April; 30 July-2 September; 26 November-31 December). This included both 2.6 and V3 as well as other HL7 standards artifacts.

For information:

- The Message Development Framework (MDF) is obsolete, and the HL7 Development Framework (HDF) has now been developed to the point where it can add value to HL7, and using it will assist its further development. The project initiation and specification approval sections are ready for use.
- The 2006 edition of V3 adds in normative content for registry messages, personnel management messages, and some additional CMETs.

5. Board Meeting

This meeting marked the commencement of Charles (Chuck) Meyer's two-year term as HL7.org Chairman. His background is standards manager for a large vendor (McKesson) and also HL7.org's liaison to other government and standards organisations.

The Board confirmed 14 board-appointed committees (Architectural Review, Education, Electronic Services, Finance, Marketing, Organisational Review, Process Review., Publishing, etc.) as well as the positions of TSC Chair (John Quinn) and TSC Vice Chair (Ed Hammond).

An update from was received from external consultants conducting the Strategic Planning Initiative. After extensive verbal and written interviews, two workshops and many teleconferences, they have distilled nine draft recommendations – see Section 17 below.

The draft recommendations were well received and brisk progress on the re-organisation is expected.

In other business, HL7's participation in HIMSS 2006 events was confirmed and MoUs with the following organisations advised: ADA, ASTM, CDISC, CEN, DICOM, eHI, IEEE, IHE, MedBiquitous, NCPDP, OASIS, OMG, SNOMED and X12.

Note: Klaus Veil commenced his 4th two-year term on the Board as the only non-US directly-elected member.

6. EHR TC

A Co-Chair election was conducted. 86 ballots were cast and David Rowlands was elected.

Draft Conformance Clauses and a "How To Guide" for developing conformance criteria for the EHR-S DSTU have been balloted at the Committee level. In overview:

- Some confusion in scope was evident – i.e. what should be in the functional model vs. profiles (granularity).
- 88 votes were returned from 101 enrolled parties – 25 in the affirmative, 56 negative, 7 abstentions.

EHR TC sub-groups/work items include:

- Certification – the US certification agenda, led by the Certification Commission for Healthcare Information Technology (CCHIT) has seen groups set up in the US to look at functionality, security, interoperability, and certification processes. The US certification priorities are ambulatory EHRs (Year 1), then acute inpatient EHRs (Year 2) and broad health information exchange services (Year 3).
- Personal Health Records (PHRs) – the PHR functional model was derived from the EHR-S functional model in 2003, with 64 functions, as opposed to 130. Subsequent activities have included describing what constitutes a PHR; environmental scanning to see what products are currently available and how they fit this scope; and upgrading the PHR functional model on the basis of this work. Conformance criteria will then be developed. Whether this ends up as an EHR profile or a distinct but related model will need to be determined. A critical issue is that PHRs and EHRs will need to be able to interoperate, but they are currently being geared to different markets – consumers vs. providers.
- Harmonization – profiles developed by disparate groups require harmonization to be consistent within the HL7 EHR realm, let alone with other HL7 activities. Outcomes to date include the Glossary (see above).
- Long term care – the Long-Term Care Group is trying to develop a long term care profile, but at this stage the group of stakeholders is quite disparate and finding it difficult to consolidate an agenda.
- Paediatric profile (joint with Paediatrics SIG) – a profile is under development.

Reconciliation of ballot comments - there are 3043 line items to be resolved, and the process was initiated. It is proposed to finalise this work by the end of February.

Conformance – every function is associated with a set of conformance criteria, which form the basis for determining if the function has been implemented. The overall approach taken is to keep the functional model at a high level, since it has to satisfy a wide range of contexts, and provide the overall range of conformance criteria; and have the profiles translate this into specific contexts, in which product offerings will be assessed against the criteria. There was extensive and at times heated discussion concerning the extent to which the draft standard can mandate specific functions given the breadth of settings to which it will apply while still meeting the intent of a standard, which is to encourage consistency. Accordingly, an approach was taken to include a “dependent shall” criterion, in which the condition is mandatory in those settings/circumstances where a specified condition (e.g. jurisdiction specific legislation) exists.

The EHR Interoperability project has 3 areas of work:

- Compilation/analysis of relevant definitions and concepts. A first draft is ready, will shortly be posted to the HL7 list, is being prepared for publication and will be presented at HIMSS in February.
- Defining EHR interoperability. The base definition of interoperability adopted by the (US) National Alliance for Health IT (NAHIT) being built upon.
- Developing the interoperability model (specifying characteristics of an EHR record that ensure its interoperability, referenced to HL7 artifacts) and building conformance criteria. The current draft has 101 functions, of which about 30 comprise a minimum function set. It will have the same approach as the functional model – an model and profiles. ISO 21089 (Trusted End to End Info Flows) is a key reference. Public comment on this was from early December 2005 to early January 2006, and input was limited.

The Emergency Department (ED) SIG has made substantial progress on a functional profile for EDs, strongly led by practicing clinicians (apparently with some international participation. The aim is to ballot this by December 2006.

7. Patient Care TC

Considerable discussion has taken place in Patient Care regarding how to handle particular realm requirements within the domain (& normative) standard. The recommendation from the International Affiliates Meeting was that these should be included in an appendix and tools should be developed to act as filters. There seems to be substantial work required before this is fully resolved.

Patient Care has completed the disposition of comments from the V3 Care Provision September ballot. Plans are to publish ballot content that is reasonably stable to give it a good chance of passing DSTU status in May.

A joint meeting with Pharmacy SIG continued the work to refine the Allergy/Intolerance structure, which will be published as part of the Clinical Statement Domain in the next ballot cycle.

The requirement to request the medical records from a care provider when the responsibility of care has transferred to another care provider led to a number of possible solutions depending on the interpretation of the scenario. After the requirements were finally teased out (i.e. this is not just a query for an EHR), there is a need in certain jurisdictions to request the discharge of a patient (in HL7 V3 terms, request to complete the responsibility of care provision). As part of the response confirming the completed care provision, a care record can be provided. After it was confirmed by the Modeling and Methodology TC that it is possible to request a completed state transition, this new set of interactions and messages was endorsed to be included in the Care Provision domain.

Discussions with parties interested in producing a CEN 13606 based EHR Extract in HL7 V3 has resulted in the resurrection and refinement of a prototype model previously published as Draft and then withdrawn. The intent is to support the complete EHR Extract structure and include the Clinical Statement Acts at the Entry level of the model. This work is being lead by Heath Frankel and Dipak Kalra (UCL) with the support of Mark Shafarman. A session in the Templates SIG was dedicated to reviewing the prototype model to begin the process of more formally mapping the CEN-13606 model to the HL7 message and supporting the higher level structures, such as EHR_Extract and Folders. The model will continue to be owned by Patient Care and derived from the Care Provision Domain but this work was re-initiated in the Templates SIG because most of its participants have a general interest in the HL7/CEN/ISO harmonization process. Several other parties expressed an interest in an EHR_Extract message including members from the UK and US. The availability of an EHR_Extract and associated interactions will also make the semantics of the Care Record message clearer as it currently attempts to perform an EHR_Extract like function along with the responsibility of care provision lifecycle.

8. Community Based Health Services (CBHS) SIG

Max Walker was re-elected as Co-Chair of the CBHS SIG, which has attracted some interest on the part of senior personnel within the US DHHS and growing interest in the private long-term care sector.

CBHS SIG ran an information session to enable people not experienced with/knowledgeable of HL7 to gain an insight into the organization and its processes. This was specifically designed to cater for people who are going to work on 3 projects based in the Aged Care setting, however was attended by many other people who found this a very helpful exercise. It now being considered that this be an annual event.

CBHS took the Collaborative Care Messages (CCM), as proposed for V2.7 to the Patient Care TC. The TC formally endorsed CBHS to move the CCM towards Ballot. Patient Care will conduct the Ballot on behalf of CBHS.

9. Clinical Statement Project

A presentation was given by David Markwell from the UK that simply described Clinical Statement versioning requirements when implemented in a distributed virtual

EHR environment. It described scenarios where clinical statements are created, distributed to remote systems, revised or linked to from other clinical statements in originating system and/or remote systems, and merged back into systems that may or may not already have the same clinical statement or some previous version of it. A power point presentation is available on the Clinical Statement Project web site at www.hl7.org.

The use of existing CMETs in the Clinical Statement was discussed and agreed in the case of R_Patient for starters. A new CMET may be required to support the current Related Entity structure provided in the Clinical Statement pattern to ensure committees do not use an alternate CMET which does not comply with the Clinical Statement and carry the same semantics.

To support the need for constrained Clinical Statements models (Templates), such as Allergy/Intolerance, to be referenced from a single source, it was agreed that these Templates would be published in the Clinical Statement domain. This would allow implementation profiles, such as the Continuity of Care Document, to reference the Allergy/Intolerance Template from the Clinical Statement Domain rather than replicating the content within profile causing consistency and maintenance issues.

Planning was done to publish an updated draft of the Clinical Statement Domain in the next ballot cycle.

10. Structured Documents TC

The Structured Documents TC is developing a Conformance Profile for a Continuity of Care Document (CCD), which is a Clinical Document Architecture (CDA) representation of the ANSI Continuity of Care Record (CCR). This work builds on the HL7 Care Record Summary implementation guides and the IHE cross-enterprise document sharing (XDS) Medical Summary profile by specifying additional sections with CDA Level-3 structured data. Sections currently being profiled containing CDA Level 3 structures include Lab Results, Allergies and Conditions.

A joint meeting with Patient Care, Structured Documents and Clinical Decision Support (CDS) discussed the topic of Order Sets, the common term in the US for a standardized set of test/intervention orders applied to a patient based on their current care needs. We would call these clinical guidelines. It was proposed to develop a CDA style structured document to represent these order set definitions but because these order sets definitions are not for a specific patient and most of the Acts involved will be in Definition mood, they are not Clinical Documents. The CDS participations were to develop a model for an Order Sets structured document based on the CDA pattern. This may be the first of a family of Knowledge Documents.

11. Templates SIG

Templates continue to be difficult topic for Modeling & Methodology TC and Templates SIG. Limited progress had been made on the prototype HL7 Query and Constraint Language (HQCL) prototype that was endorsed for exploration at the constraints meeting held in Alexandria (Virginia) in late October 2005. There was a

formal presentation of the work being done by Alan Rector's group in Manchester on OWL and suggestions that HL7 should look at existing constraint language such as OWL and ADL in preference to HCQL and that different languages may be required for different purposes. It was agreed that there need to be some implementation experience using these languages for specifying template constraints. For example, OWL is good at validating models and ensuring that a refined model is indeed a constraint on its parent while being inefficient for run-time message validation. The latter is one of the primary purposes of ADL but there is limited ADL tooling (editors & validators) to support the use of ADL in HL7 V3.

Heath Frankel demonstrated an ADL representation of an HL7 Observation CMET developed 2 years ago and showed how the Ocean Archetype Editor is intended to work with a variety of reference models, currently openEHR and CEN-13606. HL7 V3 could be another option but significant work would be required to incorporate the HL7 RIM classes into the editor if it was seen as an appropriate tool to represent HL7 V3 content. It was agreed that there need to be some implementation experience and project funded trails in using these languages for specifying template constraints.

While a constraint language for HL7 seems distant, there is a need to represent the clinical knowledge of concept representation that needs to be shared and referenced by other published materials such as the CCD. The need for a process of registering and retrieving concept representations has been identified even if structured natural language assertions in word documents is used until a constraint language is agreed. This would also provide a human readable form of these concepts for consensus building, which could also be represented using various machine readable technologies. This would ensure the policy and infrastructure is in place when the technology is ready.

The SIG agreed to use Patient Care Storyboards to test template models. A repository of this work is to be established.

Parties interested in producing a CEN 13606 based EHR Extract in HL7 V3 have resurrected discussions, with Dipak Kalra (UK) presenting the CEN EN 13606 standard, supported by Heath Frankel's elaboration of a prototype 13606 R-MIM including Clinical Statement Acts at the Entry level. This work was generally well received as a potential contribution to harmonization, subject to completion of the model. See similar item in Patient Care above.

12. Healthcare Services Specification Project (HSSP)

HSSP was endorsed by the HL7 board to become the Services Oriented Architecture SIG as of the May WGM.

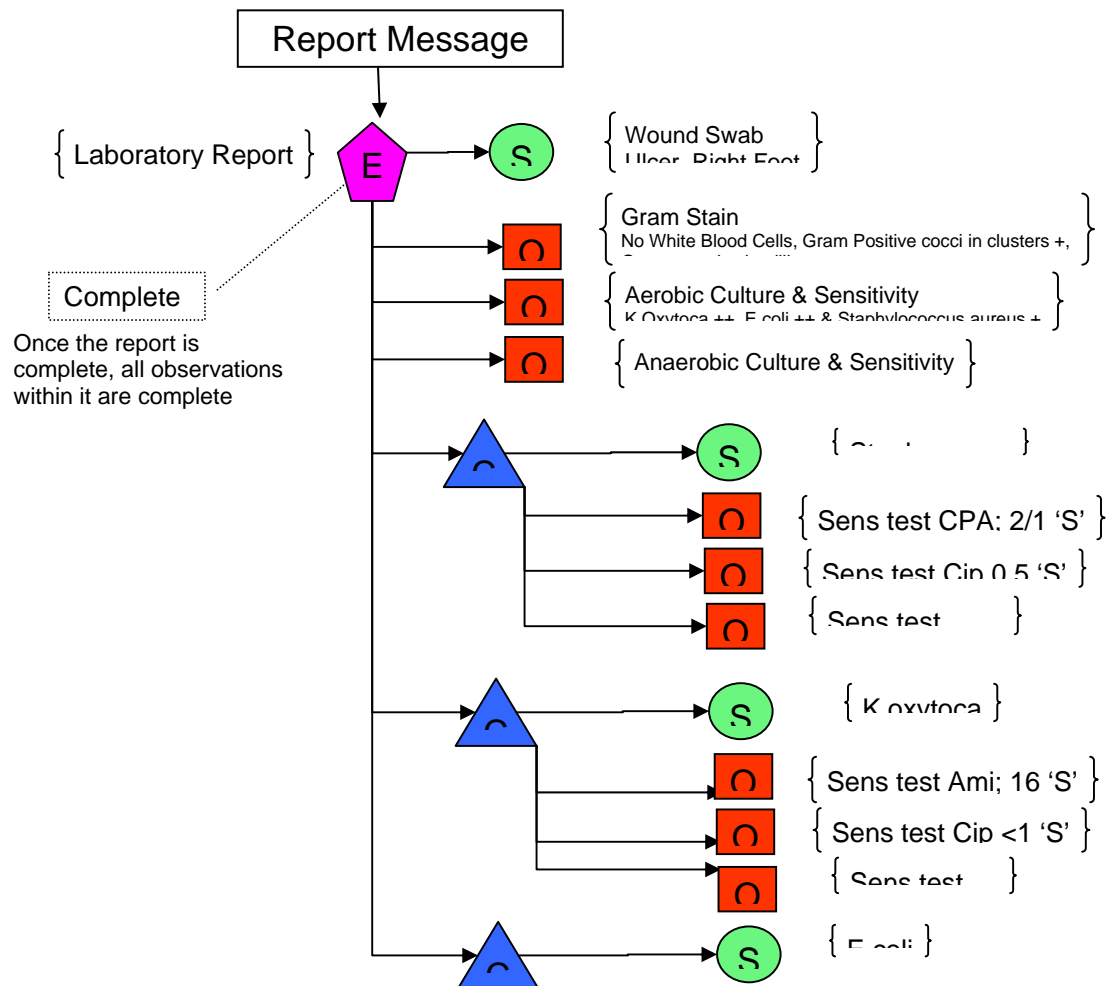
The Record Locator and Update Service (RLUS) specification is progressing slowly and is currently transitioning to a new leader. Most of the review of the specification focused on the scenarios for which the service would be used, providing the basis of the requirements for the service.

A conformance profile approach was discussed allowing conformance statements to be made by vendors indicating which set of interfaces their service implements.

These conformance profiles are based on three interfaces, Locate; Access; & Update. The base profiles will be agnostic to message format while constrained profiles may specify a particular message² format such as HL7 CDA R2 and constrained further to a particular implementation guide such as the Integrated Healthcare Enterprise, Cross-Enterprise Document Sharing, Medical Summary (IHE XDS-MS). This approach makes the RLUS specification widely applicable to many healthcare applications with the potential to support message formats other than HL7 V3 including V2, CEN-13606 and openEHR.

13. Pathology

The Laboratory out-of-session meeting immediately prior to the Working Group Meeting was able to agree a structure (effectively an archetype) for Microbiology acceptable to all participants including US, UK, Canada and Australia. Critical to development of this acceptance was a formalism for diagramming the structure.



² Here the term 'message' does not relate to HL7 message but is used in the context of a services oriented architecture (SOA) where every interaction between a service and its consumer is called a message.

Many minor issues with v3 Pathology were resolved so that v3 Pathology should now be ready for ready for the April ballot.

A group is starting to work on v3 representations of Histology. They will initially base this work on the existing Pathology structures.

14. Modeling and Methodology TC

14.1 Constraint Mechanisms and Harmonization (including Templates and Archetypes)

There was consideration of constraint mechanisms and their impact on harmonization between various groups within HL7 and with the work of CEN, OMG, ISO and others working on EHR, terminology and applications (specifically *openEHR*). This consideration is occurring in various forums attended by different delegates, making it unlikely that a strong coordinated position will be resolved quickly. Templates TC, Modeling and Methodology (MnM), Structured Documents and the joint clinical statement meeting plenary spent considerable time on constraints and harmonization. Other groups such as Services Architecture, Patient Care, Laboratories and clinical specialty groups including Emergency Medicine, Community Care and Genomics are also impacted.

A submission from HL7 to the US National Library of Medicine (NLM) is being prepared for funding a proof of concept for creating HL7 templates for a master set of data elements and mapping these to the HL7 RIM. This work has many similarities with the work of NEHTA's Clinical Information Initiative in Australia. The HL7 initiative is being led by Shafarman, Hammond, Huff, Hamm and Solbrig with some potential to involve international collaborators.

In addition to the ADL demonstration in the Templates SIG, Heath Frankel also demonstrated the ADL representation of a HL7 V3 CMET to the MnM templates task leader, who seemed impressed with its expression of co-occurrence relationships and other invariants, a primary deficit in the HL7 Model Interchange Format (MIF). This is likely to be the first time a MnM leader seriously looked at ADL as a template representation option.

14.2 Identifiers, Versioning and Control Acts

There has been an issue regarding the use of instance identifiers for different purposes. Three types of identifiers have been identified, longitudinal (version set) identifier; revision (version) identifier; and view identifier. Different committees and implementations use the existing id attribute differently depending on their requirements, e.g. Laboratory use id as a longitudinal identifier while CDA use it as a revision id because the Document class has an additional attribute *version_set_id* used as the longitudinal identifier. This is of critical importance to Patient Care as there is a need to have both a longitudinal and revision identifier in the Condition/Problem and Allergy/Intolerance structures as do most clinical statements

stored in an EHR. Pending a concrete RIM harmonization proposal, an id attribute within a Control Act associated with a clinical statement is used as the revision identifier while the clinical statement id attribute is the longitudinal identifier. This approach proves to be very clumsy, especially with the need to link to another clinical statement using the revision Id such as linking to a previous version of a clinical statement.

15. Terminfo

Considerable time was spent in detailed discussions of committee comments on the proposed Terminfo ballot draft document and whether it was ready for release. After a contested vote, it was agreed that it should go to ballot as a DSTU in March, subject to finalisation of a section being prepared by Alan Rector and a range of editorial modifications based on the day's discussion. It was recognized that it might well fail to gain required support in this first ballot but that it was also time to expose the issues for wider input.

Ed Cheetham (UK) presented on the topic of 'vocabulary constraints' and the dangers of ambiguous interpretation of post-coordinated SNOMED-CT expressions. Considerable debate followed, including lengthy contributions by Shafarman, Solbrig, Markwell and Huff, over the merits and demerits of using a canonical transformation of clinical expressions on entry for retention in the ECR. The consensus view appeared to be that this approach (suggested by Cheetham) led to longer term problems of accurate interpretation.

Bob Dolin presented on issues where representation of common patterns (particularly clinical statements) conflicted with terminology. He gave examples of CDA information and SNOMED codes not matching in domains that included: family history, medications and immunizations.

16. Genomics “Birds of a Feather” Group – Communication of Family History

A proposed HL7 format has been developed and is being trialed for exchange of genetic family history data between applications that use family history data for care provision (including cancer assessment and prevention programs). A demonstration was given of profile collection software used at Massachusetts General Hospital feeding clinical information to a predictive analysis system used in University of Texas.

There was considerable discussion of associated issues including privacy and consent (particularly in relation to other family members), whether genetic data should be allowed to be embedded in the messages without being further encoded as RIM classes and how constraints might be specified and used with genetic data.

17. Strategic Planning Initiative – Task Force

The Board is undertaking a Strategic Planning Initiative, funded by a grant from the Robert Wood Johnson Foundation, to define long term goals and positioning for HL7. The outcomes will be a 3 year strategic plan and a 12-18 month implementation plan. The Initiative is considering HL7's organization and processes, and its internal and external positioning. This is still work in progress. Klaus Veil and Dick Harding are members of the Task Group engaged in this work.

The Task Force and consultants have developed nine priority strategic recommendations which will form the base for the Strategic Plan. The working drafts of these statements, with the substantiating text omitted, are:

- Establish HL7 Global as an international standards development organization.
However, existing Affiliates have highlighted potential threats to HL7 as an on-going force in global e-health standards if this results in the HL7 standards developed becoming fragmented.
- Enhance HL7's organizational and technical leadership capacity.
It is likely that a full-time CEO and a full-time Chief Technical Officer will be appointed.
- HL7's Board will formally enunciate a product and services strategy that is reviewed annually .
- HL7 will build and maintain the capacity to be responsive to users' needs, within its broad product and services strategy.
- HL7 will optimize the effectiveness of its volunteers and other resources.
- HL7 will develop a brand hierarchy that helps the marketplace understand the relationship of its products to each other and to the overall organization.
- HL7 will develop consistent organizational messages and a communications strategy to disseminate those messages.
- HL7 will implement a product project management approach to ensure development of high-quality standards in a committed timeframe.
- All standards will be quality-tested before being submitted for a normative ballot.

18. ISO TC215 Planning

Since many of the Heads of delegations to ISIO TC215 were present at the Working Meeting, the opportunity was taken to hold a meeting to continue the business planning initiated after the Global Health Information Technology Summit (GHITS) in Hamamatsu last year.

An analysis of issues arising from GHITS was presented, which will be validated with a wider range of national programs. Activities to be progressed prior to the April 2006 TC215 meeting include:

- Identifying the standards development organisations (SDOs) and other key stakeholders (vendors, national jurisdictions, standards adoption organisations, health informatics associations, etc) with which TC215 needs active and ongoing relationships.
- Reviewing the roles, functions and business model of TC215 and those of its peers, articulating possible adjustments to ensure coherent international standardization and identifying the change implications. Note that David Rowlands was requested to lead this group and accepted.

- Developing an ongoing industry engagement strategy.
- Developing harmonisation/rationalisation processes between SDOs to ensure globally interoperable standards.
- Developing an accountable work plan

19. Recommendations

It is recommended that IT-014

1. Direct IT-014-09-03 to lead the development of an Australian response to the balloting of the entity identification service specification in the May 2006 ballot cycle. IT-014-09-03 will need to confer with NEHTA on this.
2. Consider whether, how and where service specifications are handled by IT-014, given NEHTA's strategic direction on service oriented architecture.
3. Direct IT-014-09 to review the Glossary that has been developed for the EHR System Functional Specification.
4. Draw NEHTA's attention to European Union standards development priorities including patient summaries, provider and patient identifiers and emergency data sets.
5. Note and consider attendance at the International HL7 Interoperability Conference (IHIC) to be held in Koln, Germany on August 24-25 2006.
6. Direct IT-014-06 to consider, in conjunction with HL7 Australia, the number of HL7 ballot cycles per year.
7. Direct IT-014-09, IT-014-06 and IT-014-02 to monitor activity on the comparison of archetypes and templates and articulation of the generic versus the technically specific components within the Templates SIG, as well as questions of how the generic components could be governed; and report back to IT-014 on work program implications.
8. Direct IT-014-09 to review the HL7 Interoperability Model and develop an Australian position on this prior to the ISO TC215 meeting in April, since there is likely to be relevant discussion there.
9. Direct IT-014-09 and IT-014-06-06 to assess the importance to Australia of producing a CEN 13606 based EHR Extract in HL7 V3 and make recommendations as to its place in IT-014's work program. Note that NEHTA should be consulted on this.
10. Consider, subject to funding, identifying Australian representatives to assist in exploring the use of ADL to represent HL7 Templates, including the development of a set of template examples such as Microbiology Result, Allergy/Adverse Reaction, Medication and Problem/Diagnosis based on NEHTA data group specifications. Prototype tooling for validating a run-time instance using ADL could also be explored. Rationale - Australia is one of the leading advocates of Archetypes and their representation in ADL. If we intend to use any HL7 V3 artifacts such as CDA in the medium or long term, we should be actively involved in the HL7 Templates representation to ensure that an alternate/potentially inferior solution is adopted due to lack of exploration of ADL.
11. Consider, subject to funding, including a specialist nosologist/coder as part of the Australian contingent to HL7 meetings. Detailed discussions have been occurring about the difficulty of representing complex clinical statements with SNOMED. This is not specifically a problem of HL7 or of SNOMED – it is a generic problem associated within any clinical coding scheme. While some of the issues being discussed may be more complicated than Australia is planning to implement in

the near term, we need some understanding of the implications of these discussions as we formulate policies for our early use of SNOMED.

12. Continue to advocate the participation of Australian Experts in the international standards development.
13. Work with HL7 Australia to identify the strategic implications of HL7's business planning and develop a plan to manage Australia's interests.
14. Post this Report on the IT-014 and HL7 Australia websites, and circulate a notice concerning its availability through the IT-014, HL7, GPCG and other relevant listservers, and by alerting CHIK to its availability.