



**Report of Australian Delegation
to the
HL7 Working Group Meeting
held in San Antonio, Texas
13-18 January 2008
(and related events)**

This Report was compiled by Richard Dixon Hughes and Elizabeth Hanley from material supplied by Australian representatives at the meetings covered.

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List of Acronyms

ADL	Archetype Definition Language
AHIC	American Health Informatics Community
AHML	Australian Healthcare Messaging Laboratory
ANSI	American National Standards Institute
CCHIT	(US) Certification Commission for Health Information Technology
CDA	Clinical Document Architecture
CDISC	Clinical Data Standards Interchange Consortium
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CMET	Common Message Element Type
CfH	Connecting for Health [within UK NHS]
DCM	Detailed Clinical Model
DHHS	US Department of Health & Human Services
DICOM	Digital Imaging and Communications in Medicine
DIS	[ISO] Draft International Standard
DMIM	Domain Message Information Model
DoHA	(Australian Government) Department of Health and Ageing
DMP	Dossier Médical Personnel (Personal Medical Record)
DSTU	Draft Standards for Trial Use
EC	European Commission [the administrative arm of the EU]
EHR	Electronic Health Record
EHRIS	Electronic Health Record System
EHRVA	Electronic Health Record Vendors Association
EMEA	European Medicines Agency
EN	European Standard (Européen Norm)
EU	European Union
FDIS	[ISO] Final Draft International Standard (for publication vote)
HDF	HL7 Development Framework
HIMSS	Healthcare Information and Management Systems Society
HISO	(New Zealand) Health Information Standards Organisation
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
HSSP	Healthcare Services Specification Project [joint HL7/OMG]
HTTP	HyperText Transfer Protocol
ICH	International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
ICSR	Individual Case Safety Report [related to Medicines/Devices]
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standards Development Organisation
IS	International Standard
ISO	International Organization for Standardization
IT-014	Standards Australia Committee IT-014 (Health Informatics)
ITS	(HL7) Implementation Technical specification
JI	Joint Initiative [of ISO, CEN and HL7]
JTC 1	ISO/IEC Joint Technical Committee 1 Information Technology
JWG	Joint Working Group [under the JI, unless otherwise specified]

LOINC	Logical Observation Identifiers Names and Codes
NCI	(US) National Cancer Institute
List of Acronyms (continued)	
NCI EVS	NCI's Enterprise Vocabulary Service
NEHTA	(Australian) National E-Health Transition Authority
NHIN	(US) National Health Information Network
NHS	(UK) National Health Service
NIH	(US) National Institutes of Health
OCL	Object Constraint Language
OID	Object Identifier
OMG	Object Management Group
ONCHIT	Office of the National Coordinator for Health Information Technology
OSI	Open Systems Interconnection
OWL	Web Ontology Language
PDF	Portable Document Format
PHR	Personal Health Record
RHIO	(US) Regional Health Information Organisation
RIM	(HL7) Reference Information Model
RMIM	Refined Message Information Model
SDO	Standards Development Organisation
SIG	Special Interest Group
SMTP	Simple Mail Transfer Protocol
SNOMED	Systematised Nomenclature of Medicine
SOA	Service Oriented Architecture
SOAP	Simple Object Access Protocol
TCP/IP	Transmission Control Protocol/Internet Protocol
UML	Unified Modelling Language
VHA	(US) Veterans' Health Administration
W3C	World Wide Web Consortium
WG	Working Group
XDS	(IHE's) cross enterprise Data Sharing protocol
XML	eXtensible Markup Language

Acknowledgements

Standards are central to Australia's national e-health agenda, and contribution to and awareness of the status of international standardization is important to standards developers, the health ICT industry and the health sector generally.

Contributions to this report from Australian delegates to the HL7 working group meeting are therefore gratefully acknowledged along with the financial support of the Australian Government Department of Health and Ageing.

1. Introduction

The Working Group Meeting (“the San Antonio Meeting”) was held in San Antonio, Texas, USA from 13 to 18 January 2008. There were 553 registered attendees from 18 countries, including 14 Affiliates. There were 134 delegates from outside the US, comprising some 24% of the overall attendance.

As usual, a range of formal and informal meetings were held in conjunction with the HL7 program allowing the experts who had assembled in San Antonio to exchange experiences and opinions and plan activities. In particular, a meeting of the ad hoc group promoting HL7-ISO-CEN Collaboration was held in the evening of Sunday 13 January and was well attended.

In continuance of a pattern followed on some previous occasions, the ISO TC 215 /WG2 (Data Communication) committee and its two special working groups held two days of meetings on 18-19 January, at the tail end of the HL7 activities. Many of the WG2 experts also participated within the wider HL7 program – including a series of joint meetings with DICOM held on Thursday 17 January.

There were eleven Australians in attendance, including the Standards Australia delegation of: Klaus Veil, David Rowed, Richard Dixon-Hughes, Chris Lynton-Moll, Dick Harding and Vince McCauley (all funded via the Department of Health and Ageing), Heather Grain (funded by self and LaTrobe University), Grahame Grieve (Jiva Medical/Kestral), Elizabeth Hanley (Standards Australia) and Max Walker (Department of Human Services, Victoria). Another Australian, Matthew Moores (Oracle) was also present at the meeting.

Of note was the first-time attendance of Elizabeth Hanley, Senior Project Manager at Standards Australia, who provides the international secretariat to ISO TC 215 /WG 9, responsible for advising on coordination of the HL7, ISO and CEN health informatics work programs. In addition to enhancing international collaboration, her participation further enhanced collaboration between Standards Australia and HL7 – both globally and within Australia.

2. HL7 Background

Health Level Seven Inc (HL7) (www.HL7.org) is a significant, global, ANSI-accredited not-for-profit standards development organization (SDO) which has been operating since 1987. It provides frameworks and standards for the exchange, integration, sharing, and retrieval of electronic health information to support clinical practice and the management, delivery and evaluation of health services. In particular, HL7 standards address ways in which clinical and administrative healthcare data may be represented and communicated as messages and electronic documents.

HL7's activities are geared toward pursuit of its strategic vision:

To create the best and most widely used standards in healthcare.

HL7 seeks to collaborate actively with a range of significant stakeholder communities in the achievement of its stated mission, which is:

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

HL7 is a volunteer organisation with more than 2,300 members some of whom are representatives of over 500 major organisations, including over 90% of information systems vendors serving healthcare in the USA. HL7's members – health care providers, payers, IT vendors, consultants, government groups and others who have an interest in the development and advancement of clinical and administrative standards for healthcare – participate in the development of HL7 standards.

In recent years, HL7 has begun a series of outreach programs to obtain input and guidance from the leadership of member organisations as well as from a wider circle of influential stakeholders including clinical groups, national e-health programs, pharmaceutical and medical device industries, public health institutes and health care consumers.

Based in the USA, HL7 has become an increasingly international organisation with its standards being adopted in many parts of the globe. It actively seeks to work collaboratively with other SDOs that produce standards, specifications, profiles and protocols used for representation and communication of healthcare information, of which there are over 70 doing significant work in the area - including organisations addressing standards for medical devices, diagnostic imaging, clinical vocabulary and terminology, health insurance claims, patient and provider identification, clinical documentation, logistics and clinical trials.

HL7 takes its name from the highest level (“Level Seven”) of the [International Organization for Standardization](#) (ISO) communications model for [Open Systems Interconnection \(OSI\) - the Application Level](#), which addresses definition of data to be exchanged, the timing of the interchange, and the communication of certain types of errors between application. It also supports such functions as security checks, participant identification, availability checks, exchange mechanism negotiations and, most importantly, the structure of exchanged data.

Like all accredited SDOs, HL7 adheres to a strict and well-defined set of operating procedures that seek to ensure consensus, openness and balance of interest.

Standards development in HL7 is undertaken via Technical Committees (TCs) some of which have subordinate Special Interest Groups (SIGs) to address new areas. The current TCs, SIGs and other representative bodies are listed in Attachment 1; however, as discussed further in the body of this report, the HL7 organisational structure is going through a period of considerable change to implement the outcomes of a major strategic review carried out over the past 2 years.

Working Group (WG) meetings are held three times a year. At each WG meeting, the various Technical Committees (TCs) and Special Interest Groups (SIGs) responsible

for parts of the HL7 suite of health informatics standards meet to agree upon the content of draft standards documents and standards proceeding to publication, to resolve issues arising during balloting, to exchange information with each other (often through joint sessions) and to plan their work for the ensuing four months (much of which is actually achieved by teleconferences). The plenary meeting, held in conjunction with the WG meeting in September each year also involves a series of high-level presentations of import to HL7's overall strategic direction.

Draft standards developed by TCs and SIGs are balloted by members of the relevant TC, and if successful proceed to full HL7 membership ballot. Typically there are three ballot cycles per year, each closing several weeks prior to the next WG meeting. As with other recognised SDOs, balloted material can be commented on as well as voted by the eligible balloting pool, and all comments must be individually reconciled and the agreed TC responses fed back to those submitting comments.

The WG Meetings provide the main opportunities for the HL7 Board, Technical Steering Committee, International Council and other standing committees and task groups to hold face-to-face meetings. At the San Antonio Meeting, there were 63 formal plenary and committee meeting streams, with 32 education sessions also being held. The complete program and more details on the activities of each TC/SIG can be found by following links from www.hl7.org/events/sanantonio012008.

At a WG meeting, TC, SIG and administrative committee meetings are generally held concurrently, which requires significant coordination and an adequate number of members in the Australian delegation to ensure Australia's interests are represented.

Standards development activities continue intensively between meetings via teleconferencing, email and face to face where there are clusters of participants within geographic proximity. For example, the Electronic Health Records (EHR) TC meets weekly via teleconference, as do its Personal Health Record (PHR), Interoperability and Legal EHR working parties. Recent work on harmonized data types, clinical statement and patient care has also involved regular out-of-session teleconferences.

HL7 promotes the use of its standards within and among healthcare organizations to increase the effectiveness and efficiency of healthcare delivery for the benefit of all.

3. Broad Objectives of Australian HL7 Participation

Australia participates in international standards development activities in recognition of the growing importance of international and global standards to Australia as it pursues its obligations and interests under World Trade Organisation treaties. The over-arching objectives of this participation are:

- improving Australian capacity to apply health informatics and develop health informatics standards by expanding domestic knowledge and expertise based on international best practice.
- promoting free trade and its benefits to health ICT (by lowering the cost of integrating and implementing health information systems, many of which are imported, and by reducing costs to Australian exporters) – both these

outcomes require Australian requirements to be embedded into global standards so that they can be adopted in Australia, rather than having different standards across domestic and international markets, and

- improving Australian health information systems by facilitating a standards-based approach to development and implementation, and achieving interoperability between systems.

Recent objectives for the Standards Australia IT-014 (Health Informatics) committee's support of international standardization activities include the following aspects related to HL7:

- Monitoring and influencing HL7's strategic positioning as a global SDO, encouraging its collaboration with other international and global SDOs and assessing and contributing to the strategic positioning of its key products (HL7 V2.x, V3, CDA, EHR Models, etc.) so as to encompass Australia's health information interchange and related requirements.
- Negotiating the inclusion of Australian healthcare messaging requirements into HL7 V2.7, V2.8 and V3 specifications for:
 - Patient administration;
 - Diagnostics (pathology, radiology); and
 - Collaborative care,

so that Australian technical domain requirements become a formal part of these Standards.

- Negotiating the inclusion of Australian health sector requirements into the EHR Interoperability Model and PHR Functional Model so that Australian EHR developments can be supported by the upcoming HL7 and related ISO EHR Standards.
- Negotiating the harmonisation of ISO, HL7 and CEN Standards (in particular CEN/ISO 13606 and HL7 V3), to achieve progressive inter-SDO E-Health standards harmonisation with the long-term goal of a unified set of global health informatics standards.
- Monitoring, and influencing as necessary, new initiatives to standardise clinical data content so as to improve Australia's ability to unambiguously and safely exchange semantically interoperable clinical data.
- Assessing and influencing HL7's work on service oriented architectures (SOA), as required by Australia's national direction setting, and negotiating the inclusion of Australian health sector requirements (in particular, those described by NEHTA) into service specifications being jointly developed by HL7 and the OMG.
- Assessing and influencing the positioning, development, implementation, utility and effectiveness of CDA (including CDA Release 3), to support Australia's interest in CDA in its national E-Health program.
- Assessing, exploring and proposing approaches to the embedding and transportation of archetypes in HL7 V2.x messages for referral, diagnostic

results and collaborative care to support Australian interest in the use of archetypes for the exchange of clinical information.

- Progressing the international harmonisation of common data types and vocabulary for healthcare information that will meet Australia's identified requirements.

Additional Australian interests may be pursued opportunistically, and additional specific objectives may arise from time to time as a result of the development of Australia's national e-health agenda and other national interests.

4. Key points from the San Antonio Meeting

Organisational strategy and direction

- The beginning of 2008 brought a new HL7 Board structure with much stronger focus on strategic issues.
- The HL7 Board now has significantly more input from major international stakeholders, with the direct appointment of "external" directors - Dennis Giokas (Canada Health Infoway), Ken Lunn (UK NHS) and Don Simborg (US) and the election of Michael Van Campen (Canada) as a second director from affiliates.
- It is almost 12 months since the appointment Dr Charles (Chuck) Jaffe as the first full-time CEO of HL7 – which appears to be bearing fruit in strategic planning, stakeholder engagement and driving change in HL7.
- One of H7's key initiatives is to build (and maintain) an "**HL7 Strategic Roadmap**" defining a forward path for HL7, its products and services. Initial versions were produced in mid-2007 and were refined through consultation with internal and external stakeholders. HL7 is inviting feedback on the Roadmap, a recent draft of which is at Annexure A below.
- The HL7 Strategic Roadmap summarises principles, objectives and milestones under 23 topics, assembled under the following major headings:

- | |
|--|
| <ul style="list-style-type: none">• General Principles• Standards (including Architecture, v2, v3, other)• Services (including certification, implementation services, tooling, vocabularies and ontologies)• Organizational Development (including project management and marketing/ communications)• Financial Development (including development of funding sources and HL7 Foundation)• Affiliate Development• Outreach & Relationship Development |
|--|

- HL7 is actively pursuing engagement with stakeholders and potential stakeholders including influential decision makers in health provider

organisations, national health programs, major health-related industries, health systems vendors and clinical communities.

- The first **HL7 Stakeholders' Roundtable** was hosted by Dr Martin Harris at the Cleveland Clinic on 29-30 October, 2007. Some 20 participants representing leading provider and vendor organizations and health agencies from around the globe are reported to have provided significant input to the HL7 Strategic Roadmap. David Rowlands represented Australia.

Completion of Klaus Veil's term as an HL7 Board member

- Klaus Veil's term as a member of the HL7 Board of Directors concluded at the end of 2007. He continues to be invited to attend Board meetings as a co-chair of the international affiliates and he was honoured with an HL7 award for his significant contribution as a member of the HL7 Board of Directors.

HL7 technical strategy and direction

- Responsibility for HL7's technical activities and work program has been successfully transitioned from the Board to the Technical Steering Committee (TSC), which has been very active with 15 meetings being held from when it was formed in September 2007 up to the San Antonio Meeting.
- The TSC is working with the John Quinn as Chief Technical Officer (CTO) to coordinate HL7's program of technical work, manage the committee structure and standardization processes, resolve technical issues and improve communication. New communication channels include:
 - The TSC wiki at: <http://hl7tsc.org/>
 - The gForge issue tracking system, which may be accessed at: http://hl7projects.hl7.nscee.edu/tracker/index.php?group_id=52&atid=313
- The leadership of HL7 now accepts the ongoing role of HL7 v2.x as part of the longer-term strategic vision - with v2.8 now solidly on the drawing board.
- There is also recognition that better v2.x implementation guidance is needed to provide consistency and address inter-version and backward compatibility issues. [More comprehensive and consistent training of new HL7 practitioners also needs to be part of the approach and is addressed by the web-based learning initiative].
- v3 message development and implementation processes are to be re-focussed, streamlined and made more consistent through new tooling and a collaboration with the OpenHealth Tooling Group and Implementation Guides. HL7 v3 may be re-branded.
- CDA r2 is in rapid ascendancy around the world (including CCD in the US) with interoperability being challenged by inconsistency in content, implementation and vocabulary – particularly where a dynamic model is needed.
- Planning is underway at committee level for CDA r3 in response to rising pressure. [But has HL7 established the guiding principles needed to control this activity and position CDA r3 correctly to address real stakeholder needs?]

- There is growing realisation among HL7's leadership team that the technical architecture must actively embrace and achieve greater consistency between all three HL7 mainstream product lines (CDA, v3 and v2). A harmonisation project to remove inconsistencies between HL7 v2.x and HL7 v3/CDA is underway.
- Use of HL7 across a domain/realm is increasingly being addressed by local Implementation Guides that define message content and/or clinical documents in more detail for specific business contexts, provide supporting information necessary for consistent implementation and, sometimes, to define conformance testing.
- It has been recognised that Implementation Guides are proliferating exponentially but without commonality of approach or output, thereby putting the possibility of broader interoperability and re-use of artefacts at risk.
- Automated generation of more consistent document and message specifications and Implementation Guides is therefore a key aim for HL7 in moving to more advanced tooling.
- Within the community involved with clinical documentation (particularly in the US) it has been noted that efforts in groups external to HL7 are proliferating (e.g. CCD/CCR development) and may have outpaced HL7's ability to leverage them. The risk is that HL7 will be irrelevant to the clinical community if HL7 does not have an effective way to incorporate the work that is happening outside HL7.

Liaison and alliances between SDOs

- The executive leadership of HL7 continues to work collaboratively with the ISO TC 215 and CEN /TC251 to realise the Joint Initiative (JI) on SDO Global Health Informatics Standardization (the Geneva Charter).
- The JI is controlled by a Joint Initiative Council (JIC) of SDO leaders – represented by their respective chairs: Ed Hammond (HL7), Kees Molenaar (CEN TC251) and Dr Yun Sik Kwak (ISO TC215).
- The JIC is supported by a Joint Working Group (JWG) with open membership from the three organisations and has three Co-chairs - Charles Jaffe (HL7), Melvin Reynolds (CEN) and Don Newsham (ISO).
- The JWG has been constituted as ISO TC215 WG9 with Elizabeth Hanley of Standards Australia providing its Secretariat in line with Australia's strong commitment to the principles of harmonisation of health informatics standards.
- Discussion at the San Antonio Meeting emphasised the challenges facing practical implementation of the ISO/CEN/HL7 Joint Initiative (JI) – particularly the need for all SDOs to make uncomfortable changes in practices and procedures when progressing joint work items.
- As CTO, John Quinn has been nominated as the HL7 contact point for coordinating all HL7 work activities, particularly where these involve joint projects with other SDOs. This was stressed to the active HL7 membership at the San Antonio Meeting.

- Working primarily from within HL7 but collaborating with relevant ISO and CEN experts Grahame Grieve from Australia is spearheading the production of a new international standard for a common set of abstract data types for use in HL7, CEN and ISO. This key piece of work needs strong support from the rest of the Australian health informatics community to maintain momentum by participation in relevant international forums until its completion toward the end of this year.
- Another pathfinder project for the JI, ICH message harmonisation is of less concern to Australia, but also offers both potential benefits and significant challenges.
- In other areas, HL7 is renewing and strengthening its alliances with other organisations both in the US and internationally. Australian involvement in international health informatics forums aims to ensure that our interests and needs are being considered.
- For some years, senior members of the HL7 community have worked with CDISC to develop HL7v3-based messaging protocols for collection of clinical trial information. This is supported by an MOU between CDISC and HL7. CDISC and HL7 are collaborating in CDISC's move to become the global leader in standards and methods for capturing, communicating and managing clinical trial information.

Clinical Information Council

- An important and potentially valuable development for HL7 has been the establishment of the Clinical Interoperability Council (which first met in May 2007) as a non-technical, clinically focussed group to bridge the gap between HL7's acknowledged technical expertise in clinical informatics and those who practise in various clinical domains.
- The CIC is intended to provide outreach beyond HL7 and the ability to mentor new clinical groups as they come into the organization.
- While formation of the CIC is seen by most as a positive move, its exact role and capabilities in relation to the overall work program and to the other units within HL7 that have more technical responsibility for identifying and specifying clinical needs is still unclear.
- There is some concern that the proposed CIC work program may lead to further divergence in the development of standards for the clinical domain and compete for resources with other groups, such as the DCM collaborative, EHR-TC, SD-TC, PC-TC and their SIGs.
- There was a lot of discussion about the CIC's role and how to achieve HL7's goals for much stronger clinical interaction and the needs for a clinically oriented work program, but no substantive actions.
- Despite HL7 attempting to ensure that the CIC is internationally inclusive, its detailed activities, proposed work and leadership have all become very US-centric.
- The importance of Australia being active within the CIC was noted as it will assist us in the task of ensuring HL7 meets Australian clinical needs.

International interest and growth in use of HL7 (particularly CDA)

- Increased international interest in the adoption and implementation of HL7 is evidenced by recently reported activities, such as:
 - Some recent projects in which HL7 CDA r2 is to be the standard for clinical communication were noted, including:
 - national discharge summaries in Germany, Switzerland, Taiwan and Korea, and
 - all referrals, patient collectible laboratory results, pharmacy prescriptions and over-40s health-check reports in Japan
 - Microbiology and laboratory reporting in The Netherlands
 - Notifiable diseases (North Rhine Westphalia) and clinical indexes in Germany
 - This trend being reflected in HL7 CDA r2 implementations being selected as the primary theme for several key international events:
 - International HL7 Interoperability Conference 2008 (IHIC 2008), October 2008
 - The 7th Asia-Pacific HL7 conference, Taiwan, November 2008
- The maintenance of local Implementation Guides is a major task for some international Affiliates (including UK, NL, DE), particularly for HL7v3, and many affiliates are finding that they need professional support to assist in this task.
- European Commission (EC) Mandate M/403 has established an activity through CEN, CENELEC and ETSI to define the standards for eHealth interoperability in Europe, the coordination group meetings for this project now being open to HL7, IHE, IHTSDO and ISO TC 215.

Confluence of US, EU and IHE activity

- Partly as a result of the activities of ONCHIT, AHIC, HITSP and CCHIT in the USA, and their moves toward certification of EHR systems, and partly because of user needs, it is becoming increasingly clear from attendance at international standards meetings that the adoption of a standard in an IHE profile is increasingly becoming the sign of approval for a health information standard.
- Along with developments in North America aimed at implementing eHealth interoperability, the eHealth standards plan being developed under EC Mandate M/403 has the potential to have a major impact on the global eHealth standards marketplace and future directions in global eHealth standardization.
- With HL7, IHE and IHTSDO (as well as ISO TC 215) having observer status in the coordinating committee and the EC DGEI seeking greater adoption of international and global standards in Europe, it is increasingly likely that EC decisions and investments by EU member states will align with mainstream global interests.
- Coupled with these developments and growing acceptance in North America, Europe and Asia/Pacific, the influence of the IHE (Integrating the Healthcare Enterprise) consortium, in particular, is growing and is likely to define what

constitutes the mainstream –at least for each major region of the world. Australia needs to monitor and work more closely with the IHE organisation, whose processes and profiles are progressing toward becoming international standards in ISO.

Human Services Directory (HSD) projects

- The joint HL7/OMG HSSP project coordinating the specification of web services for use in health care has resolved to re-orient its “Services and Provider Directory” project to address the wider needs for a “Human Services Directory” and is re-naming its SPD project to reflect this shift.
- CBCC SIG and PC TC, which are the expert committees that are progressing the work, are examining the existing DHS Victoria HSD with a view to developing use cases that address a wider range of human-services needs for inclusion in the HSSP specifications.

HL7 standards development

- A proposal to remove most mandatory field lengths from HL7 v2 standards was put forward in IC TC. It was strongly opposed by some members of the Australian delegation, notably Klaus Veil, who led opposition to the proposal in InM TC, concerned that would undermine the authority of the V2 standard itself and the AS 4700 series of implementation guides – replacing universal conformance tests for length with profiles that would only guarantee functional interoperability within a limited number of related implementations

When put to ballot at InM TC (with many IC TC members present) the proposal was accepted with most Australians opposing.

- It has been suggested that the Templates SIG be disbanded and absorbed back into its parent InM, or into the ITS SIG.

Now that the Templates specification has passed DSTU stage and the role of defining clinical information content is being progressed by other groups, continuing with a separate Templates SIG may be unnecessary. Another significant consideration is the strategic shift toward better modelling and tooling to capture requirements and create container structures, rather than using templates to constrain generalised representations.

- At the joint meeting of Templates, DCM and TermInfo the following suggestion concerning responsibilities for specifying clinical content was resolved:

To bring the work on DCM to the TSC via the Domain Expert Steering Division with a view to sorting out responsibilities with:

- *Templates SIG to have responsibility for technical representation of clinical content including requirements for supporting metadata*
- *TermInfo to have responsibility for the and appropriate use of clinical information models and the principles for how they interact with terminology*
- *Patient Care TC, Structured Documents TC, (CDA), O&O TC and joint Clinical Statement group be responsible for formal definition and support for the actual use of clinical statements in messages (v2 and v3) and CDA*

- *The DCM Collaborative continue as a forum to develop, share and maintain actual instances of clinical content and bindings etc. granular, including assessment scales*
- *The PV group enlarging its scope from assessment scales to DCM at large, and*
- *The CIC being responsible for identifying clinical content and managing its progression through HDF.*
- In Clinical Decision Support, a proposal is being prepared to refine the GELLO query and clinical guideline specification language, following a review of the standard (approved as a normative ANSI/HL7 standard in 2005) by major users, including Medical Objects Pty Limited from Australia. Key issues include:
 - inconsistent and unnecessarily complex language definition
 - whether to loosen encapsulation principles to allow operational controls in a declarative language (and, if not, provide guidance on how this functionality might be standardized),
 - whether to continue GELLO's alignment with OMG/OCL, and
 - using GELLO with reference models other than V3 RIM (e.g. SNOMED).
- Arden V2.7 Syntax has now passed committee ballot and will be submitted to full membership ballot next cycle. It appears that Arden Syntax can be effectively used for formal specification of implementation guidelines but precious work on this was never shared.
- Despite HL7v3 committee ballots on Infobutton capability having passed, it is difficult to see it gaining the consensus needed to pass a full membership ballot, given that some major interests (notably GE Medical) remain opposed to the delivery of the functionality within messages, rather than services.
- Vocabulary TC has a very heavy work program, compounded with difficulties migrating to new tooling and addressing the potential volume of data items that are arising through increased use of HL7 for clinical documentation.
- Attempting to support applications using both LOINC and SNOMED CT codes in the same specifications causes major problems in practical implementations. Guidance appears to be needed on which terminology to extend when (1) gaps were identified and (2) both terminologies had released content for common areas of representation. TermInfo would like to consider doing this, provided the three organisations involved - HL7, LOINC, IHTSDO - are agreeable and prepared to support the activity.

Involvement in EHR-S Functional Model (EHR-S FM) and PHR-S FM

- The EHR-S FM has gained major acceptance in the US through functional profiles being developed and used to support of CCHIT systems validation processes. The standard is also now being progressed through ISO for world-wide acceptance and use as an International Standard.
- From non-US delegates, some concern was raised regarding the US-centric nature of the EHR TC and the potential implications for compliance of the

resulting standards with wider international requirements in support of the WTO barriers to trade agreement.

- Extensive use has revealed changes that need to be made to the underlying functional model. However, the potential impact on existing profiles of making such changes is raising concerns; therefore fundamental principles and a process for doing such changes need to be agreed, if progress is to be made on Release 2 (R2) of the standard now being planned.
- Balloting of the EHR-S FM as a DIS in ISO is also expected to generate comments requiring the resulting International Standard to differ from the original HL7 version. While HL7 intends that these comments be considered for inclusion in R2, harmonising HL7's subsequent work on R2 with the international version has yet to be addressed.
- This is becoming an issue with all international adoptions of standards that continue to be developed within their originating SDO. As Secretariat for the JWG Australia should consider raising with the JI/JWG the need for principles and guidelines to resolve how this issue may be managed.

Other developments

- A major HL7 "SOA in Health Care" conference/workshop is planned for 15-17 April 2008 in Chicago to present the work of HL7 and OMG through the HSSP and those looking to apply service oriented architectures (SOA) in health care.

It features some 45 speakers, including Max Walker from DHS Victoria.

- Interest in Personal Health Records (PHRs) is rapidly accelerating world-wide and particularly in the US. The associated standards and technologies are of growing relevance to Australian plans for shared EHR services, which are much closer to the emerging PHR concept, than to the US-derived concept, which is that of an EHR as the clinical information system in a health care organisation.
- Significant new paradigms (such as Microsoft's HealthVault) are emerging for the collection, sharing and dissemination of consumer health information. These appear to pose challenges to many of the underlying assumptions and models traditionally underlying standards for information interchange in health.

Australia needs to ensure that developments in these emerging fields are tracked and considered in planning Australia's health informatics standards agenda.

- Profiles for CCDs (Clinical Care Documents based on CDA) to define the information content of clinical (and other) documents for use in various application domains are proliferating. There is a lot of anecdotal evidence that users in many different areas are independently creating document definitions based on the CCD framework to address their local needs with little regard, guidance or understanding of how to preserve semantic interoperability and allow broader sharing of information.

By its selection of specific CCD profiles for interoperability testing, IHE may be able to exert a moderating influence on this proliferation, but only within specific data interchange environments within a region. The challenge for Australia (potentially through NEHTA, NEHIPC, IHE and industry collaboration)

is to ensure that broad interoperability is achieved in Australia – particularly given that we have the opportunity to enter the field with a “clean sheet”.

5. Board and Executive Reports

5.1 Report of the CEO – Dr Charles Jaffe

This was the third HL7 Working Group meeting attended by the new CEO, Dr Charles Jaffe. He reported briefly on “The Year in Review and the Year Ahead” emphasising the following aspects:

1. His thanks to key contributors:
 - HL7 members, volunteers and staff
 - The Board, especially the outgoing and incoming chairs – Chuck Meyer and Dr Ed Hammond
 - HL7 stakeholders
2. Key accomplishments in the preceding 10 months:
 - Reorganisation of HL7 as a technical organisation, particularly through:
 - the appointment of John Quinn as CTO
 - restructure of the Technical Steering Committee with more responsibility for defining, delivering and coordinating the HL7 work program and the management of its working groups.
 - Improving HL7 engagement with its stakeholders, including:
 - holding the inaugural 2-day “Stakeholder Roundtable” in October, and
 - restructuring the Advisory Council to be chaired by a stakeholder and provide independent advice more directly to the HL7 Board.
 - Restructuring the HL7 Board leading to direct appointment of three new directors – Dennis Giokas, Ken Lunn and Don Simborg. [Further details of these directors are provided at section 7.1 below].
 - Provision has also now been made for a second Director from the Affiliates, with Michael Van Campen of Canada being elected.
 - Creation of a “Marketing Council” supported by professional marketing advice from an external marketing organisation (Extraordinary Work Group led by Ms Sherold Barr).
 - Development of new funding initiatives, potentially to include formation of an HL7 Foundation.
 - Creation of HL7’s first “Strategic Roadmap” – including wide consultation with HL7 stakeholders. [A Working Draft of this document is included as Annexure A below with comments and input being welcome].

- Commencing work on re-design and evolution of the HL7 website. This has turned out to be more complex than originally expected but is likely to be delivered by Q2/2008. [See section 7.4 below].
 - Enhancement of HL7's technical capabilities, in particular:
 - Renewal and strengthening of successful alliances with other organisations both in the US and internationally
 - Supporting the foundation of the OpenHealth Tooling group
 - Building new relationships.
 - Establishing the Joint Initiative Council (JIC) and Joint Working Group (JWG) with ISO TC 215 and CEN TC 251 to facilitate harmonisation of health informatics standards development.
3. Some of the key activities on the road ahead include:
- Deployment of the Strategic Roadmap and developing a model for its maintenance.
 - Empowering the newly restructured TSC to lead HL7's work program, architecture and technology effectively in collaboration with the CTO.
 - Building and rebuilding alliances with an increased emphasis on effective cooperative charter agreements and MoUs.
 - Capitalising on interest in new technologies and new domains, including:
 - Progressing HL7 architecture and tooling through the Architecture Board
 - Service-Oriented Architecture (SOA) including the HSSP
 - Closer alignment of HL7 work with a broader spectrum of clinical requirements - through the Clinical Interoperability Council
 - Moving HL7's activities beyond patient care in collaboration with organisations such as CDISC (clinical trials), GS1 (identification and supply chain) and SAFE-Biopharma.
 - new frameworks (EH, ph)
 - Building end rebranding HL7 Version 3, to include
 - Exploiting the successes of CDA
 - Increasing reliance on stakeholders – including holding a Roundtable in 2008 and beyond
 - Re-valuing the contributions of our members
 - Active outreach:
 - Marketing HL7 more strongly beyond North America and the English-speaking world,
 - Expanding educational initiatives and educational marketing
 - The Ambassadorial Program, which aims to equip members involved with HL7 with the messages and information needed to represent the organisation effectively to executives and decision-makers.
-

- The member as "a role model"

In concluding his presentation Dr Jaffe thanked everyone for their support in what had been a great year for HL7.

5.2 Report from HL7 Board Meeting

In his role as a co-chair of the Affiliates Council, Klaus Veil attended the HL7.org Board meeting held on Tuesday afternoon and evening and provided feedback on the outcomes.¹

- As noted elsewhere in this report, four new members have joined the Board and were welcomed to this, their first meeting:

- Michael van Campen from Canada (Second Affiliate Director, replacing Klaus Veil),

and three nominated Board members:

- Kenneth Lunn, PhD - Director of Data Standards and Products, NHS, UK
- Dennis Giokas - Chief Technology Officer, Canada Health Infoway, Inc.
- Donald W. Simborg, MD – a renowned health informatician, clinical researcher and entrepreneur, who was also a co-founder of HL7.

Further information about these individuals may be found in section 7.2 below.

- The Board heard presentations [see Annexure C below] from:
 - Microsoft on its new "HealthVault" product
 - Don Mon about the strategic direction and activities of the American Health Information Management Association (AHIMA) and potential for collaboration with HL7
 - A presentation on the lack of activity and uptake of the HL7 decision support Standards.
- The project to improve the HL7 V3 documents is moving forward slowly.
- The "HL7 Ambassador" program is underway to improve the promotion of the HL7 Standards and provide outreach into communities not yet exposed to HL7.
- In line with HL7's transformation into a more "corporate" organisational structure, the CEO and CTO delivered reports to the Board.
- A draft of the HL7 "Roadmap" (or business plan) was presented. It was agreed that substantial further work was needed and to include the Affiliates in the development process. [See Annexure A for a subsequent discussion draft of this document].

¹ Klaus Veil has retired as a Board member, having served the maximum two terms as Affiliate Director and a further maximum two terms as Director at large and was not eligible for re-election of the current Board but continues to be invited to attend and participate in Board meetings as a Co-Chair of the Affiliates Council.

- The incoming Treasurer Dan Russler (Oracle Corp.) made an impressive debut with a work plan that focussed on financial prudence, probity and governance as well as more effective generation of the monthly financial reports.
- The Board agenda also included reviews of the job descriptions and 2008 evaluation metrics for the CEO and CTO. Due to lack of time, this was held over to the next meeting.
- It was noted that HL7 has formal Memoranda of Understanding with the following organisations: ADA, AHIP, ANSI, ASTM, CDISC, CEN, CHCF, Continua, DICOM, eHI, GS1, IEEE, IHE, Liberty Alliance, MedBiquitous, NCPDP, Oasis, OMG, SNOMED, UNLV, WEDI, X12
- HL7 will be a sponsor for the following upcoming events:
 - HIMSS 08 RHIO/HIE Symposium, Feb 24, 2008 in Orlando, USA
 - SOA in Health Care, April 15-17, 2008 in Chicago, USA
 - 5th Annual World Health Care Congress, April 21-23, 2008, Washington DC, USA

5.3 Report of the CTO – John Quinn

In September, senior Accenture health partner, John Quinn was seconded to HL7 to perform the role of Chief Technology Officer (CTO), with the following roles and responsibilities:

- *oversee the development of standards and technical publications;*
- *create and maintain a de-facto and strategic objective understanding of the "architecture" of HL7 in cooperation with the ARB and TSC;*
- *coordinate, track and report on the activities of the Technical Committees and Special Interest Groups;*
- *assure the timely delivery of such products;*
- *support the harmonization of work products with other Standards Development Organizations;*
- *provide periodic updates to the Board and CEO on TD objectives and deliverables;*
- *lead the development of the technical component of the Roadmap project;*
- *contribute to the educational activities that support the technical products; and*
- *participate in the development of criteria and metrics for evaluation of success.*

At the San Antonio Meeting, it was strongly emphasised that communication between HL7 and other SDOs needs to be tightened so that HL7 is aware of potential joint commitments and can ensure that, where commitments are made, they can be resourced from within HL7 the work program. Therefore John Quinn needs to be advised of potential joint work and is the HL7 contact point for communication about joint work with other SDOs.

John Quinn, reported to both the Affiliates Council and to the general membership, covering a range of topics including the following. [Note that matters covered in more detail other sections of this report have not been repeated].

CTO Activities

Since taking up his role as CTO, John Quinn has had a full agenda with some of the major activities being:

- Activation of the TSC as the peak decision making body within HL7 responsible for structure and coordination of the HL7 product set and work under the chairmanship of Charlie McCay. This has included John's participation in weekly planning and conference calls as well as working with Karen Van Hentenryck to ensure that TSC work is progressed by HL7 between meetings [See TSC report at section 6 below for more detail on TSC].
- Re-structure and reactivation of the Architecture Review Board (ARB) – now re-named the "Architecture Board" with a revised mission and charter to become more proactive in leading the "architecture of HL7" (see below) This has been the activity which has consumed most time since the Atlanta meeting.
- Bringing into reality the TSC as "the place of decision and recommendation" for all technical matters in HL7. He is pleased that understanding of the TSC's new role and objectives is evolving rapidly.
- Support of the CEO and incoming Chair in pursuing enhanced stakeholder engagement – including the Cleveland Roundtable in October at which both Canada Health Infoway and the NHS CfH programs made significant inputs on HL7 and the direction of its products.
- Representing and negotiating on behalf of HL7 in meetings with national ehealth programs, standards bodies and technical consortia including:
 - The Canada Health Standards Collaborative (Canada Health Infoway)
 - Open Health Tools Community Architectural Council
- Making contributions to the HL7 Strategic Roadmap and ensuring that technical goals including the adoption of emerging technologies are appropriately represented in the Roadmap. The role of the CTO in relation to the Roadmap is becoming clearer and has two main foci:
 - Managing translation of Roadmap strategies into tactical projects, and
 - Providing a path for discoveries and issues identified by the TSC back to the Roadmap and to the Board

Architecture Review Board (ARB)

The Roadmap identifies that "Architecture" is an essential characteristic of HL7 standards, to be managed by the ARB within the following guiding principles:

"HL7's Standards and Technologies are founded and managed by a set of Architecture principles that help to assure that they are internally congruent, consistent with appropriate measures of quality and have been prepared according to the appropriate approved associated HL7 methodology.

HL7's Architecture Review Board (ARB) keeps and manages the HL7 architecture(s). The ARB defines and documents both the "goal architecture" for the suite of current HL7 products and the gaps that exist between this "goal architecture" and the current or "de-facto" architecture as it currently exists. The HL7 "goal architecture" is consistent with both the HL7 Mission and the current HL7 Strategic Plan as defined by the HL7 Board.

The ARB provides recommendations to the TSC and CTO that move the HL7 organization and their products towards the current "goal architecture".

The ARB works to improve the consistency and effectiveness of committee operations relating to overlap of committee scope or gaps where no committee is working."

The ARB needed to be reconstituted in order to address these principles effectively, giving rise to the following specific Roadmap goals:

1. Reorganize and establish a new ARB based on the above principles by Jan 2008.
2. Create a defined set of Architecture principles associated with each HL7 product by June 2008.
3. Position the ARB to work with all relevant committees of HL7 to proactively lead HL7's adoption of HL7's approved Architecture and establish a process for its continuous review and update by December 2008, and, to address principles for adoption of Emerging Technologies:
4. Working with the ARB, include coherent and complementary static and dynamic modeling concepts in HL7s "goal" Architecture by December 2008.

The ARB has now been re-established with Charlie Mead as chair and other members appointed by invitation on account of their specific expertise and ability to cover HL7 organisational, v2, v3 vocabulary, domain and international (realm) interests. Current membership of the Architecture Board is:

Person	Affiliations	Country
Chair: Charles Mead MD MSc	Booz Allen Hamilton	United States
John Quinn	HL7, Chief Technology Officer (CTO)	United States
Yongjian Bao	GE Healthcare Integrated IT Solutions	United States
Jane Curry	Health Information Strategies Inc	Canada
Grahame Grieve	Kestral Computing Pty Ltd	Australia
Anthony Julian	Mayo Clinic/Foundation	United States
John Koisch	Booz Allen Hamilton	United States
Cecil Lynch	OntoReason, LLC	United States
Nancy Orvis	U.S. Department of Defense, Military Health System	United States
Abdul-Malik Shakir	Shakir Consulting	United States
Rene Spronk	Ringholm Institute	The Netherlands

Person	Affiliations	Country
D. Mead Walker	Mead Walker Consulting	United States

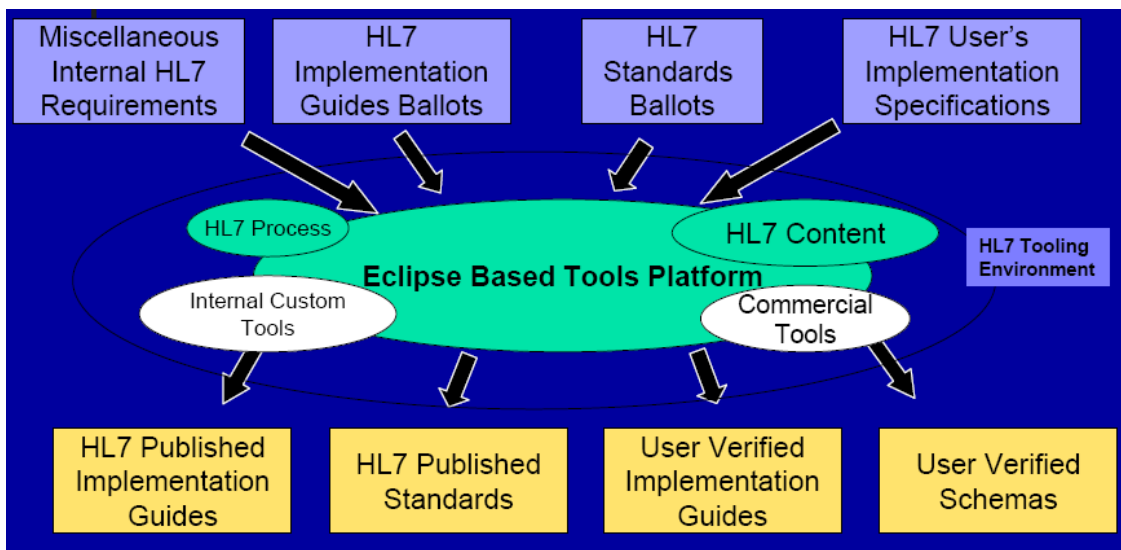
Tooling and Implementation Support

Effective tooling for HL7 v3 has been a major topic for the HL7 Board which has now moved decisively to close out previous activities and seize opportunities to leverage HL7's tooling efforts by building on substantial investments being made in the wider stakeholder community. Many outside stakeholders are already investing far more money in tooling than HL7 would be able to afford and there is much parallel activity taking place in the Open Health Tools Community.

Accordingly, key focus areas for tooling are:

- Having tooling that is consistently able to support BOTH internal HL7 standards development AND external users seeking to implement HL7
- Aiding the consistent publishing of Standards, Implementation Guides and specific-use instance specifications
- Goal of supporting all HL7 products – CDA, v3, v2 and others (where appropriate)
- Existing problems with publication, schemas and CDA templates
- Implementation guides that people actually use or need for implementation
- Making best use of the Eclipse open source platform and potentially useful donations of existing tools that might be adapted to HL7's particular needs.

The vision for tooling is illustrated in the following diagram from John Quinn's presentation to the general session on Monday, 14 January:



Current activities underway to support the above focus and vision include:

- Evaluating the suitability of the IBM model-based publication tool, which IBM is prepared to donate. This is an needed sooner rather than later given obsolescence of current Visio-based approaches.
- Completing internal MIF requirements
- Creation of a User Requirements document to identify key areas of user need.
- Actively supporting and participating in the “Open Health Tools Community” (OHTC) including input at the level of the OHTC Board (which is broadly formed) and the Architecture Council.

v2.6

John Quinn confirmed that v2.6 was sent to publishing in late December and is now available for download. Attempting to retain backward compatibility with some events being retained but deprecated has resulted in nasty problems. It was found that the specification had many out of date examples based on items now deprecated in v2.6.

Keeping to the rules about “no substantive change” during publishing poses a major challenge where the publishing process reveals a need for obvious corrections or improvements.

6. Report on Technical Steering Committee (TSC)

As previously reported from the September Plenary and WG Meeting, the TSC has been restructured into a smaller, formally constituted organisational unit with the following structure and membership:

Position/Role	Person
Chair, TSC (& International Representative) (to Dec 09)	Charlie McCay, Ramsey Systems Ltd (UK)
Chief Technology Officer (CTO)	John Quinn, HL7
International Representative (to Dec 08)	Frank Oemig CTO, Agfa Healthcare
Domain Experts – Representative (to Dec 08)	James Case. American Association of Veterinary Laboratory Diagnosticians
Domain Experts – Alternate (to Dec 08)	Austin Kreisler SAIC - Science Applications International Corp
Foundation & Technology – Representative (to Dec 08)	Ioana Singureanu Eversolve LLC, supporting US Dept of Veterans Affairs
Foundation & Technology – Alternative (to Dec 09)	George (Woody) Beeler Jr PhD Beeler Consulting LLC
Structure & Semantic Design – Representative (to Dec 08)	Calvin Beebe Mayo Clinic/Foundation

Position/Role	Person
Structure & Semantic Design – Alternative (to Dec 08)	Gregg Seppala US Dept of Veterans Affairs
Technical & Support Services – Representative (to Dec 09)	Kenneth McCaslin. Quest Diagnostics, Inc.
Technical & Support Services – Representative (to Dec 09)	Helen Stevens Love Canada Health InfoWay

Karen van Hentenryck, Deputy Executive Director, provides staff support to the TSC on behalf of HL7 Headquarters.

It was noted that the TSC held its kick-off meeting in September, with this San Antonio Meeting being the first opportunity for a full face-to-face meeting; however, some 13 meetings of the TSC had been held by teleconference over the intervening period with significant progress having been achieved. Key activities have included:

- Confirming the TSC Mission and Charter; decision making practices; and areas of responsibility
- Setting up the TSC wiki (at <http://hl7tsc.org>) for dissemination of information including minutes, agendas and committee documents
- Posting foundation documents to the Wiki including the full, updated version of the Mission, Responsibilities, Composition and Formation document
- Establishing a good working relationship with the CTO
- Drafting and discussing new processes for formation and dissolution of HL7 committees
- Bedding in the Steering Divisions, and establishing their respective roles and committee responsibilities
- Considering how non-technical committees such as PIC, Marketing, Project Services, CIC and ARB should relate to each other, the Steering Divisions and to the TSC
- Implementing gForge as a common resource for issue tracking. The web address for accessing the issue tracker is: http://hl7projects.hl7.nscee.edu/tracker/index.php?group_id=52&atid=313
- Approving scope statements for various projects – as part of the TSC's expanded role of the coordinating and ensuring the quality of HL7's technical activities
- Coordinating the migration of website content to the new HL7 web portal (see separate report at section 7.4 below).

Some of the TSC activities in train and planned for 2008 include:

- Renewal of the Architecture [Review] Board as a more effective element with direct responsibility for decisions about HL7's technical architecture

- Establishing a new Project Services Committee with the aim of establishing metrics and processes to link project office and committee work more effectively and get better visibility of what is happening in the organization.
- Dealing with the many issues being logged in gForge (with 25 or so having already been submitted)
- Providing input to and then bringing the "HL7 Product and services strategy" (Roadmap) into reality – and deliver against stakeholder needs.
- Releasing a single HL7v3 edition for 2007+2008
- Improving reporting and communications processes and achieving greater visibility of work plans and project activities
- Ensuring committee roles, responsibilities and processes are clear
- Managing the work program to address overall priorities
- Identifying TSC success metrics and planning to deliver against them.

Specific issues addressed by TSC have included:

- v2.6 publishing issues in relation to deprecated messages
- Managing ISO/CEN/HL7 collaboration and associated work
- Scope of HDF, and relationship to other architecture and process documentation, and
- Others - schema errors, ballot quality

These activities are being conducted under the TSC Mission Statement, which is:

"The HL7 Technical Steering Committee oversees and coordinates the technical effort contributed by the HL7 volunteers who make up the HL7 Working Group. Its mission is to assure that the efforts of the Working Group are focused on the overall HL7 mission. It shall operate in such a way so as to:

- *respect the contribution and ideas of the talented individuals who make up the Working Group;*
- *maintain an effective focus on the goals of HL7;*
- *assure that all major decisions are based on consensus of stakeholders;*
- *maximize sharing and "re-use" of work products within the Working Group;*
- *use project management to assure that project goals are articulated and met;*
- *reduce redundancy, competition and conflict within the Working Group;*
and
- *assure that HL7 standards are developed on an architectural foundation that assures consistency and interoperability.*

Specific TSC responsibilities supporting this mission include:

Overseeing execution of standards development

Assures that the efforts of the Working Group (WG) are effectively focused on accomplishing the product and services strategy set forth by the Board.

Providing a coherent architecture and development process

Establishes (or reviews) the Technical Architecture, the development methodologies, and the work processes to be used by the WG in developing HL7 consensus-based standards specifications.

Overseeing the Technical Operations of the Working Group

Assures that the WG works smoothly together and covers the work scope in a consistent manner.

Primary Communication Vehicle for the Technical Operations of HL7

Serves as technical authority of HL7, communicating status and guidelines regarding standards and operations and providing the ultimate escalation point for questions related to the technical operations of HL7.

Reports on technical operations, news, status, and issues to the Board, the WGM, and the membership as appropriate.

Has responsibility for official interpretation of the HL7 standards.

Steering Groups

As can be implied from the titles of some of the representatives on the TSC, there are four Steering Groups, with the distribution of TCs and SIGs between the four Steering Groups being as set out in the following table:

Domain Experts Steering Group			
Anatomic Pathology	Anesthesiology	Attachments	
Cardiology	Clinical Guidelines	Community Based Collaborative Care	
Emergency Care	Government Projects	Health Care Devices	
Imaging Integration	Laboratory	Patient Care	
Patient Safety	Pediatric Data Standards	Public Health Emergency Response	
Pharmacy	Regulated Clinical Research Information Management (RCRIM)		
Foundation & Technology Steering Group			
Implementable Technology Specifications		Implementation/Conformance	
Infrastructure & Messaging	Java	Modeling & Methodology	
Security	Service Oriented Architecture	Templates	Vocabulary

Structure & Semantic Design Steering Group		
Arden Syntax	Clinical Context Object Workgroup	Clinical Decision Support
Clinical Genomics	Electronic Health Record	Financial Management
Orders & Observations	Patient Administration	Scheduling & Logistics
Structured Documents		
Technical & Support Services Steering Group		
Education	Electronic Services	Process Improvement Committee
Project Services Committee	Publishing	Tooling

7. Other organisational and governance matters

7.1 Strategic Initiative and HL7 Roadmap

The HL7 Strategic Initiative for a comprehensive review of its structure and processes commenced in 2005 with the view of improving the efficiency of the standards development process. It was funded by a grant from the Robert Wood Johnson Foundation and sought to achieve the following overall goals:

- Restructure the organization to address longer-term goals;
- Support HL7's role at the international and affiliate level; and
- More efficiently and expeditiously develop standards.

The Strategic Initiative has now largely been completed with the appointment of the CEO (Charles Jaffe) and the CTO (John Quinn), reconstitution of the Technical Steering Committee to manage the technical activities with the assistance of new Steering Divisions and refocussing the HL7 Board on strategic management of the organisation with external appointees.

Other aspects have included increased stakeholder engagement and the redesign of the HL7 website to make it a more effective information resource for both the HL7 community and its stakeholders.

The "Roadmap" of actions needed to implement the Strategic Initiative was an initial priority of the new CEO, Dr Charles Jaffe and has now been developed considerably further through:

- Discussions in early August 2007 at meetings of the HL7 Advisory Council and HL7 Board at their annual retreat in San Francisco;
- A 2-day facilitated workshop for the HL7 Board held in mid-August 2007;
- Initial presentation to members and feedback at the Atlanta Plenary and WG Meeting in September; and

- Workshops at the first HL7 Stakeholders' Roundtable held at the Cleveland Clinic on 29-30 October, 2007, attended by some 20 invited participants representing leading provider and vendor organizations and health agencies.

A recent draft of the HL7 Strategic Roadmap is provided as Annexure A to this report and it is understood feedback from international affiliates would be most welcome. The Roadmap sets out principles, objectives and, in some cases, milestones to be achieved under the following high level headings:

<p><i>General Principles</i></p> <p><i>Standards</i></p> <ul style="list-style-type: none">• Architecture• Version 2• Version 3• Other Existing Standards / Implementation Guides• Evolving Standards / Implementation Guides <p><i>Services</i></p> <ul style="list-style-type: none">• Certification• Implementation Services• Tooling• Vocabularies and Ontologies• Evolving and emerging Technologies <p><i>Organizational Development</i></p> <ul style="list-style-type: none">• Technical Services• Operations Management• Project Management• Marketing/Communications• Industry Advisory Council <p><i>Financial Development</i></p> <ul style="list-style-type: none">• Funding sources• HL7 Foundation <p><i>Affiliate Development</i></p> <p><i>Outreach & Relationship Development</i></p> <ul style="list-style-type: none">• Associate Charter Agreements• Memoranda of Understanding• New partnerships
--

Australian delegates will be observing through 2008 to see how and whether these measures improve HL7's relevance, responsiveness and operations.

7.2 New Board Appointees

HL7 recently adopted revised bylaws that include the addition of three voting members to the Board of Directors nominated by the Chief Executive Officer and ratified by the Board. At the recommendation of the CEO, the Board approved the appointment of the following three members selected for their ability to bring to the

Board diverse experience in healthcare IT management, a longitudinal international perspective, and a unique vision for standards development:

Dennis Giokas, MS

As Chief Technology Officer, Canada Health Infoway, Dennis Giokas heads the Solution Architecture Group and is responsible for the overall electronic health record (EHR) business and technical solution architecture as well as the health IT standards agenda. This includes responsibility for the EHR Solution Blueprint, the Privacy and Security Conceptual Architecture, and the Infoway Standards Collaborative for the governance, development, support and maintenance of all health informatics standards in Canada.

He has more than 25 years of experience in the information management and information technology field. He has previously held executive positions at Sapient Corporation, most recently as vice-president and managing director of its Canadian subsidiary. He has also consulted on IT strategy in a number of industries including healthcare, financial services, insurance and energy services. In addition, Giokas held several senior positions with Digital Equipment Corporation, including those of consulting engineer and group technical director.

He has served as a board director of Canada's Health Informatics Association (COACH) and holds a Master of Science in Computer Science from Boston University.

Donald W. Simborg, MD

Don Simborg was one of the co-founders of HL7 and a founding member of the American Medical Informatics Association's (AMIA) College of Medical Informatics. He also founded, and is the former CEO, of two EHR companies and the author of more than 100 articles and book chapters on a wide range of medical informatics topics.

Simborg has served as a member of the Computer Science and Telecommunications Board of the National Research Council, National Academy of Sciences. In 2007, he chaired the expert panel on anti-fraud requirements for EHRs for the Office of the National Coordinator for Health Information Technology. He is a board member of the Foundation on Research and Education, American Health Information Management Association.

Simborg currently consults with venture capitalists, start-up healthcare IT companies, and provider organizations regarding healthcare IT. He received his medical degree from the Johns Hopkins School of Medicine.

Kenneth Lunn, PhD

Ken Lunn is the Director of Data Standards and Products for NHS Connecting for Health (CfH) in the United Kingdom, where he leads a team of 84 staff developing and maintaining standards products for the NHS, including terminologies, classifications, messaging, clinical documents, the NHS data dictionary and clinical content models.

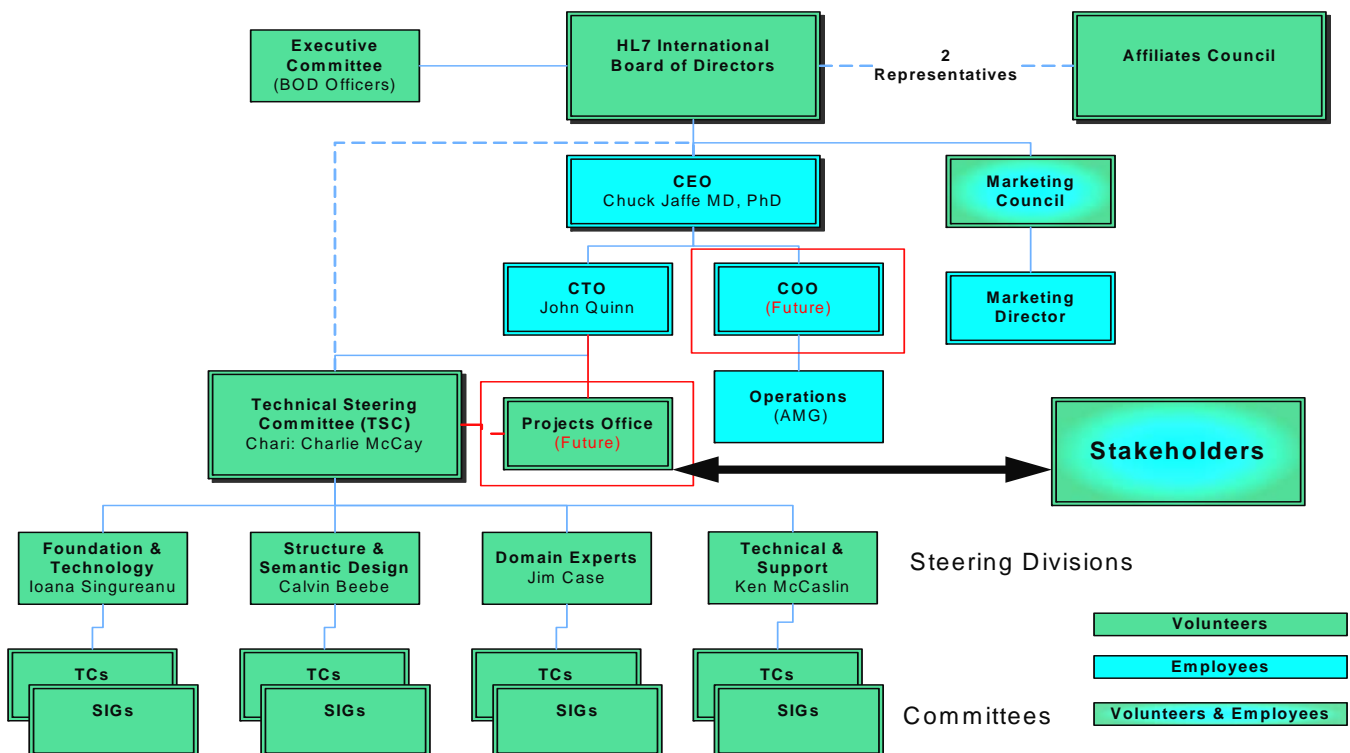
He earned a Ph.D. in distributed computing from Keele University and completed postdoctoral training in artificial intelligence and model-based methodologies, and has contributed to a number of academic publications and textbooks. His career has spanned both industrial and commercial R&D, both in consulting and management roles.

Lunn currently heads of the UK [Health] Terminology Centre, which was established to manage the UK edition of SNOMED CT, and sits on the International Health Terminology Standards Development Organization (IHTSDO) technical committee. In addition, he is the nominated deputy for the UK on the IHTSDO management board and general assembly.

Lunn is also on the board of stewards for the newly formed Open Health Tools, and successfully proposed a charter through that organization for the further development of HL7 tooling. His team is developing state-of-the-art tooling for HL7 message design and support, and is working to integrate that tooling into other standards tooling in terminology and content modelling.

7.3 HL7 Organisation Structure

The HL7 organisation structure as currently proposed is as follows:



7.4 HL7 Website/Portal

The Electronic Services Committee (ESC) is appointed by the Board of Directors to oversee and prioritize HL7 headquarters' electronic services with a mission of optimizing all forms of electronic interaction with HL7.

A greatly improved web presence for HL7 based on implementation of a more effective portal for communicating information within the HL7 community and to the wider audience needing information on HL7 and its products is one of the key initiatives flowing from the HL7 strategic initiative.

Ken McCaslin, a co-chair of the ESC, who is overseeing the website redevelopment project on behalf of HL7, reported on progress with the web portal developments since the last WG meeting, noting that the new web portal will have:

- A greatly improved search function that it is able to search and retrieve information from across the entire site including from within office documents and PDFs.
- E-commerce capabilities, along with increased security and the workflow automation features needed to handle orders and payments.
- Features that assist individual workgroups to publish, maintain and customise the content of their own pages.
- Improved features and tools including document libraries, templates and procedures and tools to facilitate the production and maintenance of online documents and associated metadata.
- Network and server infrastructure - enhanced and upgraded for speed and security.
- Individual member profiles - including expanded information about participation as co-chairs, facilitators etc.
- MyHL7, providing personalisation of the portal interface for each registered user, including the ability to flag conference calls and documents.

An extensive User Acceptance Testing (UAT) program has been commenced, with a view to ensuring that the content of the site is appropriate, current and well constructed.

Extensive work and collaboration on the part of both headquarters staff and volunteers has been a key feature of the program to date, with much of the effort involving the identification of requirements and review of content as the site is developed. These activities have been led by Dave Hamill, Mike Kingery and Karen Van Hentenryck, who manages the contract with external developers, Ascentium. Sherold Barr and Shelly Ross from the new HL7 marketing team are reviewing the site from a marketing and user perspective.

Zoran Budzakoski, a network/security expert and Patrick Loyd (Gordon Point Informatics) have both donated a lot of time to the project, as volunteers.

The checking, cleansing and migration of content from the old site to the new portal is proving to be a massive undertaking, which needs input from appropriately authorised and knowledgeable individuals across HL7. Identification and engagement with the appropriate people is one of the major challenges facing the project. Where content is not migrated, it needs to be archived in an organised and accessible fashion.

Most workgroups and affiliates need to have identified a person at co-chair or executive level to take responsibility for ensuring that the contents of their portion of the new website is appropriate, complete, authorised, indexed, tested and correct,, and that superseded information is identified and archived. Getting this feedback in a timely fashion is essential to delivery of the new capability.

Management of headquarters and other high-level content is also a concern, with it often being difficult to identify someone with appropriate authority and time to review and approve content being moved to the new portal or archived.

Currently, the main need is for assistance with the continuation of UAT in the areas of work group sites, affiliate sites, standards, standards for sale, event registration and the new MyHL7 functionality. Volunteers with the following characteristics are being sought to assist with the UAT process:

- Working knowledge of the existing website
- A willingness to review and document issues
- Preferably, a minimum of 5 hours per week, and
- Able to join weekly ESC conference calls on Tuesday at 11 a.m. US Eastern Time.

Gap reviews are needed to ensure that the content of each segment of the portal site is appropriate, to find what may not have been migrated and to initiate timely development of corrective plans. The right people, including some from each involved area, are needed – but it is a challenge for the project to ensure that they have people with the right knowledge involved in UAT and gap analysis.

Work groups and affiliates who have not yet nominated their contact point for the web portal project were asked to forward an appropriate name immediately.

HL7 Australia needs to consider, resolve and advise the team of its contact point for this work.

Another problem has been some workgroups that are looking for solutions that are more customised than allowed by the common development process now being used to produce and populate the website content. The use of a common process has enabled the migration cycle to be shortened through the use of contract assistance. It is also intended to reduce errors and longer-term maintenance issues, but does not readily support special requirements that are unique for individual work group or affiliate sites.

The next steps are:

1. Complete UAT of templates and high-end pages

2. Complete main and top-level page content migration
3. Link new production website to old website.
4. Release new production website.
5. Begin migration of remaining content.
6. Complete and validate move of contents.

Contact information for the website team:

Ken McCaslin - Kenneth.H.McCaslin@QuestDiagnostics.com

Dave Hamill – dhamill@hl7.org

Mike Kingsbury – mkingery@hl7.org

Karen Van Hentenryck – karenvan@hl7.org

Patrick Loyd – Patrick.loyd@gpinformatics.com

7.5 Marketing Committee

The following are among the matters considered at the Marketing Committee.

1. Ken Rubin spoke to the upcoming HL7-sponsored conference on SOA in health care to take place on 15-17 April in Chicago [see section 14 below for details]. From a marketing perspective, the health SOA community was already engaged and over 20 outlines of papers had been received. It is targeting a US audience, building on their current needs for better quality of care information and it would be promoted heavily at HIMSS in February.

Ambassador Program.

2. The objective of the Ambassador Program is to equip engaged members of the HL7 community with the materials and information to enable them to confidently and consistently present an aspect of HL7 work with which they are familiar to health service and ICT executives. Standardised presentations on the first two topics were available for distribution to ambassador speakers and were demonstrated at the San Antonio Meeting:
 - Personal Health Records (PHR) by John Ritter (Tue, pre-breakfast)
 - SOA in health by Ken Rubin (Thu, pre-breakfast)
3. HL7 Ambassadors are being actively sought from across the active HL7 community including the international Affiliates such as HL7 Australia.
4. Those wishing to be an ambassador must be an HL7 subject matter expert and have attended at least 3 of 6 HL7 WGM, meetings prior to application. Gora Datta and his team will be setting up a basic PowerPoint presentation on the Ambassador program for the HL7 website.
4. Training for Ambassadors is expected to be ready in time for intakes from the September WG meeting.

HL7 Distance Learning Program

5. Mark Shafarman introduced the Distance Learning Program to the Marketing Committee as a potentially powerful outreach tool. The program was based on materials and approaches developed by HL7 Argentina [see 8.2.9 below].
6. Students with a need for HL7 skills but minimal exposure to existing WGM and educational activities, are required to trial the new updated English-language version of the program in both developing and developed countries. The following countries have been selected for the trial – China, India, Sweden, Australia, USA & Canada.
7. Affiliate countries are being asked to advertise the course on websites or other appropriate media and select no more than 15 registrants, after which HQ will organise their participation. Most of funds stay with the Affiliate, to ensure there is an incentive. Main tutors will be from Argentina, who will train other tutors for continued rollout. Outstanding issues were the need for:
 - A project plan
 - Enrolment and application page
 - Publication on HL7 website
8. Possible titles for publicising the course were discussed, including:
 - *Announcing the first HL7 e-learning course*
 - *Introductory online course: HL7 standards v2, v3, and CDA*
 - *Creating and exchanging electronic healthcare information.*
9. Chris Lynton-Moll from Australia was asked and agreed to sit on the Marketing Committee to act as the Affiliate liaison for this project. Committee conference calls are held fortnightly at 4.00 pm (US) EST [or 8.00 am AEDT].

8. International Activity

8.1 Introduction

People from 18 countries were present at the San Antonio Meeting with around 133 from outside the US, including significant contingents from Canada (31 people), UK (27), Japan (15), The Netherlands (15), Australia (11), Germany (8), France (7) and Korea (7). Of the countries present, 12 international Affiliates were officially represented as voting members of the Affiliates Council (compared with 15 in Atlanta and 20 in Cologne). In total around 25% of all participants came from outside the United States.

HL7 has approved recognition of international Affiliates in around 30 countries:

Argentina (AR)	Finland (FI)	New Zealand (NZ)
Australia (AU)	France (FR)	The Netherlands (NL)
Austria (AT)	Germany (DE)	Singapore (SG)
Brazil (BR)	Greece (GR)	Spain (ES)
Canada (CA)	India (IN)	Sweden (SE)
China (CN)	Ireland (IE)	Switzerland (CH)
Colombia (CO)	Italy (IT)	Taiwan (TW)
Croatia (HR)	Japan (JP)	Turkey (TR)
Czech Republic (CZ)	Korea (KR)	United Kingdom (UK)
Denmark (DK)	Mexico (MX)	Uruguay (UY)

Of these, some have been approved but are still in the process of completing or renewing their affiliate agreements with HL7.

8.2 Affiliates Council

The HL7 Affiliates Council met from 0900 until 1530 on Sunday, 13 January and was attended by some 83 participants, with 12 national Affiliates being represented for the purposes of voting.

Significant apologies for the Sunday meeting of the Affiliates Council were received from:

- Charles Jaffe, CEO of HL7, whose travel had been interrupted
- Mark McDougall, Executive Director HL7)
- Yun-Sik Kwak, Chair ISO/TC 215,
- Kees Molenaar, Chair of the CEN VTC251 Health Informatics Committee in Europe, and
- Miroslav Koncar (HL7 Croatia), a co-chair of the Affiliates Council.

8.2.1 ISO TC 215 report

Dr Yun Sik Kwak was unable to be present; however, Audrey Dickerson of HIMSS (which provides the TC 215 Secretariat for ANSI) briefly addressed the Council noting that:

- There has been no TC 215 since the last HL7 WG meeting in September 2007 (about 3 weeks after the last TC 215 meeting in Brisbane).
- The next TC 215 meeting is the annual plenary meeting and will be held in Gothenburg, Sweden from 30 May to 2 June 2008.
- Ed Hammond was reporting separately in some depth on progress with the ISO-CEN-HL7 Joint Initiative.

8.2.2 Report of Joint Initiative on SDO Global Health Informatics Standardization

As the HL7 representative on the Joint Initiative Council (JIC), Ed Hammond provided a status report and update on the activities of the JIC and Joint Working Group (JWG). Matters covered included:

- A brief history of the Joint Initiative (JI) going back to its formation in Geneva in 2006 (following previous discussions) to provide a framework by which ISO TC 215, CEN TC 251 and HL7 could collaborate and better harmonise their standards development activities.
- Governance of the JI by through the JIC and JWG under the terms of the Joint Initiative Charter.
[For more background on the JI and the JWG– see section 9.2 below].
- Feedback on early lessons suggests that it will take considerable effort and goodwill to make the Joint Initiative work and overcome the problems and practical difficulties that are being encountered as the concept is implemented.
- The development of better procedures, with recognised communication pathways and greater understanding of the role of the JI is seen as critical to success.
- A brief summary of some of the main projects being progressed jointly by the JI which include:
 - Harmonised Data types, being led by Grahame Grieve;
 - Projects sponsored by ICH in the area of medicines and device safety based on common standards for:- individual case safety reports (ICSR), medical product terminology, and medical product and device listing.
- The Joint Initiative Council (JIC) consists of three representatives – one from each participating SDO. The HL7 representative is Ed Hammond, who will be assisted by Charles Jaffe and John Quinn.
- To facilitate communication and resource management, there is to be a single point of contact within each SDO for JIC activities.

- For HL7, the point of contact will be John Quinn in his role as CTO. Individual working groups and members of the HL7 community seeking to participate in collaborative JIC activities on behalf of HL7 are required to initiate HL7 involvement through John and keep him informed.
- The Joint Initiative is now engaged in working up the policies and processes needed for effective identification and management of joint projects. Some key elements include:
 - For a project to become a “Joint Project”, the JIC must approve it as a joint project and will appoint a lead SDO to manage the project.
 - The lead SDO will establish and provide a chair for the joint initiative task group that will produce ballot drafts and deal jointly with comments submitted. The other SDOs will provide co-chairs and facilitate broad engagement in the Joint Project.
 - Selection of the lead SDO may take into account a range of relevant factors such as available expertise, origins of the project, external stakeholder interest and/or support, and any need to satisfy official directives,
 - Where the result is a “joint product”, there will be one single ballot, run simultaneously through all three SDOs.
 - Processes for Joint Projects are to be open and encourage participation from members and other participants from any of the SDOs.
 - A Joint Project will deliver co-branded products with copyright owned jointly by all three SDOs.
 - Work on Joint Projects must be completed in a timely fashion in accordance with an appropriate timeline that allows adequate lead time.
 - Avoiding miscommunication is a major issue in getting the Joint Initiative to work successfully – open lines of communication need to be maintained between the three SDOs, and be reflected at project level in accordance with an agreed communication hierarchy allowing escalation of issues.
- In response to questions from the Affiliates Council, it was noted that some of the issues needing to be dealt with include:
 - Alignment of very different ballot cycles – ISO/CEN ballots are open for 90 days up to 5 months (depending on the type of document and stage of approval) compared with 30 days for HL7.
 - [In theory] the members that participate in ISO/CEN ballots are “national member bodies” (NMBs) that represent and attempt to resolve differences between various stakeholder interests within their realm before voting; whereas, HL7 ballots are open to votes by individuals.
 - HL7 ballots often run for several ballot cycles until consensus is reached, whereas ISO, CEN and their NMBs tend to use alternative processes to negotiate agreed positions that can then be ratified by ballot.
 - Some of the longer periods that by ISO and CEN members need are to allow them to have material translated and get stakeholder consensus.

- In the case of HL7, some Joint Projects may need to be balloted "out of cycle".
- The potential for very large groups to become involved in Joint Projects and how this might be effectively managed.
- The need for more timely and efficient processes to address rapid obsolescence of material endorsed as International or Joint Standards - noting that the ISO Standard version of the HL7 RIM is now some five years behind the version of the RIM being used in current implementations.

[A counter view is that standards adopted for actual implementations change very slowly and that even HL7v2.5, as adopted by ISO, is not yet widespread].

- Whether consideration is being given to limiting the number of projects initially (to get some quick results) before "opening the floodgates" and whether HL7 has developed an internal process to determine its preferred priorities for the joint work program.

Ed Hammond noted that HL7 has a responsibility to its members and stakeholders to meet standardization objectives and that, whilst each of the three SDOs strongly supports the Joint Initiative, there will still be work that each SDO may not be in a position to progress as a Joint Project, or which an SDO may simply complete and offer for adoption as an International Standard [preferably allowing stakeholders of other SDOs to participate during its development].

Those involved in HL7 working groups were particularly asked to recognise that the commitment of HL7 resources to participation in joint work with other SDOs is not a decision for individuals and working groups but needs to involve HL7 as an organisation. HL7's reputation has suffered when some ad hoc arrangements have broken down or the wider HL7 community has not been informed of proposed activities. Early communication with the CTO (John Quinn) and TSC is needed to ensure that such arrangements are properly supported by HL7 and are recognised by other SDOs participating in the JI. It was noted that HL7 is not attempting to stifle the exploration of opportunities, rather, it is just seeking better and earlier communication with those tasked with responsibility for joint activities.

[The Australian delegation notes that the JI may therefore need to consider having several different pathways for harmonisation of health informatics standards and for collaboration between SDOs. It has also been noted that there are many other SDOs active in the health informatics field and that the currently proposed JI processes are unlikely to scale effectively to participation by many more SDOs.

Also each SDO has commitments and joint ventures with other organisations, such as the joint HSSP activity between HL7 and OMG. Potentially valuable collaborations needing to be fostered between ISO, CEN and HL7 acting jointly and other SDOs include relationships with IHTSDO (SNOMED), CDISC, DICOM and, potentially, UN/CEFACT, OASIS, ASTM, WHO and others].

Elizabeth Hanley was introduced to the Affiliates Council as head of the JWG Secretariat and she advised the meeting of the web address (on the Standards Australia website) where members could find up-to-date information on the JWG and its activities. The URL is:

<http://www.e-health.standards.org.au/cat.asp?catid=43>

8.2.3 CEN TC 251 report - Melvin Reynolds

Melvin Reynolds gave the report on the European CEN /TC 251 Health Informatics Committee on behalf of Kees Molenaar, Chair of the Committee. As reported in more detail in section 9.4 below, topics covered included:

- The TC 251 committee structure
- Work by CEN, CENELEC and ETSI toward a co-ordinated work program for eHealth standardization in Europe under European Commission Mandate (M/403), with HL7, IHE and IHTSDO now included in the planning
- Upcoming TC 251 meetings – Cyprus 11-14 March; Gothenburg, Sweden on 31 May – 3 June (concurrent with ISO TC215)
- Joint ISO-CEN-HL7 projects sponsored by ICH in area of pharmacovigilance reporting and terminology, and
- Standards policy reviews by the EC DGEI (Enterprise & Industry) – seeking increased competitiveness of EU firms in ICT

8.2.4 Progress of EN/ISO 13606

On the invitation of Kai Heitmann (Germany), Dr Dipak Kalra provided brief comments on development of the EN 13606 EHR Communication standards and recent work in conjunction with HL7 committees. In summary, he advised the Council that:

- Adoption of 13606 is making good progress in both CEN and ISO. The present status is as follows:

13606 Part Standard	Status in CEN	Status in ISO
1: EHR Reference Model	Published in February 2007	Currently out for FDIS ballot
2: Archetype Interchange Specification	Published in July 2007	Currently out for DIS ballot
3: Reference Archetypes and Term Lists	Currently out for Formal Vote	About to be released for DIS ballot
4: Security	Published in March 2007	About to be released for DTS ballot
5: Interface Specification	Informal comment phase concluded. Next step: to be balloted as ENQ/DIS early next year under Vienna Agreement (CEN lead)	

- In the UK, NHS CfH is championing work on and implementable transformation between 13606 Parts 1 & 2 and templated CDA documents.

Charlie McCay, Robert Worden and Dipak Kalra are involved with this work which will initially focus on discharge summary.

An associated project seeks transform clinical knowledge represented through *openEHR* archetypes into HL7 templates (ideally in collaboration with DCM).

- Discussions are underway with the HL7 Services Oriented Architecture (SOA) SIG, on ensuring that RLUS services will support request and provision of ISO/EN 13606 artefacts.
- With respect to Data Types, EN 13606 data type profile requirements have been passed on to Grahame Grieve as CEN comment for inclusion in the proposed joint ISO/CEN/HL7 standard.

8.2.5 ISO/ CEN/ HL7/ IHE Collaboration

Mark Shafarman invited Affiliates to participate in the regular ISO/CEN/HL7/IHE Harmonization Group, which was held later in the evening of Sunday, 13 January – see notes at section 9.5 below). The Affiliates Council were also advised that:

- Efforts to harmonise 13606 and CDA are underway as an outcome of the JWG meeting held in conjunction with the CEN TC251 meeting in Dublin.
- Flowing from this, the ISO 13606 Part 1 FDIS ballot was accompanied by a letter explaining the process of SDO harmonisation. The letter was a combined effort by experts from CEN TC 251, ISO TC 215 and HL7.
- Dipak Kalra and Gary Dickinson advised the Affiliates Council of a broad agenda to align the work of HL7 EHR TC and ISO WG1 on EHR-related requirements and to try and coordinate efforts toward the medium term in areas such as:
 - Revision of ISO TS 18308 (Requirements for an EHR architecture)
 - EHR-S Functional Model
 - Requirements for EHR communication, including: EHR life cycle, and EHR interoperability model, and
 - Personal Health Records

The Council sought information toward achieving the goal of harmonising archetypes and templates (Jane Curry). It was noted that the previous approaches had not proven fruitful, partly because the nature of both archetypes and HL7 templates had continued to evolve. Nevertheless, the CfH program in the UK has defined a local structure for HL7 templates and is also using *openEHR* archetypes and *openEHR* templates to capture requirements for clinical content and anticipates that appropriate tooling will be developed to enable translation between *openEHR*/13606 and HL7 representations.

8.2.6 Report of International Mentoring Committee (IMC)

The International Mentoring Committee (IMC) assists potential Affiliate organizations and struggling Affiliates with guidance and education to permit them to improve their processes and procedures to become more viable. It may also provide assistance and education to strengthen support for the work of the Affiliate from government

agencies in the Affiliate's home country. The IMC report was presented by IMC Co-chairs John Ritter and Jim Leach) with the following being noted:

- John Ritter and Ed Hammond spoke at an HL7 Brazil event in October 2007, as an outreach to potential benefactors to HL7 Brazil. About 100 attendees were present at the event, which was hosted by Dr. Marivan Abraha, the chair of HL7 Brazil, and there was strong interest in PHR.
- Newsletter articles are desired by HL7 China (per Steven Yeo).
- The IMC continues to seek funding that may support its mentoring activities and assisting new or struggling Affiliates. The IMC is encouraging HL7 to support the creation of a foundation to support such activities.
- Cheryl Warner has resigned from her role as IMC co-chair due to a change in position.
- IMC is encouraging people to participate in HL7's new Ambassador program, which can also be a valuable source of targeted expertise for IMC outreach.

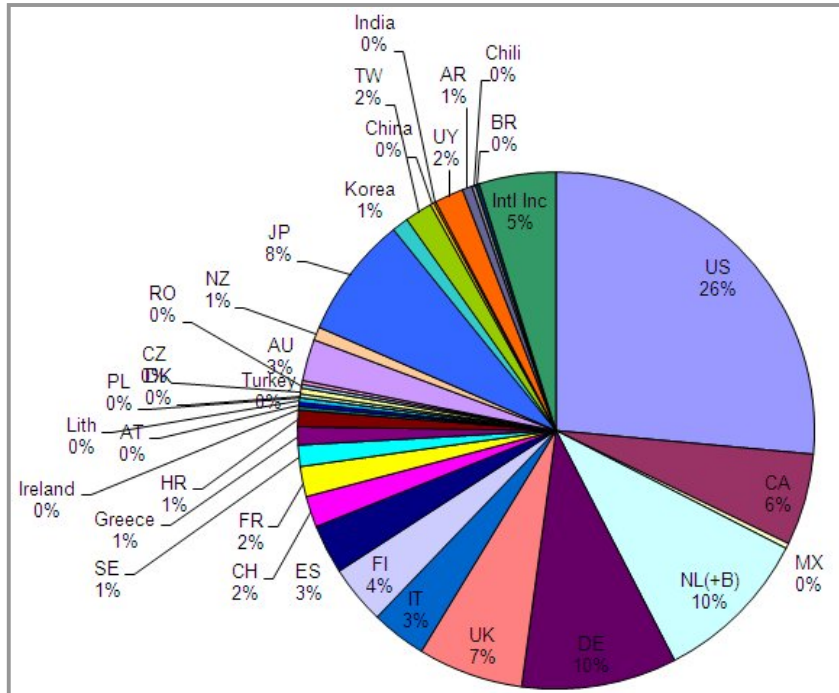
8.2.7 Implementation Conformance Committee (ICC)

Charlie McCay reported on ICC activities, noting:

- Current activities being progressed at the San Antonio Meeting :
 - Implementation Guide Project, Implementation FAQ,
 - Implementation Case Studies, and
 - DSTU testing project
- Input was sought from Affiliates at the implementation case studies sessions on Tuesday and Wednesday morning.

8.2.8 Worldwide HL7 Membership

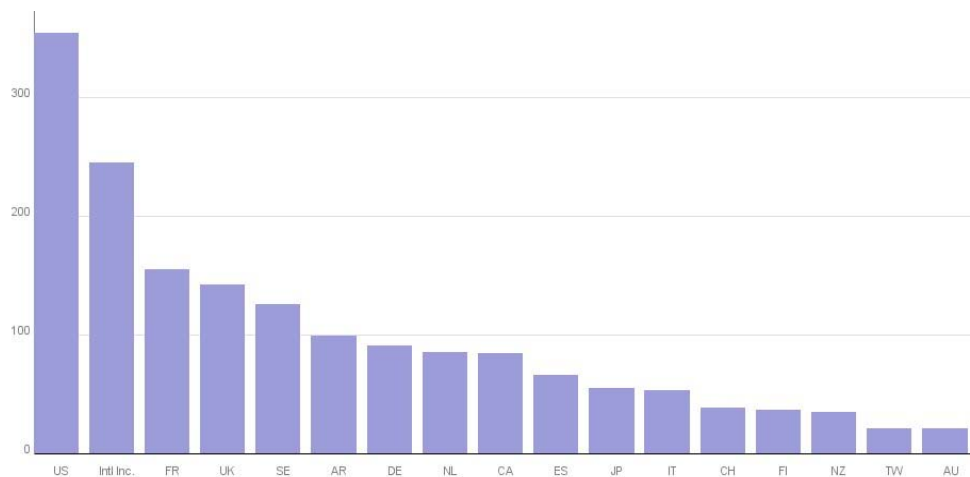
René Spronk (The Netherlands), former Co-chair of the HL7 Marketing Committee summarised a high-level analysis of the international character of the world-wide HL7 organisation which among other things, identified the following distribution of stakeholder participation based on an estimate of "HL7 Interested Persons":



HL7 Stakeholder location²

It was noted that the proportion of overall participation attributable to stakeholders outside the US had increased from 72% in September 2006 to 74% by the end of 2007.

On the other side of the coin, around 60% of HL7 revenues are derived from US sources, with the revenue per "Interested HL7 Person" being distributed as per the following histogram.



Revenue per HL7 Interested Person (\$US by Affiliate)

² For this analysis, organisational members are counted as having 3 stakeholders

The membership fee charged to belong to HL7 Australia is considerably less than the equivalent fees charged by many other Affiliates.

8.2.9 Web-based Distance Learning Project

HL7 Argentina has developed and implemented a 10-week interactive internet e-learning training program "Introduction to HL7" providing practical skills needed to successfully implement HL7 v2, v3, and CDA. The course has been successfully delivered to several intakes totalling over 100 students from across the Spanish-speaking world. The online content includes team assignments with online tutorial support from instructors experienced in HL7 implementations.

Information on this training program was provided as Attachment A to the report of the Australian delegation to the September 2008 Atlanta Plenary and WG Meeting. In Atlanta, HL7 agreed to form a project team to pilot delivery of the program in English. Mark Shafarman presented on behalf of the project team:

- Diego Kaminker (HL7 Argentina), co-chair
- Mark Shafarman, co-chair
- Gora Datta, Jill Kaufman, Abdul-Malik Shakir
- Mark McDougall (Executive Director, HL7) and Mary Ann Boyle (HL7 HQ)

For the proposed pilot of the program in English, HL7 Argentina has agreed to provide an English translation along with email, web and server support, and instructor training. The HL7 Board and administration is providing

- Publicity and administrative support, including flyers and online registration, and
- a guarantee to cover HL7 Argentina's outlays if the pilot doesn't pay for itself.

The activity is being sponsored by the Education Committee, which planned to meet with the Project Team at various times during the San Antonio Meeting to:

- Finish the project plan
- Complete negotiations and agree on the Affiliates participating in the pilot
- Complete staffing choices and resolve other open points (including ownership of IP, reimbursement of instructors, etc.)

The initial intake is to be limited to 100 participants, with differential pricing for developed and developing nations and maximum seats as per the following table.

	Price - USD	Max Seats
China	\$100	13
India	\$100	13
Australia	\$350	13

Canada	\$350	24
USA	\$350	24
Sweden	\$350	13

Australian delegates noted that HL7 Australia would publicise the existence of this opportunity for Australians to participate in the program and that Chris Lynton-Moll has agreed to join the Marketing Committee's conference calls to assist HL7 in promoting and organising the program.

8.2.10 Translations of HL7 Standards by Affiliates

Kai Heitmann noted the list of translations of (HL7) standards by Affiliates that had been drawn up by the marketing consultants Sherold Barr for presentation at HIMSS and suggested that the list be kept up to date by HL7 Staff and be made available on the Affiliates Council website.

8.2.11 Status report on migration to new HL7 organisation

The Chair of HL7, Ed Hammond, summarised progress in migrating HL7 to its new organisational structure, noting that:

- The reconstituted Board would hold its first meeting on Tuesday afternoon and evening.
- The voting members of the Board comprise 4 office bearers, 6 other members elected by the members at large, 2 members elected by Affiliates, and 3 external members recommended by the CEO and appointed by the Board. The CEO, CTO, Executive Director and TSC Chair are ex-officio members of the Board without a vote.
- The HL7 Board now has a more strategic and less technical focus and will be proactive in pursuing the development of HL7 and its products.
- The 'Roadmap' which sets out how HL7 will achieve its objectives has been under development for some months but is still in early draft (see Annexure A below). Feedback is invited with a view to producing a version that can be widely endorsed within HL7. Once released, update of the Roadmap will be a continuous process
- Good communication with stakeholders, members and participants in the HL7 community continues to be a vital concern of the Board.
- The Board is reviewing the MOUs it has with other organisations – confirming the reasons it has entered into various MOUs, what it is looking to achieve from each MOU and by whom and how will HL7 meet its commitments under MOUs.

It was noted that 2008 is a transition year through which the four Board members elected by the members at large at the end of 2006 will continue to serve; however, only two will be elected to replace them – reducing the number of Board members elected by the members at large from a total of 6 to 4 commencing in the 2009 year.

8.2.12 Report of HL7 CTO, John Quinn

John Quinn reported to the Affiliates Council that the reorganisation initiative was completed in 2007, with the appointment of Charles Jaffe as CEO, and John as CTO, and the restructure of the Board to include outside board members, including two from outside the US - Dennis Gioakas from Canada Health Infoway and Ken Lunn from the UK NHS CfH program.

The HL7 Architecture Review Board has been reformed and will manage the organisation to create a documented "goal architecture", which will span all HL7 technical products.

The content of various presentations by the CTO at the San Antonio Meeting is provided in section 5.3 above.

8.2.13 Technical Steering Committee (TSC) report

The TSC guides and manages the creation and maintenance of HL7 products and services, working closely with the CTO. Charlie McCay (UK), Chair of the TSC, reported on the activities of the TSC since it was re-formed in September 2007, covering:

- Membership of the TSC and its relationship to the new Steering Divisions
- TSC activity and deliverables since September 2007
- TSC objectives for 2008

Details of the composition and structure of the TSC, its recent activities and objectives are provided in section 6 above.

It was noted that the TSC would like input from the Affiliates Council on issues and requirements associated with HL7's products and technology and assistance in realising the promises of the HL7 Products and Services Strategic Roadmap.

The suggestion that TSC might lead the production of a technically focussed electronic newsletter to keep the membership abreast of technical developments was discussed, with considerable support from the affiliates represented.

8.2.14 Detailed Clinical Models (DCM) report

Dr William Goossen advised that the summary report from the Workshop on Care Information Models in Brisbane had just been completed and is to be made available on the DCM wiki: <http://detailedclinicalmodels.org/wiki>.

Activities at the San Antonio Meeting of particular relevance to those involved in DCM included:

- The HL7/CEN/ISO/IHE harmonisation meeting (on Sunday night)
- Representation of assessment scales (Patient Care TC Q4 Monday)

- The joint meetings of Patient Care TC and Templates TC on Q1, Q2 and Q3 on Friday 18 January to discuss DCM

8.2.15 Changes in affiliates' status

It was noted that new affiliates have up to one year from approval of their admission to execute the affiliate agreements required to complete their admission. This can take considerable time – especially where there is a need to get approval from various Government agencies or where a relationship with HL7 may have implications for national e-health programs.

Although approved by HL7, the affiliates in Singapore and Colombia have yet to execute their affiliate agreements. Singapore is expected to have completed by May 2008 and Colombia by September 2008.

Most affiliates have two year contracts expiring in 2008. Delays are being encountered when affiliate agreements, are renewed – which can cause an organisation's affiliate status to lapse. Affiliates were invited to provide feedback on how these processes might be improved.

Negotiations on becoming affiliates are continuing with organisations in several other countries – notably in Asia (including China) and the Baltic States, and there is new interest in Russia from both government and industry. Establishment of an affiliate in Chile does not appear to have progressed significantly since the Atlanta Plenary and WG Meetings in September 2007.

It was also noted that:

- The first invoice for affiliate dues will be despatched at the end of January 2008.
- This year the affiliate dues are stepping up from 10% of member revenues to 15%
- The documentation required to renew New Zealand's affiliate status has been sent to HL7.

It was suggested (Robert Stegwee, NL) that discussion of the affiliate agreements should be scheduled for the May Working Group meeting in Phoenix.

8.2.16 Affiliate access to new HL7 web portal

Ken McCaslin provided a brief status report on the development of the new HL7 web portal, noting that the new HL7 website is to go live in April 2008 after the completion of user acceptance testing and top level migration of pages.

His report to the Affiliate Council covered a subset of the topics that he later presented to the general membership (detailed at section 7.4 above).

Noting the emphasis on individual registration when accessing the new portal, Richard Dixon Hughes (Australia) questioned the implication that members of affiliates around the world content might have to register separately to access internal HL7 content, rather than being granted access from their local affiliate's website via the current "proxy" facilities.

The Affiliates Council expressed concern at the possibility of any such change and strongly affirmed their commitment to the retention of the proxy facility as an essential requirement allowing affiliates to manage their own members and their access to members-only material on the HL7 corporate website.

[It was later confirmed that secure access to HL7 internal content on the website would continue to be available via the proxy facility to affiliates and their members but that co-chairs and individuals requiring upload rights would need to be individually registered in order to exercise their full range of privileges.]

8.2.17 Budget allocations and other formal agenda items

The Affiliates Council meeting also received reports and/or took actions on the following:

- The upcoming IHIC 2008 conference. This is to be staged by HL7 Hellas in Crete. Organisation is well advanced for this event on 9-11 October 2008 (the week prior to the ISO TC 215 meeting in Istanbul). For more details, see information on upcoming events in section 14 below. Allocation of \$US5,000 from Affiliates Council was confirmed.
- INFOLAC 2008, being organized by AAIM (the Argentinean Medical Informatics Association) and IMIA-LAC (Federation of Latin American Health Informatics Societies) to be held in Buenos Aires on 29-31 October 2008. For more details see information on upcoming events in section 14 below. Allocation of \$US2,000 from Affiliates Council to support one international speaker for the conference was confirmed.
- The 7th Asia-Pacific HL7 Conference on Healthcare Information Standards, which is being planned for 19-22 November 2008 to be hosted in Taipei by HL7 Taiwan. Allocation of \$US2,000 from Affiliates Council was confirmed.
- Discussion of the financial resources available to the Affiliates Council. It was noted that the Council has a US\$25,000 revolving budget in which unspent funds may be carried forward and used in subsequent years. The possibility of funding visits by "HL7 Ambassadors" to affiliates was discussed without any specific action being agreed.
- Call for Proposals for IHIC 2009. A proposal to host this event in Kyoto was received at the September Plenary/WG from HL7 Japan (Michio Kimura). This proposal, which involves moving the conference forward to May is under consideration. Any other affiliate interested in hosting IHIC 2009 should make their interest known.
- One member one vote. Michael Van Campen (affiliate representative on the HL7 Board) regretted that the discussion of this had not been progressed and stated that he was seeking to have a session on it during the week of the San Antonio meetings.

8.3 Reports from International Affiliates

Updates presented to the meeting of the HL7 Affiliates Council provide an overview of the state-of-play across a large proportion of the international HL7 community. Inputs to the meeting included reports from a number of countries.

8.3.1 Argentina

Diego Kaminker, Chair of HL7 Argentina, was unable to be present; however, Mark Shafarman, a regular visitor had earlier presented information on INFOLAC 2008 (see section 14 below for details) and noted the significant contributions that HL7 Argentina continues to make in development of the online e learning program.

8.3.2 Australia

As Chair of HL7 Australia, Klaus Veil reported briefly, tabling an overhead presentation for inclusion in the minutes and highlighting that:

- HL7 Australia has subcontracted a large part of the organisation and delivery of HL7 training to a University-based training organisation (CCeH), and
- HL7 volunteers in Australia are leading efforts to establish an IHE organisation in the Asia-Pacific region, recognising that while the standards themselves are pretty good, implementation varies and can be assisted by IHE processes.

His overhead presentation addressed the following:

- Recognition of HL7 standards by NEHTA, the (Australian) National eHealth Transition Authority (NEHTA), which recommended in March 2007 the following as national standards for electronic communication of health information:
 - HL7 v2.x standards for existing messaging systems
 - HSSP (services) and CDA R2 (documents) for new national projects
 - Progressive migration of industry to HL7 V3 methodologies

These recommendations followed previous endorsement/acknowledgement of HL7 by the NHIG (National Health Information Group) in August 2004 and the Department of Health in 1997.

- An agreement between NEHTA and HL7 on "Working Together" more closely is being progressed.
- Membership is steady at around 180 for 2007/08.
- Distribution of HL7 standards materials is through several channels:
 - Free Access to HL7 Standards for HL7 Australia Members
 - HL7 Bookshop supported by Australian Healthcare Messaging Laboratory (AHML) and Collaborative Centre for e-Health (CCeH)
 - Licence to Standards Australia for use in standards development
 - License to Australian Government Department of Health and Ageing

- Proposed universal availability through a national licence.
- Education and promotional activities during 2007 had included:
 - Running a joint booth with HL7.org, Standards Australia and NEHTA at the international MedInfo 2008 congress held in Brisbane in August. This featured an IHE-style interoperability demonstration and over 300 HL7 information kits were handed out.
 - A two-day seminar held in Melbourne in October
 - A four-day education series conducted in Melbourne on 3-7December – the first provided under the new arrangements with CCeH
- Active support for HL7 and its users in Australia and other countries through:
 - The HL7 Australia website (15,000 hits/month from across the world)
 - Email lists (with over 600 subscribers), and
 - Supporting moves to establish IHE activities in the region.
- An MoU with AHML at the University of Ballarat supports the provision of an expanding range of HL7 certification services through AHML (www.ahml.com.au), used by organisations in over 16 countries. Consideration is being given to the question of professional accreditation.
- HL7 Australia has developed a 3-year strategic plan detailing its stakeholders; mission, vision and values, key result areas; and projects, supported by a more specific business plan. Key focus areas include:
 - Standards development
 - Education and capacity building
 - Support (eShop, website upgrade, regional outreach and student sponsorship)
 - Certification, and
 - Membership services.

8.3.3 Canada

Michael Van Campen, Chair of HL7 Canada and one of the two international representatives on HL7 Board presented a report on behalf of HL7 Canada, noting that:

- HL7 Canada's membership continues to grow. For 2007/08 there are 427 members, up 22% from 348 in 2006/07 and double the number three years ago (2004/05).
- Canada was represented by over 25 delegates at the San Antonio Meeting.
- [As previously reported] HL7 Canada has been fully transitioned into the Standards Collaborative, an arm of Canada Health Infoway which supports all of Canada's engagement with e-health SDOs (including: HL7, ISO, DICOM, IHT, IHE Canada, LOINC, SNOMED/IHTSDO)
 - providing stakeholders with "one-stop-shopping" via a single secretariat.

- Standards selected for transition to maintenance include those for:
 - Laboratory and Nomenclature
 - Interoperable EHR
 - Artefacts supporting cross domain harmonisation - wrappers, data types, CMETs
- Standards close to completing first full specification maintenance release include:
 - National eClaims Standard (formally known as NeCST)
 - Pharmacy (formerly known as CeRx)
 - Client Registry
 - Provider Registry (by end January 2008)
- Several web forums were launched and have been very active with spirited dialogue on key initiatives and standards issues.
- A review of release and product management processes for the ongoing maintenance of HL7 (and related) specifications was launched. In particular, input is being sought on how to manage change requests.
- The Canadian Standards Governance model involves:
 - Oversight by “Standards Custodians” – SCC (Standards Council of Canada); through CSA (Canadian Standards Association); CIHI; and Infoway (as the agency with overall responsibility)
 - Strategic direction by the “Standards Collaborative Strategic Committee” (SCSC), which is directly accountable to Infoway
 - Coordination of work through the “Standards Collaborative Coordinating Committee” (SCCC) which is directly accountable to the SCSC and is supported by a “Technical Subcommittee” and a “Clinical Subcommittee”
 - Standards Collaborative Working Groups, which together comprise the pan-Canadian Standards Collaborative (pCSC) are currently operating in the following seven areas, with a group on Public Health to be formed in the next year:
 - Individual Care (Delivery Of Care)
 - Managing the Health System
 - Medication Management
 - Laboratories and Diagnostics
 - Infostructure and Shared Interactions
 - Non-Clinical Registries
 - Security /Architecture.
- The Standards Collaborative held its second set of working group meetings in Halifax, Nova Scotia in October 2007 with:
 - participation by over 180 delegates

- significant cross-SDO discussions throughout the meetings, and
- Joint sessions to continue cross-project and cross-SDO harmonization in areas such as HL7 / ISO data types.
- The drug system for Prince Edward Island being showcased as an HL7v3 application.
- There are close relationships between HL7, the Standards Collaborative and Canada Health Infoway that benefit all three organisations. In particular:
 - Dennis Giokas, CTO of Infoway is now on the HL7 Board
 - Michael Van Campen (Chair of HL7 Canada and International Member of the HL7 Board), represents HL7 Canada at the SCSC and SCCC.
 - Garry Cruickshank represents HL7 Canada on the Clinical sub-Committee
 - Lloyd McKenzie represents HL7 Canada at the Technical sub-Committee)

The HL7 Canada presentation concluded with an invitation to delegates to attend the 22nd HL7 Annual Plenary & Working Group Meeting in 2008 to be held at the Sheraton Wall Centre Hotel in Vancouver, British Columbia, 14-19 September, 2008.

8.3.4 France

The report from HL7 France (officially: Association HL7 France – HPRIM) was introduced by Nicholas Canu, supported by a presentation by Ana Estelrich on the current status of HL7 in the French DMP [Personal Medical Record] project.

Nicholas Canu reported that:

- HL7 France is working at a high political level to ensure that the climate is favourable to HL7. On 28 September 2007 influential VIPs were invited to a third meeting on e-health standards, held in the Chamber of the French Senate with a particular focus on standards for the cornerstone DMP project
- An active program of technical committee meetings and education sessions is being conducted. There is considerable demand for information on CDA and two new in-depth courses are being introduced on:
 - CCD, and methods for working on templates
 - Terminology services
- HL7 France plans to hold its Annual Plenary on 20 March.
- HL7 France is working with AFNOR to re-establish the AFNOR Health Informatics Committee, which had been boycotted by many vendors.
- The rebuild of the HL7 France web site has been delayed. Information is being sought about whether affiliates can use the HL7.org website to host their sites.
- A project for “rapidly” uploading laboratory results into a client’s DMP to ensure a critical mass of useful information has run into a snag getting agreement with pathology laboratories.

- The whole DMP project has been more or less delayed since the election of the conservative government last year.

Ana Estelrich (ana.estelrich@sante.gouv.fr) gave her update on HL7-related issues for the DMP project, noting that:

- The Ministry of Health has released a document explaining the process and benefits of standardization for the national EHR project, recommending that the DMP project use IHE XDS with HL7 documents as its core architecture.
- All DMP documents, regardless of the amount of structured content, are to include a CDA header with the clinical document type being identified using LOINC nomenclature to facilitate their registration, indexing and retrieval.
- A new IHE profile for sharing a value set is being fast-tracked in IHE International. This has been accepted to be ready for implementation in August, for testing at the 2009 Connectathon based on HSSP/CTS
- A working group has been established to get consensus on the content of DMP documents.
- The DMP project is providing the work package leader for Part 3.5 (Semantic Services) of the Open eHealth Initiative for a European Large Scale Pilot of Patient Summary and Electronic Prescription.

The Affiliates Council raised questions on:

- Whether there had been reaction from the vendor community about the requirement of a CDA header for all documents.
- Given the use of a nomenclature based on LOINC, French plans for SNOMED were questioned. It was noted that France has national rights for historical SNOMED 3.5 but no plan to move to SNOMED CT. Most practitioners are still using plain text to record and communicate information.

It was noted that the Ministry has a high degree of control and that it is therefore necessary to move one step at a time in close collaboration with the Ministry, addressing its priorities.

8.3.5 Germany

Thomas Norgall, Chair of HL7 Germany, presented briefly on behalf of HL7 Germany, reporting that:

- He is the current Chair of HL7 Germany, Kai Heitmann is the Immediate Past Chair and Bernd Blobel is the Incoming Chair.
- The work of maintaining and extending the V3 implementation guidelines is a major task – with a need to develop more detailed guidelines in complex areas such as the diagnosis and characterisation of tumours.
- Guidelines have been prepared for order entry/communications and patient transfer requests and have been balloted ready for public comment. These are particularly needed for interoperability between GPs and hospitals.

- Three other sets of HL7v3 Implementation Guidelines are in the process of approval:
 - Assessment scales and scores (e.g. GCI, Barthel etc)
 - CDA documents for notifiable diseases (for the State of NordRhein Westfalia)
 - Discharge notification letter (ArtzBrief)
- In Germany, there is considerable competition between federal and state government in terms of requirements and funding responsibilities for delivery of healthcare and associated information management requirements.
- Terminology - Germany is a founding member of IHTSDO with Stefan Schultz being a member of IHTSDO Content Committee.

Responding to a question (from France) on why SNOMED CT is not yet being used in clinical work, it was noted that a German translation of SNOMED CT based on 2003 edition is being prepared. Until this is available and checked for quality SNOMED CT is only being used in research.

France also questioned where Germany was using HL7-based messaging. With input from the Federal Ministry, it was noted that HL7 Germany is collaborating with DIN to use HL7v3 to model secure messages on a State-based project for EHR.

8.3.6 Greece

Catherine Kronaki presented on behalf of HL7 Hellas, reporting that:

- HL7 Hellas was established as an HL7 Affiliate in 2002 and has grown to 28 full members in 2007, including: 19 health ICT companies, 7 universities and research centres, the Ministry of Health primary care management organization (AEMY SA) and the Information Society SA.
- It was particularly pleasing to have more than half the paying membership of HL7 coming from industry.
- There are also 18 Honorary Members including the Ministry of Health and various healthcare institutions. There is close collaboration between HL7 Hellas and the healthcare research sector.
- Prof. D. Koutsouris of National Technical University of Athens (NTUA) is the current President of the HL7 Hellas Management Committee.
- HL7 v2.5 certification examinations were conducted in November 2007, with four new HL7 v2.5 control specialists being certified.
- A training seminar was also organized in November at which Rene Spronk provided instruction on HL7 v2. The event was attended by 15 participants: 6 from companies; 5 from academia; and 4 from hospitals.
- HL7-Hellas co-sponsored a very successful workshop attracting 287 participants (including 137 from companies in the health informatics industry) to discuss the e-health vision 2009-2013 and review lessons learned and proposals for the 4th Greek/EU Community Support Framework program .

- HL7-Hellas continues to actively support OpenECG, a European initiative that promotes world-wide interoperability through use of open standards in electrocardiography. With more than 750 members in 60 countries OpenECG supports the sharing of expertise, open source tools, and interoperability testing. The proliferation of medical devices in the consumer market is highlighting the need for better integration with the EHR and other e-health services and this is becoming a patient safety issue.
- The two major activities for HL7 Hellas in 2008 are:
 - Organisation of the 3rd HL7-Hellas Conference; and
 - Hosting the IHIC 2008 International HL7 Interoperability Conference in October to which all HL7-ers are invited [see details in the upcoming events at section 14 below].

8.3.7 Japan

Dr Michio Kimura, Chair of HL7 Japan, presented the report on HL7 Japan's activities, focussing on:

- the May 2009 HL7 Working Group Meeting in Kyoto on 10-15 May 2009; and
- the HL7 Japan proposal (yet to be accepted) to run IHIC 2009 at the same venue on 17-18 May. [If accepted, this will be the first time that IHIC be joined with a WG meeting – a total commitment of almost 10 days]

Both these events are covered in more detail in section 14 below.

With regard to other activities, HL7 Japan has around 250 members and runs three major seminar sessions per year. Support for HL7 has been enhanced by recent national projects requiring everything to be reported in CDA R2:

- For the routine health checkups provided for all citizens aged 40 and over, and
- For referrals and patient collectible laboratory results and pharmacy prescriptions.

8.3.8 Korea

From a brief verbal report, it is understood that Korea has a strong focus on electronic exchange of health document in a standardised form based on HL7 CDA r2 and has:

- Programs now under way for CDA certification testing, and
- A registry and repository for CDA documents operating in Seoul.

Implementations are understood to be based on v2.x messaging and CDA templates, registries and repositories

8.3.9 The Netherlands

Robert Stegwee presented the HL7 Netherlands (HL7-NL) report noting that it has been “business as usual” and that:

- The National Conference celebrating 15 years of HL7 in the Netherlands was held on 6 December 2007, attracting over 120 participants
- There were two more issues of the HL7-NL Magazine in 2007,
 - In March: v3 Architecture and RIM-based databases
 - In December: standards for EHR architecture models (*openEHR*, 13606, HL7v3 etc)
- Further updates were made to the local implementation guidelines and a first-round ballot for patient care completed.

Upcoming activities expected to take place in 2008 include:

- Development of CDA representations for Pathology and Microbiology reports
- Consideration of standards needed to support the multidisciplinary chronic diabetic care use case
- A joint IHE-HL7 Lab project commissioned by NICTIZ
- Reconciliation of comments on DataType / CMET implementation guide
- Establishment of an OID registry in coordination with Germany

Membership continues to grow and currently includes 214 organisational members. Activities are supported by a strong base of volunteers with 45 people being active in various capacities.

There continues to be a need for professional support, particularly to assist in maintaining the implementation guidelines and other documentation.

A representative from the UK questioned what level of structured data the Netherlands would be supporting in their CDA-based microbiology reporting.

8.3.10 Switzerland

Beat Heggli provided a brief report on behalf of HL7 Switzerland (HL7-CH), highlighting:

- Work by HL7 Switzerland to provide CDA standards to complement the Swiss Government's e-health strategy. This has involved:
 - Formation of a working group (vendors, practitioner associations, government)
 - A tutorial on CDA r2 given by Dr Kai Heitmann (HL7 Germany)
 - Development of a CDA r2 document specification similar to the German, *Arztbrief* [Doctor Summary], and

- 3 formal meetings and 3 months work to produce a 90 page draft implementation guideline for a CDA discharge letter. This work was out for a 6 week ballot at the time of the San Antonio meeting.

The production of a 90 page specification was seen as a significant achievement for HL7-CH, which had existed for 5 years but had not previously developed any standards products.

- The Annual Meeting of HL7-CH was held on 29 October, 2007, attracting 25 participants, with a keynote address by Prof. Bernd Blobel.
- Thanks from HL7-CH to HL7 Germany for their ongoing support !!

8.3.11 Taiwan

Dr Jin-Shin Lai, Chair HL7 Taiwan (Jslai@ntu.edu.tw) provided a brief report on behalf of HL7 Taiwan, highlighting:

- His re-election as Chair of HL7 Taiwan for the two year period November 2007 to November 2009, with S.J. Vann being elected Secretary General for the same period.
- The National Healthcare Information Project spanning the four year period 2008-2011 being led by the Taiwan Department of Health, with the top two priorities for 2008 – 2009 being:
 - Ethics, Legal, & Security Issues (ELSI)
 - Standards for EHR and PHR

An allocation of US\$15 million is understood to have been made for work on EHR of which some US\$3 million is for standards development.

- 7th Asia-Pacific HL7 Conference. Following a request from the Taiwan Department of Health, this conference will now be held on 19-22 November 2008 in Taipei. The Department is keen to explore effective use of CDAR2 for electronic discharge summary.

8.3.12 United Kingdom

Rik Smithies (NHS CfH) gave a brief update on HL7-UK activities, reporting that:

- The 4th Annual HL7 UK conference was held in a London hotel over two days in November 2007. It was a successful event attracting over 100 delegates including attendees from the UK, Netherlands, Turkey and the US with addresses from visiting speakers - Ed Hammond, Charles Jaffe and Keith Boone
- Numbers at the annual conference, which has a more general focus, are holding up at around 100-120 people (compared to smaller technical meetings).
- As part of its marketing, promotion and outreach activities (following the recent engagement of a marketing advisor), HL7-UK are trying to evaluate how best to relate to decision makers and communicating the "standards message".
- The third issue of the HL7 E-Zine is about to be published. It contains news and articles and is available as a PDF for download with a target of 3 issues

per annum. Copies may be accessed at:

<http://www.hl7.org.uk/marketing/ezine.asp>

- The second edition of the well-known HL7v3 Primer (Red Book), released at the Atlanta Plenary and WG meeting in September 2007 has been selling well.
- Primer 2nd edition ready for last WGM, selling well
- There are now two UK members participating in meetings of the HL7 Board of Directors – Ken Lunn and Charlie McCay (as TSC Chair).

9. Collaboration with other major SDOs

9.1 Collaboration Discussions at the San Antonio Meeting

Collaborative activity with other major SDOs was a central topic at several points during the San Antonio Meeting, specifically:

- Presentations at the Affiliates Council on behalf of ISO TC215 and CEN TC251 in relation to their activities and also on the ISO/CEN/HL7 Charter and Joint Initiative (see summaries at 8.2.1 and 8.2.3 above).
- The regular meeting of the ISO–CEN–HL7 Collaboration Group held on the Sunday evening, which on this occasion attracted over 60 attendees. (See section 9.5 and minutes at Annexure B below)
- Mentions in several other key presentations – including the Monday report of the Affiliate Chair, the CEO's report and later briefings following the TSC and Board meetings.
- A significant level of informal discussion as a result of the concerns and lobbying by some delegates about ISO TC215 work on ICH and EN13606.

9.2 ISO–CEN–HL7 SDO Joint Initiative

Details of the genesis and progress of the ISO–CEN–HL7 Joint Initiative have been addressed in IT-014 reports from previous international meetings. In summary, the current situation is as follows.

Various standardization stakeholders including e-health program leaders and the health ICT vendor community have called for greater cooperation between global SDOs to ensure that available standards are complementary rather than duplicative and competitive. One of Standards Australia's continuing international standardization objectives for health informatics has been to encourage this.

A significant step was taken towards this collaboration and cooperation at the ISO and CEN JWG meetings in Geneva in October 2006, with the signing of a broad agreement between ISO TC215, CEN TC251 and HL7. A more detailed Charter for

SDO harmonisation was subsequently prepared, largely drafted by Don Newsham of Canada, and submitted to fast-track ballots in ISO TC 215 and CEN TC 251 and within the HL7 Board and Affiliates. Essentially, the Charter:

- Articulates a series of affirmations about the need to collaborate on global standardization and standards development, and aims to achieve “one standard-one test”;
- Commits to an integrated work program across the signatories, common processes for selection of projects, and common, cooperative communications; and
- Commits to resolve issues as they are identified.

Following circulation and ballot, the Charter on SDO Harmonisation was accepted by all parties and was formally executed by leaders of the three participating SDOs at the August 2007 ISO TC 215 meeting held in Brisbane.

The essence of the purpose of the Joint Initiative is:

“ The Joint Initiative on SDO Global Health Informatics Standardization is formed to enable common, timely health informatics standards by addressing and resolving issues of gaps, overlaps, and counter-productive standardization efforts through ... ”

Its future goals include: *Making all Health IT standards available through ISO.*

Its over-arching vision for collaboration, coordination and cooperation is *one of harmonization, where a singular set of standards and tests addresses a singular health business need.*

This initiative is guided by a Joint Initiative Council (JIC) of SDO leaders – led by their respective chairs: Ed Hammond (HL7), Kees Molenaar (CEN TC251) and Dr Yun Sik Kwak (ISO TC215).

The JIC is supported by a Joint Working Group (JWG) with open membership from the three organisations and has three Co-chairs - Charles Jaffe (HL7), Melvin Reynolds (CEN) and Don Newsham (ISO). The JWG has been constituted as ISO TC215 WG9 with Standards Australia providing its Secretariat.

The JWG’s role is to undertake more detailed planning, review and coordination activities, with a view to progressively harmonising outcomes. The first meetings of the JIC and JWG were held in conjunction with the August 2007 TC215 Meeting in Brisbane.

The second meeting of the JWG was held in Dublin, Ireland on October 2, 2007 (in conjunction with CEN TC251).

Discussion at the San Antonio meetings emphasised the challenges facing practical implementation of the ISO/CEN/HL7 Joint Initiative (JI) – particularly the need for all SDOs to make uncomfortable changes in practices and procedures when progressing joint work items. These issues were reported in some length in the report of the Australian delegation to the Atlanta HL7 Plenary and Working Group meetings in

September 2007. That report identified two quite distinct philosophies emerging about the way in which the JI/JWG should operate:

- (a) As a facilitator, focussing mainly on areas of opportunities where work programs can be aligned to progress collaborative projects across the three SDOs and then agreeing processes to allow this to happen ; or
- (b) As a policeman, based on trying to avoid any overlap or potential inconsistency by trying to stop projects that potentially “compete” at ISO level. However, if duplication and overlap is to be overcome, this also means JWG decisions affecting the work programs of individual SDOs.

It was suggested that Australia should support the facilitator role as this is likely to have the greater real traction. It appears that the HL7 leadership has formed a similar view as this was the approach that they strongly supported during the San Antonio Meetings – particularly in the meetings of the HL7/ CEN/ ISO Collaboration Group, where arguments against international adoption of EN 13606 as an ISO standard were again raised by some German and Dutch representatives but were gently put aside by the HL7 leadership as a secondary issue. Part of the reason for this moderate approach on HL7’s part appears to be a realisation that a rigid interpretation of the harmonisation rules and processes has as much potential to limit HL7’s activities and its ability to respond to the needs of the US Government and its other major stakeholders as it does to control potentially competing activities in other SDOs, who also need to respond to the needs of their local regulators.

The main focus for those involved with the JI is now to define new processes for carrying out joint work as well as reviewing work programs for harmonisation opportunities and refining communication between the participating organisations. Some areas for improvement were summarised in Dr Hammond’s discussion to the Affiliates Council as reported at section 8.2.2 above.

Since his appointment as HL7’s Chief Technology Officer in September, John Quinn has been given responsibility for the practical involvement of HL7 in JI/JWG activities, managing its contribution to the joint work and looking for ways in which to better align processes and outcomes from joint work.

It was agreed that the schedule for the next JWG meetings would be as follows:

- Saturday, 23 February 2008 - In conjunction with HIMSS in Orlando, Florida
- Friday 30 May - Gothenburg Sweden (in conjunction with joint ISO TC215 and CEN TC251 meetings).
- September 2008 - Vancouver Canada (in conjunction with HL7 Plenary and WG Meeting).

It now seems to be generally agreed that the HL7/ CEN/ ISO harmonisation group provides a useful complementary forum in which to review JWG activities from an HL7 viewpoint and that it should continue to meet at HL7 WG Meetings where the JWG itself is not meeting. Elizabeth Hanley’s presence in San Antonio helped to ensure that the JWG works closely with HL7’s HL7/ CEN/ ISO Harmonization Group – to the extent of developing a common email distribution list.

9.3 ISO TC215 Report

As there had been no ISO TC 215 Health Informatics meeting since the HL7 Plenary and Working Group meetings held in Atlanta in September 2007 and Dr Kwak, Chair of TC 215 was unable to attend the San Antonio Meetings, there was no formal ISO TC 215 report. Nevertheless, the relationship between HL7 and ISO TC215 was considered and furthered through:

- Audrey Dickerson (TC 215 Secretariat) being present and involved in key meetings throughout the week including presenting a brief segment on ISO TC 215 at the Affiliates Council meeting;
- Consideration of relevant ISO TC 215 issues at the HL7/ISO/CEN Collaboration Group held in the evening of Sunday, 13 January;
- Provision of information on ISO TC 215 through discussion of JWG activities during some Working Group and informal meetings.

Some HL7 delegates (including the Chair, Ed Hammond, and CTO, John Quinn) also participated in a meeting of ISO TC 215 Working Group 2 (Data Communication) which was held on Friday 18 and Saturday 16 January immediately after the main part of the HL7 business meetings.

9.4 CEN /TC 251 report

9.4.1 General

As briefly introduced in section 8.2.3 above, Melvin Reynolds, Vice-Chair of the CEN /TC251 Health Informatics Committee presented the CEN Status Report to the Affiliates Council on behalf of Kees Molenaar, Chair of CEN /TC 251. He also represented and spoke to the report on CEN /TC251 at the HL7/CEN/ISO Harmonization Group meeting. Overall, the topics addressed included:

1. The TC 251 committee structure, noting:
 - The relationship between the 4 TC 251 Working Groups (WGs) and the 8 ISO TC 215 Working Groups that prepare standards;
 - CEN /TC 251 is formally constituted as a committee of national member body (NMB) representatives but its Working Groups consist of individuals nominated by their NMBs for their expertise;
 - Relationships between TC 251 WGs and other European SDOs, in particular:
 - CENELEC TC62 – Electrical equipment in medical practice
 - ETSI (European Telecommunications Standards Institute), with coverage of telecoms and Internet technologies and strategic links with IETF, ITU, IEEE, JTC-1
 - Through “CEN Workshop” processes, which provide forums for engagement with consortia such as OASIS, W3C
2. Upcoming /TC 251 meetings:

- Cyprus, 11-14 March; and
- Göteborg (Gothenburg), Sweden, 31 May-3 Jun (joint with ISO TC215)

3. The following 13 standards documents published by CEN /TC 251 during 2007:

CEN/TS 15211:2007	Mapping of hierarchical message descriptions to XML	Feb 2007
EN 13606-1:2007	Electronic health record communication - Part 1: Reference model	Feb 2007
EN 13606-2:2007	Electronic health record communication - Part 2: Archetype interchange specification	Sep 2007
EN 13606-4:2007	Electronic health record communication - Part 4: Security	Jun 2007
EN ISO 21459-4:2007	Patient healthcard data - Part 4: Extended clinical data	Feb 2007
EN 13940-1:2007	System of concepts to support Continuity of care - Part 1: Basic concepts	Sep 2007
EN 1064:2005 +Amdt 1:2007	Standard communication protocol - Computer-assisted electrocardiography	Sep 2007
CEN/TR 15640:2007	Measures for ensuring the patient safety of health software	Aug 2007
EN 12967-1	Service architecture - Part 1: Enterprise viewpoint	Nov 2007
EN 12967-2	Service architecture - Part 2: Information viewpoint	Nov 2007
EN 12967-3	Service architecture - Part 3: Computational viewpoint	Nov 2007
EN 15521	Categorial structure for terminologies of human anatomy	Nov 2007
EN 14463	A syntax to represent the content of medical classification systems - ClaML	Dec 2007

4. Progress of work by CEN, CENELEC and ETSI on European Commission Mandate (M/403) and the recent inclusion of HL7, IHE and IHTSDO in these activities.
[See section 9.4.2 below for more details].
5. Progress of joint ISO-CEN-HL7 work sponsored by ICH and the EC in the area of pharmacovigilance reporting and terminology [see section 9.4.3 below]
- Ian Shepherd, who is leading the ICH pharmacy work as chair of ISO /TC215 /WG6 (Pharmacy), has been invited to join TC 251 management team meetings for the duration of the ICH project [a very practical approach to improving communication on a harmonised work item].
6. Possible impact of the recent Review of European ICT standardization policy by the EC DGEI (Enterprise & Industry). Despite some concern over the initial report from this review (with its emphasis on standards as a competitive tool for EU industry), it appears that broad consultation with European industry and global SDOs and enterprises and recognition of WTO obligations have convinced the DGEI that:
- Europe should seek to use international/global standards in preference to mandating local European standards, only adopting a local standard when absolutely necessary
 - SME representation in standards development and adoption should be increased

- Effective methods are required for European policy-makers and regulators to engage with global SDOs, which are not part of the EU standardization framework
- There be tighter coupling between EU research and international standards development so that the fruits of EU innovation are more widely adopted and deployed.

The recommendations from the review [which are more fully summarised in section 9.4.4 below] were further discussed at a conference on 12 Feb 2008 in Brussels.

If ways can be found for these approaches to be adopted and implemented by EU regulators and policy makers and embraced by stakeholders, they appear positive for further acceptance of HL7, IHTSDO, IHE and ISO TC 215 in Europe and should encourage greater direct European input to global and international eHealth standards development.

9.4.2 Progress on EC Mandate M/403

As previously reported, official Mandate M/403 issued from the European Commission (DGEI) on 6 March 2007 and is entitled:

"Mandate to the European Standardization Organisations CEN, CENELEC and ETSI in the field of Information and Communication Technologies, applied to the domain of eHealth."

What is a mandate?

A mandate is a political request from the European Commission (EC) and (sometimes) the European Free Trade Association (EFTA):

- agreed upon by the Member States
- addressed to one or more European bodies (in this case CEN, CENELEC and ETSI)
- in support of an action from the EC, such as:
 - legislative work such as a directive or
 - an industrial policy action from the EC.

In summary, Mandate M/403 requires the ESOs (European Standards Organisations) CEN, CENELEC and ETSI to propose a coordinated work plan for eHealth standards leading to interoperability of health information and, once the plan is agreed with stakeholders and approved by the EC, to work toward its achievement.

The mandate envisages that the work would proceed in 2 phases:

- Phase 1 – up to one year in planning and analysis to set up the work program, involving:

- listing existing relevant standards and technical reports with short descriptions,
- listing relevant needed tasks for achieving the result, with the most needed standards to be planned for earlier adoption.
- Phase 2 – up to 3 years for the ESOs to execute the program, delivering agreed, implementable standards, technical reports, guidelines, methods, all developed in accordance with good quality and project management principles.

Originally the program was to run for 3 years from May 2007 with preliminary work up being progressed courtesy of the Dutch Ministry of Health, with first discussions on a draft work plan taking place on 2 May 2007.

The original timeline appears to have slipped about 6 months with the formal agreement for Phase 1 being finally signed in December 2007, key appointees having just been engaged and a Phase 1 kick-off meeting being held in Brussels, on 29 January 2008. The focus is enabling eHealth and, in particular, the three issues perceived as being priorities for an interoperable European EHR:

- patient and health practitioner identifiers;
- the patient summary;
- emergency data set.

Important issues identified during the early formation of the project included:

- TC251's participation in global developments;
- Guidance for national standards bodies;
- Bringing forward national initiatives;
- ESO's being required to liaise with international consortia; and
- Reviewing current work items with international impacts.

Co-ordination of the work is via a "Co-ordination Group" of the three ESOs with the principle task of collaboratively preparing the work programme. The members of the Co-ordination Group are:

- The CEN/TC251 Chair, as chair of the Co-ordination Group;
- Representatives of the CEN Management Centre, the CENELEC Central Secretariat and the ETSI Secretariat; and
- EU and EFTA Secretariats as observers.

The EC has also recognised that many of the credible players in the mainstream of the eHealth standards are global organisations (like HL7), many of which have most of their activity outside Europe. Under the recent policies of EC DGEI on ICT standardization, it is also seen to be preferable for European interests to be actively pursuing global standards and global standardization in preference to adopting unique local standards. Collaborative mechanisms are therefore needed between the ESOs and the international/global standards community

The following measures have therefore been adopted for engaging with international/global SDOs, industry consortia and other relevant bodies for the purposes of drawing up the M/403 work program on an inclusive and coherent technical basis:

- The Co-ordination Group meetings will also be open by invitation to representatives of certain other international standards bodies;
- The Co-ordination Group will agree the list of the proposed “wider Co-ordination Group” at its first meeting;
- However, it will initially include representatives of ISO TC215, HL7, IHE and IHTSDO.

It is also important that proposed standards are implementable, work well and are rapidly brought to maturity through rigorous trialling and feedback. Close association with large-scale eHealth pilots currently underway in the EU is therefore proposed through:

- links with EU Calliope Project, and
- a cross-project survey of standards used.

Comment

Along with developments in North America aimed at implementing eHealth interoperability, the eHealth standards plan developed under EC Mandate M/403 has the potential to define the future direction for rationalisation of global and international eHealth standards. With HL7, IHE, IHTSDO and ISO TC215 being guaranteed a place in planning the program, their potential part in the future product mix has already been recognised.

9.4.3 Progress on joint ICH messages

There is a contract for standards development between the EC and CEN that requires CEN to review specifications produced by ICH (the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) to support pharmacovigilance and to prepare them for formal adoption as European standards (with a view to their acceptance as ISO standards). The following ICH specifications were those considered for adoption:

1. eCTD - the Electronic Common Technical Document
2. The scope of the ICH specification for general purposes
3. The EU Module 1 for regional specificities
4. The Product Information Management (PIM) Data Exchange Standard
5. The latest version of the E2B message for Individual Case Safety Reports (ICSRs) and Suspected Unexpected Serious Adverse Reactions (SUSARs)
6. The Medicinal Product Identifier
7. The Controlled Vocabulary Message

8. The Application Form

Following discussions within ICH in mid-2007 and with the EC and the European Commission services and the European Medicines Agency (EMA) (and partly due to concerns arising from the US FDA) the following three specifications were DROPPED from consideration:

- eCTD, which ICH did not expect to be completed within the EC's contractual timeframe due to the need to reconcile competing interests;
- The product information management (PIM) data exchange standard; and
- The application form.

Work on update and migration of the ICH specifications was progressed in Q2/Q3 2007 on the basis that it would be conducted jointly by ISO TC 215 WG6 (Pharmacy), CEN /TC 251 and the HL7 Pharmacy TC; however, this had not been formally communicated to the HL7 Pharmacy TC, which already had a full work program and was addressing competing priorities and content required by US-realm agencies.

Following discussion and resolution of these issues:

- The ISO/CEN/HL7 Joint Initiative Council has approved the development of ICH messages as a Joint Project with ISO TC 215 as lead SDO
- A JIC Task Group has been convened with Ian Shepherd (ISO TC 215 WG6) as the chair, and co-chairs from HL7 and CEN
- The Task Group has narrowed the scope of current work to focus on:
 - Individual Case Safety Reports (ICSRs)
 - Medicinal Product Identifier
 - Controlled Vocabulary Message
- The Task Group was meeting for several days at the San Antonio meetings – and was attended by a large contingent of ISO, CEN and HL7 representatives with strong pharmaceutical industry and regulator presence.
- A "Proposed Policy and Procedure for the Use of the Harmonized Task Group Standard Development Template" has been produced.

Ian Shepherd (Chair of the Joint Project Task Group) passed on his observation that the project had proven a valuable learning experience in formation of a joint project and that it pointed to the importance of open, structured communication through the right channels within, and then between, the SDOs.

The Australian delegation noted that this message has been strongly taken to heart by the leadership of the three SDOs and now forms the basis of updated JWG procedures for Joint Projects.

9.4.4 Outcomes from EU ICT Standardization Policy Review

In July 2007, the EC Director General Enterprise & Industry (DGEI) released the report of a consultancy study on specific EU policy needs for ICT standardization, the

executive summary of which may be found at:

http://ec.europa.eu/enterprise/ict/policy/standards/piper/executive_summary.pdf

In presenting the following quotations from the report, Melvin Reynolds (UK), Vice-Chair of CEN /TC251 noted that the recommendations were framed in the context of ICT and the needs of the ICT industry and ICT users and are not specific to eHealth. He also noted that, as the report was for DGEI – that may explain its emphasis on industry competitiveness.

Summary

1. The following issues have been identified as the most pertinent challenges for the EU standardization policy in the field of ICT.
2. If the EU wishes to continue having an impact on standardization efforts in the ICT area, these challenges need to be addressed.

Regional character

3. EU ICT standardization is confronted with different challenges regarding its role and influence on a global market.
 - how to ensure that EU standardization initiatives can take stock of standardization processes and deliverables created outside of the EU standardization system
 - how to marry the regional policy objectives of the EU with the global nature of ICT standards
 - how to find ways to create global acceptance of EU standards.

Mandating

4. EU ICT standardization legal framework does not allow mandates to be issued to non-ESOs. By not being able to mandate to non ESOs:
 - the EU takes the risk that it will not gain advantage from the know-how and expertise that is being built up outside of the ESO community.
 - It also runs the risk of not being able to influence their activities in Europe's favour.

Standardization organisations

5. EU ICT standardization does not take sufficient stock of standards developed outside of the standardization system.
6. The procedures for incorporating these standards into the EU standards are regarded as cumbersome and user unfriendly.

ICT Users

7. Although consumers and SMEs are formally represented in the EU standardization process, it is felt that because of the huge impact of ICT on the user (consumer/SME), the representation of these stakeholders is currently not sufficient.

When discussing user representation, the level of involvement should be balanced against the specificity of the user needs (direct/indirect) and the standardization context (support of legislation, of policies, of competitiveness or of other areas)

ICT producers

8. SMEs, although ICT producers, are not well represented in the ICT standardization process,
9. SMEs should be encouraged to engage in standardization activities.
 - The level of involvement should be balanced against the producer needs of the SME's-within a standardization context.
 - When defining standards the size of SMEs should be taken into account.
10. General access to standards should be facilitated by taking the specific needs of SMEs into account.

R&D

11. European Research and Development does not pay sufficient attention to a future standardization track, risking a delay in bringing standards to the market (standardization gap). This could raise problems concerning the EU's competitiveness.

Exploitation of EU ICT standards

12. Although many EU standards success stories can be recounted, it is nevertheless true that existing [non?] EU ICT standards have gained wider market acceptance.
13. Indeed, the most widely implemented ICT standards have been drafted by non-formal standardization organisations.

Transparency

14. The current EU ICT standardization landscape is blurred and lacks clearly defined and mapped out borders.

To facilitate further discussion of these questions, DGEI convened a conference on 12 Feb 2008 in Brussels on the theme "*European ICT standardization policy at a crossroad: A new direction for global success*". Further information related to the review may be obtained from the conference website:

http://ec.europa.eu/enterprise/ict/policy/standards/cf2008_en.htm

9.5 HL7/CEN/ISO Harmonization Group Meeting

A Coordination Meeting is now held at every HL7 meeting on the evening of the Sunday. In San Antonio this was attended by more than 65 people many of whom are active across the three SDOs.

The minutes of the meeting are attached as Annexure B to this report, with the substantive items discussed including:

1. Current Status of Joint Initiative (JI) on SDO Global Health Informatics Standardization. In particular:
 - The changes that each SDO might need to make in order to accommodate coordinated development and balloting of joint projects are becoming more apparent as experience is gained on the first harmonisation projects. The implications were discussed in some depth with a process for data types being resolved.
 - The roles and functions of the Joint Initiative Council and Joint Working Group were introduced for those unfamiliar with them and potential refinements were discussed.
 - Proposed processes for submission and approval of joint work items.
 - Each Joint Project needs to be hosted by one of the 3 SDOs, be carried out by a joint task group under a project lead from the host SDO, with co-chairs from each of the participating SDOs.
 - Clear contact points and channels of communication between the participation are needed for proposing, agreeing and ensuring that appropriate resources are engaged in joint work items.

In the case of HL7, the nominated contact point is John Quinn, the CTO.

Since the previous HL7 meeting, there has been a growing recognition and acceptance that the JI and JWG need to focus on how to identify and progress work that is agreed to be a Joint Projects and that there will be many projects within each of the three SDOs that may not yet be ready to be carried out within the JI/JWG regime.

Further information on the Joint Initiative is available through the JI website, hosted at Standards Australia:

<http://www.e-healthstandards.org.au/cat.asp?catid=43>

2. Update on preparation of ISO standard on harmonized datatypes standard for joint balloting, approval, simultaneous balloting and publishing within ISO, CEN and HL7. This joint work is being led by Grahame Grieve of Australia from within HL7 but with the final output being a harmonised standard.

Following much discussion, a timeline for completing the drafts and joint balloting was agreed. The challenge will be ensuring that it is met within all three organisations.

3. Progress with ISO/EN 13606 (EHR Communication) standard as reported at section 8.2.4 above was noted.

The acrimonious question of whether any parts of ISO 13606 should be allowed to proceed at all without prior harmonisation to HL7 v3 was again raised by Germany (with some Dutch support) but, on this occasion, senior HL7 representatives closed off debate on this issue, indicating that HL7 was not objecting to balloting of 13606, on the understanding that harmonisation would be addressed in a proposed HL7 Implementation Guide.

4. Other matters

- Progress with ICH and related pharmacy projects. [See report on ICH progress at section 9.4.39.4.3 above.].
- Update and call for support on ballot process for acceptance of HL7 CDA and HL7 v 2.5 as ISO standards.
- HL7 CDA and HL7 v 2.5 ballots in ISO. DIS ballots were about to open. HL7 members should participate through their national member bodies.
- Report on the August 2007 DCM (Detailed Clinical Modelling) workshop. Dr William Goossen had just completed the report and was to upload it to the DCM wiki and table it at the next Joint Working Group meeting.
- Mark Shafarman's mapping from the CEN HISA information model to the HL7 RIM is now accessible on the CEN TC 251 website.
- Other potential participants in JI/JWG activities.
 - IHTSDO has been invited and was represented by Martin Severs, Chair of the IHTSDO Board, at the first JWG meeting in Brisbane,
 - ATSE, who have established an e-health group, and also OASIS, were suggested as potential participants.
- Future meetings are to be held immediately after a shortened Affiliates Council meeting, rather than late into the evening.
- Email lists for the HL7/CEN/ISO Harmonization Group will now be administered with the JWG list by Elizabeth Hanley of Standards Australia.

10. Standards Development

Australia's involvement in HL7 standards development reflects the objectives and priorities expressed in section 3 above. The following are some specific observations flowing from detailed work on various standards development activities at the San Antonio Meeting.

10.1 Community Based Collaborative Care (CBCC)

The Community Based Collaborative Care (CBCC) SIG was formed within the Patient Care domain to facilitate HL7 standards that support the provision of care and services to individuals in community and non-acute residential care settings, including: home health care, long term care, hospice care, community health and day therapy centres, mental health and assisted living services.

Max Walker of DHS Victoria attended the San Antonio Meeting as one of the three co-chairs of the CBCC SIG which met on Q3./Q4 on Monday 14 January, Q1, Q2, Q3 and Q4 on Tuesday 15, jointly with Patient Care TC and PHER³ for Q1/Q2 on Wednesday 16 and then back on its own for Q3/Q4 later that day.

Max Walker of DHS Victoria was re-elected as a Co-chair for the period to January 2010. Another Australian, Dr Isobel Freaan who is currently resident in London and could not be present, was not successful when Ms Suzanne Gonzales-Webb of the US Department of Veterans Affairs was elected to the second co-chair position. This was unexpected, as Ms Gonzales-Webb had not been active in the SIG. The outcome may signify a desire by US government agencies to take greater control of the SIG's agenda and ensure the outcomes conform to their philosophies. There are several different (and sometimes divergent) groups potentially being served by the work in CBCC, including:

- Aged care across home, acute care and long-term institutional settings
- Mental health care in community, acute care and institutional settings
- Longer term developmental disability care and therapy
- The Substance Abuse and Mental Health Administration within US DHHS
- Community health and day therapy – including drug, alcohol, allied health, mental health
- Community based support of the permanently disabled and chronically ill
- Home nursing and community welfare services, and
- Providers and regulators of each of the above in different jurisdictional realms (e.g. US Federal, US States, Australia, Canada, UK, EU).

While all these groups share a strong need for standardised messages, documents, access controls and other information artefacts supporting the flow of information

³ Public Health Emergency Response

across the continuity of care, their divergent agendas often lead to differences in key areas such as privacy control and consent models, access for clients and their carers, client contributions, role of payor providers and insurers and suitability of different types of clinical care documents (CCDs). These differences are proving a challenge to efficient achievement of this SIG's important work programme.

Many of the problems stem from differences in policy and approach related to privacy, consent, access control and information sharing.

Splitting the SIG into several separate task groups is an option; however, the small numbers that currently participate and a desire to preserve common approaches to key aspects militates against splitting the SIG's activities up for the present.

As an international leader in community health and collaborative care with a need for better standards to support information sharing across the domain, Australia is working to find ways to progress this work more effectively. This would be assisted, if Australian interests were able to contribute more heavily to the work of the SIG.

Topics considered by the SIG during the San Antonio Meeting included:

1. Work programme for the San Antonio meeting and agenda for subsequent activities.
2. Review and reconciliation of ballot on the Data Consent CMET (Common Message Element Type) – a consistent approach to the notification of consent parameters for use in multiple messages.
3. Discussion of international differences and needs for consumer control of sharing personal health information – including a presentation by Max Walker on the DHS Victoria project: *"Introduction to Challenges in eHealth"*.
4. Privacy requirements for "safety net" and "public pay" consumers if all their healthcare and social service information is compiled into one omnibus e-record [in US].
5. EHR system certification for long-term care and behavioural health: experience in the US, Canada and elsewhere.

The need for better interoperability across the entire CBCC domain (particularly for long-term care sector) has led to demand for consistent standards to support interoperability and also a compliance regime to ensure that vendor systems comply with the proposed standards. Once the appropriate standards have been defined, in the US, CCHIT can be petitioned to include these standards on the CCHIT roadmap – which would help the sector achieve its interoperability objectives.

6. proposed projects on:
 - structured confidentiality code set, and
 - a joint project with Security TC.

Service functional model for a Human Services Directory (HSD)

6. Discussion of the service functional model for a health care, community services and provider directory was led by Max Walker, who spoke about the Human Services Directory introduced by DHS Victoria. A motion was put and carried for CBCC to undertake an HSD project and produce HL7 use cases to meet DHSV requirements. The results of the DHSV work can be found at: <http://humanservicesdirectory.vic.gov.au>.
7. Advice that the joint HL7/HL7 HSSP project that is coordinating the specification of web services for use in health care has resolved to re-orient its "Services and Provider Directory" project to address the wider needs for a "Human Services Directory" and is re-naming its SPD project to reflect this shift.
8. Following a presentation to a joint meeting of CBCC SIG, Patient Care TC and PHER, it was decided that PC TC will be responsible for balloting the HSD functional model, which includes many requirements put forward by Australian delegates, as well as by others (such as Canada).

Long-term care (LTC)

9. Led by Peter Kress (ACTS Retirement Life Communities, Pennsylvania), CBCC SIG discussed current activities and issues related to the work of the Long Term Care (LTC) group seeking more effective use of HL7 to support semantic interoperability and continuity of care in aged and long-term care, including:
 - The growing importance of SNOMED and LOINC encoding in LTC applications.
 - The need for broad acceptance and convergence on well formed standards to achieve the goals of semantic interoperability.
 - Recent work across many levels of different types of LTC organizations to ensure their requirements were incorporated in the CCD specifications. An IHE profile has also been developed and passed.
 - The CCD is currently being balloted in LTC and will then be brought to HL7 for membership ballot, hopefully for the September ballot cycle so that CCHIT can be notified in May for placement on their 2009 roadmap.
 - The CCD must adequately cater for the range of assessments and scales used in the long term care settings. The Continuity of Care Task Group project (see next item) is aimed at developing content to handle long term care assessments and scales and verifying that instances of the CCD can process them correctly.
 - When going to CCHIT it is necessary to go with a group or body that is representative of the sector requiring the conformance.
 - Traditionally e-Prescribing has excluded long term care. There is now a genuine desire to reverse this.

10. An update was provided on the Continuity of Care Document Project being carried out by the Continuity of Care Task Group⁴. The mission of the Task Group is to:

“Develop requirements, recommendations, guidelines and standards advocacy towards the adoption of an HL7 implementation guide for an aging services Continuity of Care Document (CCD) with support for functional status and wellness content.

- *Initiate work that will result in an HL7 approved implementation guide*
- *Progress standards related to functional status and wellness content*
- *Complete formal interoperability demonstrations of vendor, provider and consumer uses”.*

In particular:

- In the US, many assessments are proprietary;
 - The project is to standardize and support exchange of information from assessments;
 - The project addresses use of LOINC, SNOMED, HL7v2.4+ and CDA;
 - The project is sponsored by the US Government through ASPE with support from CAST⁵ and AHIMA; and
 - The project should be finished April/May.
11. There is now a strong industry push toward CCDs (which are based on CDA r2) for all LTC documentation, with the detailed specification of requirements being set out in implementation guides (for each realm) and conformance in IHE profiles. This raises the following critical questions for the PC TC and potentially for the ARB and TSC:
- (a) How does this move to CCD fit with all the previous work on deriving RIM-based models of aged-care information (including the work done by Dr Isobel Frean) and the representation of this information in v3 messages meeting current specifications?
 - (b) How does the PC TC/SAB, now consider that CCD or CDA documents should be used to achieve the goals of semantic interoperability within the overall V3 architecture? and
 - (c) What work is now needed and planned to modify the HL7 technical architecture to achieve these ends consistently across all domains?

⁴ Continuityofcaretaskgroup.pbwiki.com

⁵ Center for Aging Services Technologies (CAST), a program of the American Association of Homes and Services for the Aging, and the American Health Information Management Association (AHIMA) formed to develop requirements, recommendations, guidelines and standards advocacy towards the adoption of an HL7 implementation guide for an aging services Continuity of Care Document (CCD) with support for functional status and wellness content. Details presented to HL7 WG meeting in Köln, May 2007.

Behavioural health profile

12. Jim Kretz (Centre for Mental Health Service/ SAMSA/ US DHHS) reported on development of the behavioural health profile, noting that:
 - They produced the profile over a period of 13 months; it has passed HL7 ballot, with reconciliation to now be carried out by non HL7 members.
 - The timetable is to get it onto the CCHIT roadmap over the summer.
 - The real world scene means that there must be multiple profiles.
 - Also, there is no specification of what is required to be in or out of a EHR and, as there is no agreed minimum data set (MDS), every profile must be built from the ground up.

Some matters discussed at CBCC joint sessions but being progressed by Patient Care TC and Public Health & Emergency Response SIG (PHER) are reported in sections 10.8 and 10.9 below.

10.2 Clinical Decision Support (CDS) TC & Arden Syntax

Sessions of CDS TC and Arden Syntax SIG were mainly attended by Dr Vince McCauley and Dr David Rowed with the following matters being among those discussed.

Arden Syntax

In relation to Arden Syntax [a standard for representing and sharing clinical knowledge in Medical Logic Modules]:

1. Arden V2.7 has now passed committee ballot and will be submitted to full membership ballot next cycle
2. The potential to use Arden Syntax for formal specification of implementation guidelines was discussed. Apparently a few done in past but were not shared.
3. Consideration is being given to use of Gello expressions to replace curly brackets for data access components.
4. Rob Jenders (from Cedars-Sinai Medical Center and Co-chair of both CDS and the Arden Syntax Group) was due to visit Australia in February and sought assistance with contacts from members of the Australian delegation.

“Infobutton” ballots

5. Outcome of the HL7v3 ballot reconciliations on the Infobutton DSTU and associated informative Implementation Guide were discussed, noting that:
 - Both ballots (Infobutton URL-based R2; and Infobutton v3 R1) passed but with a substantial major negative raising recurrent issues about whether

this functionality can be implemented in v3 without being inconsistent with v3 architectural principles.⁶

- Would the DSTU be able to gain the consensus needed to pass a full membership ballot?
- 7 vendor implementations of Infobutton were demonstrated at AMIA, so the functionality exists.
- Current major objector is GE Medical which says Infobutton should not be a V3 standard but rather a web service.
- The Committee plans to move to a web service at a later stage, but may need to consider this earlier if the functionality cannot be adequately reconciled for v3.

“Morningside” initiative

6. Potential of the Morningside initiative as previously presented to the HL7 Board, with a 5 year timeline to achieve its goals of:
 - Developing and testing methodologies to enhance dissemination and adoption of CDS, and
 - Developing specific capabilities that have been missing: authoritative repositories of knowledge, execution engines etc.
7. The initiative is being sponsored by the US Army Medical service through TATRC (Telemedicine and Advanced Technology Research Centre) but as a joint project of DOD, VA, KP, Partners Healthcare, Henry Ford Health System, Arizona state Uni, Inter Mountain Health and AMIA. It is intended to engender national and hopefully international cooperation with potential for increasing Public/Private partnership.
8. Other aspects of note include:
 - An initial focus on Diabetes starting with knowledge already in computable form
 - The development of unique knowledge base content, clinical information model and workflow, which has to be translated into host specific actions
 - Possibilities for this content and interfacing to advance the use of HL7, IHE and HSSP
 - The knowledge base is potentially huge – the initiative can be expected lead to faster sharing of knowledge content
 - The initiative needs content resources, management tools, templates/models for implementation, methods as repositories of experience – and will leave a legacy of development in these areas

⁶ The objection is from GE Medical, which holds the view that: *While the Infobutton concept is laudable, it is improper to try to define it as a v3 topic, and especially as a DSTU, in its current form. Basically, the full topic implementation is dependent on interactions and responses totally out of the scope of v3 messaging, and not defined in the topic. All that is defined is a message that gives the dimensions of a query, but not the responses. ...*

9. Some issues to be addressed include:
- How much knowledge at the patient interface is core medical knowledge and how much is understanding of the patient in the local context? This balance will influence whether this is worth doing.
 - Knowledge maintenance is a large on-going burden
 - The initiative needs to address the unwillingness of some to share knowledge about both clinical processes and individual patients because they see it as their competitive advantage – the initiative plans to lead by example.
 - Columbia Arden rules have not been updated and no feedback from those that use them.

GELLO revision 2

[GELLO is a guideline expression language developed to query HL7 RIM v.3 compliant data. It is based on OMG OCL, was developed by CDS TC and was approved as both an HL7 and ANSI standard in 2005. GELLO advantages are claimed to include provision of:

- A single standard for representing clinical queries that can then be translated into other languages such as JAVA or SQL;
 - Query language aligned to HL7 v3 RIM; and
 - Standardized expression language for CDS, including time-based comparisons and other functions.]
10. IBM, WEBreach, Medical Objects (in Australia) and InferMed (UK) have implemented GELLO. Since 2005, discrepancies and inconsistencies have been identified in the language syntax that need to be addressed prior to implementing the language on a larger scale. Presenting the issues, Robert Dunlop (InferMed) and Barbara McKinnon (US) noted:
- The BNF definition of the language contains many ambiguities, making it impossible to implement with standard compiler tools.
 - GELLO syntax is difficult to read with anything more complex than one or two nested levels of conditional statements.
 - GELLO provides too many ways to describe the same semantic concept, making it difficult for a novice to determine how to develop expressions.
11. A new GELLO Authoring Tool, developed by InferMed UK, will be donated for industry use. The tool is capable of defining, encoding, and exporting structured GELLO query expressions aligned to HL7 v3 RIM class model [and be interpreted by InferMed's AREZZO workflow & inference engine product].
12. Four primary issues have arisen as a result of suggested solutions to some of these problems, and require consideration by TSC/ARB:
- (i) Syntax Library Operations. Can "operations" be specified within HL7? And, if so, what methodology should be followed:
- Retain "operations" in syntax/BNF?

- Store “operations” in separate reference library?

Another way of approaching this problem is to ask, “How the need for operations should be addressed in GELLO (e.g. post an alert) as there is difficulty with a declarative language having procedural elements?”

- (ii) Pre & Post Conditions. Current ANSI-approved specification states that GELLO is meant to query data and return a set of values, but:
 - Should GELLO be able to execute actions directly such as “Post and Alert”? or
 - Should GELLO query & retrieve values be passed to another application or engine to issue an Alert?
- (iii) How can GELLO align with Class Models outside of HL7 v.3 RIM (such as the SNOMED CT class model)?
- (iv) OCL, the language GELLO is based on, has not been widely adopted (leading to the need for constructs such as templates and archetypes) and is itself under active evaluation by the OMG/OCL work group and the University of Dresden, which leads to the question:
 - What degree of alignment needs to be maintained between GELLO and its parent language – OCL?

The above GELLO issues were reviewed with representatives of HL7’s new ARB. Once the GELLO project is officially registered and approved, each issue will be submitted to the ARB to determine HL7’s official position.

- 13. CDS TC resolved, to continue its series of bi-monthly teleconferences working toward:
 - completing its re-evaluation of GELLO syntax, identifying potential solutions, submitting these to TSC/ ARB for resolution – Q2/08.
 - based on the outcomes, produce R2 of the GELLO specifications and place into for ballot cycle as a DSTU – by Q3/08
 - testing the revised language in at least two “real world” pilot implementations (post –DSTU); and
 - holding a second normative ANSI ballot.

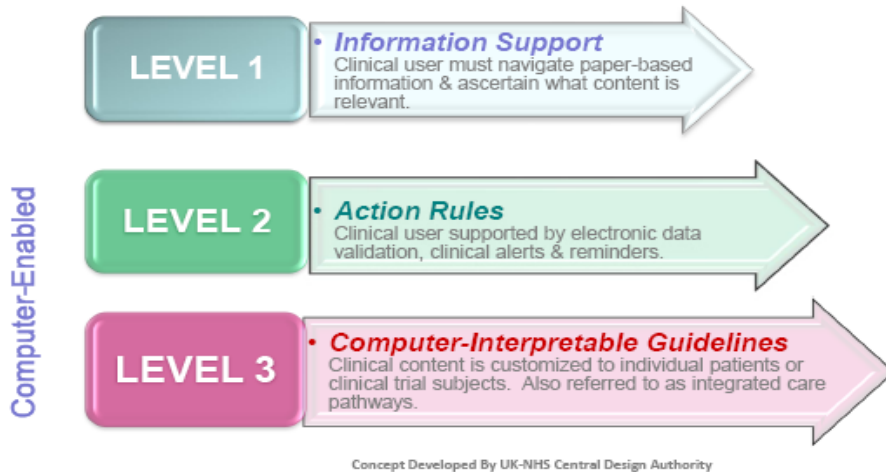
[As at 20 Feb 2008, a draft project scope paper had been produced for consideration of TSC/PMO and inclusion on the HL7 Work Program.]

HL7 vMR/GELLO presentation

- 14. Dunlop and McKinnon gave a presentation on the vMR (Virtual Medical Record) project and GELLO to four technical committees at the San Antonio Meeting: O&O TC; RCRIM Clinical Trials; PC TC; and CDS TC. Their material on GELLO was similar to that reported above under “GELLO revision 2”.

15. Underpinning the project is a 3-level model of CDS capability:

3 Levels of Clinical Decision Support Being Implemented Globally



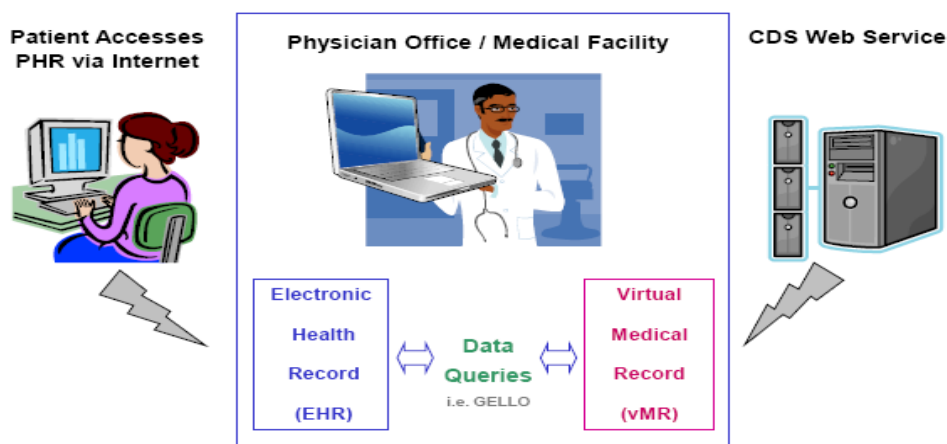
15. Within this framework, the goals of the vMR project are:

“To create an HL7 vMR data model recommendation and implementation guide, based on the HL7 v.3 RIM, and which is capable of supporting clinical decision support for “chronic disease management” at the point of care; and

To utilize existing HL7 data models as the basis for developing the vMR recommendation.”

16. Other characteristics of the project include:

vMR at the PoC



Proposed Value

- Eliminates the need for EHR vendors to maintain proprietary CDS structures and messages (by providing a consistent set of standardized data inputs and outputs).
- Advances the use of computer-enabled CDS Levels 2 & 3 by reducing costs and response turn-around time.
- Allows the physician to activate CDS via their EHR or the EHR to activate CDS triggers to alert the physician.
- Packages CDS assessments, decisions, goals, alerts & reminders for delivery to designated resources.

vMR Scope

- The Virtual Medical Record (vMR) data model recommendation will **define clinical information inputs and outputs** to/from clinical decision support services and address issues related to the effective use of a vMR (e.g. use of vMR with HL7 v2)
- The vMR will be capable of exchanging data with local clinical information systems at the point of care through a software middleware layer that translates the data into a standardized vMR format.

Timeline

- Storyboards are being prepared for Breast Cancer, Diabetes II, Asymptomatic Brain Aneurysm and Hypertension (drawing from EU @neurIST and Cocoon/RIGHT projects) – for completion Q1/08
- Gap analyses: vMR Use Cases vs (1) HL7 v3 class/data models, and CEN vMR model – for completion Q2/08
- Recommendations to other HL7 TC's & SIG's for revisions to existing HL7 data models and identification of new elements required for computer-enabled clinical decision support – Q3/08 & Q4/08
- Issue CDS recommendation for HL7 vMR (v.3) meta-model for clinical decision support representation and information exchange – by Q1/09
- Test recommendation within @neurIST and Cocoon /RIGHT Projects. (Note: *Both projects require the vMR to be comprehensive enough to support computer-enabled clinical decision support*) - Q2/09
- Issue CDS vMR implementation guide post testing - Q4/09

- Joint Europe/USA project team with Dr Robert Dunlop (UK) the team lead.
- Robert Dunlop is also currently working with NZ to create computable guidelines in the (UK Cancer Research) PROforma language
- IHE Canada will be starting a project in March looking at vMR architectures for IHE.

Challenges & issues

- How to represent CDS Service determination “pros” and “cons”; both encoded and narrative text.
- In the event you have an audit file, how do you represent it in the HL7 RIM?
- What are the technical implications of sending an entire CDS audit file vs. sending a point-in-time synopsis of an assessment?
- Re-interpretation of patient genetic profile as data elements are updated in EHR (including how it will be initiated, and how patient consent will be obtained?)
- Knowledge databases of: (a) DNA variations (or variant combinations) (b) Coded clinical significance – ? maintenance & synchronisation
- When/how to flag records for re-evaluation as more data acquired.

Other CDS matters

17. Limited current work has taken place on computable guidelines; however, it was noted that New Zealand guideline group has a contract with Kaiser Permanente to supply the executable content of their guidelines.
17. CDS regards order sets as a small element of a guideline and plans to sharing an order set as a structured document. This activity is stalled awaiting DMIM from structured documents as it is a “non-patient document”.

10.3 Data Types and ITS

Grahame Grieve led consideration of the second round ballot reconciliation outcomes for harmonised data types that are moving forwards to be balloted in parallel in HL7, ISO and CEN. The result is planned to be joint publication of IS 21090 *Health informatics - Harmonized data types for information interchange*

From the first round of balloting (before May 2007) there were 273 comments of which 173 were negatives. A decision was taken within HL7 to complete the next version of the HL7 abstract data types specification (bringing in some elements of the so-called “r2” data types) before the joint ISO/HL7 document was completed.

The second round ballot on abstract datatypes which closed in December had over 270 comments needing reconciliation. Many of these were resolved in the lead up to and during the San Antonio Meeting with approval in principle to address other issues by subsequent teleconference.

It was noted that the timetable for preparation of a joint specification ready for ballot (including completing the reconciliation of HL7 round 2 comments), balloting and ballot reconciliation within all three of ISO TC 215, CEN /TC 251 and HL7 would be affected by:

1. The time and effort that had been required and was still required to complete the Round 2 datatypes reconciliation and finalise editing of the standard (in HL7 format).
2. The time and effort still required to, re-format the HL7 document into ISO/CEN format and deliver ballot drafts to HL7 HQ, ISO TC 215 (then ISO Central) Secretariats and CEN /TC 251 Secretariat in time to meet the ballot window for September 2008.
3. The need to synchronize disparate ballot cycles. The longest ballot cycle is for ISO TC 215 which, under its rules, requires 5 months.
4. Working back from planned final reconciliation at a Joint Task Group meeting to coincide with the September 2008 HL7 WG meeting in Vancouver, the ISO NMBs will need to receive their ballot papers by end-March 2008, which means that it needs to be to ISO TC 215 Secretariat in ISO-ready form at least 4 weeks, and preferably 6 weeks before that (i.e. by mid February). Grahame Grieve undertook to do his best to meet this deadline.
5. The CEN ballot cycle is understood to be 90 days, whereas HL7's is 30 days. The plan is for all ballots to be open at or around the same time to enable a common reconciliation and acceptance to take place.
6. There is a single community of experts commenting from different perspectives; comments are handled in different SDO committees in different timeframes; problems can occur when definitive changes are made to a joint document during comment resolution in one SDO, before it is considered by those in another SDO, or where different documents are put out for comment. There must be a single ballot cycle with one version of the document.
7. The need to harmonize processes for resolution of comments.
 - The HL7 process is that the committee/work group goes through comments one by one for resolution, whereas ISO TC 215 working groups create a disposition of comments document which goes out for approval.
 - If the project team/experts review all comments as a single group, then there would be no need to repeat comment review in another forum i.e. have a single open process for submission of comments and review.
 - It was suggested that most issues can be resolved virtually, with a face to face meeting held to resolve difficult issues to finish and approve the resolutions.
 - This could occur at any SDO meeting, but HL7 has been most affected by the work and reconciliation at an HL7 meetings may enable the greatest number of issues to be resolved to finalisation.
 - It is important to engage all communities of interest in the resolution of comments. There was debate over whether a valid CEN ballot reconciliation could take place outside Europe (i.e. in Vancouver). After discussion it was resolved that the Europeans could participate in an ISO ballot reconciliation outside Europe and then endorse the international version for use in Europe.

8. In terms of substantive issues which may still cause problems for joint acceptance of the new data types at the international level, the concerns of the Japanese over the use of Unicode in strings and, potentially, some differences about imprecise time periods appear the most likely to result in challenges.
9. Grahame Grieve has agreed to come to Gothenburg in late May and to be available to discuss the ballot draft in depth at the ISO TC 215 and CEN /TC 251 meetings being held at that time.

While plans have been made for synchronisation of the HL7, ISO and CEN ballot cycles for progression of the joint data types specifications going forward; however, this will require on-going support and facilitation through JWG to ensure that they do not get out of step due to inaction on either side. Richard Dixon Hughes undertook to assist in getting relevant CEN and ISO resources engaged in the overall process.

10.4 EHR Technical Committee (EHR-TC) and PHR

10.4.1 Introduction

The EHR TC is a large, active committee that operates at a higher level than many other HL7 technical committees. It specifies processes and requirements for seamless interchange and sharing of electronic health record (EHR) data. The TC sees itself having a clinical or health system user focus, and has subsidiary work groups addressing the following:

- Behavioural health profile
- Child health profile
- Emergency care profile
- Records management and evidentiary support profile
- Personal health record (PHR)

Over the years, Australia has had strong involvement in EHR TC with Dr Sam Heard and David Rowlands having both served as co-chairs and Richard Dixon Hughes participating in its technical activities for varying periods since 2004.

EHR TC concerns itself with EHR architecture, EHR systems functionality and associated processes (such as trusted end-to-end integrity of medical records handled by electronic systems). It has been a standing principle that definition of specific information content falls to other groups HL7 within working on more detailed technical modelling of health information and representing it as messages and clinical documents. However, EHR TC also recognises that it can not work in isolation and its program at each WG meeting always involves strong interaction with both other clinical and technical groups – particularly structured documents (CDA/CCD), patient care and O&O (for clinical statement).

The EHR Systems Functional Model (EHR-S FM) is the EHR TC's signature product. Developed over several years, then released as a DSTU (draft standard for trial use) it became a full ANSI accredited standard in 2007 and is now on fast-track for adoption as an ISO standard through TC 215 for world-wide use.

The EHR-S FM defines a requirements framework against which functional profiles are written setting out conformance criteria against which the capabilities of individual EHR systems may be assessed for particular use cases (e.g. Ambulatory Care, Acute Care, Paediatrics and Health Statistics).

Following the formation of ONC in the United States and the establishment of a eHealth capability focussed on achieving interoperability through AHIC, HITSP, CCHIT and the RHIO and NHIN initiatives, it became necessary for many EHR systems to be certified to qualify for use with various US health programs. In this environment, involvement in the development and application of EHR-S functionality profiles became an urgent mainstream interest for US-based EHR-S vendors and users.

This use of the EHR-S FM standard, the emergence of new skills and capabilities based on such use are positive, as are proposed improvements that have resulted from its application. The downside for Australia, which worked hard to ensure that the EHR-S FM could be seamlessly applied in the international context had full international application, is that the activities of the EHR TC have become much more US-centric over the last 2 years.

Work has now commenced on producing Release 2 (R2) of the EHR-S Functional Model, to incorporate feedback from its use to produce functional profiles used by the CCHIT in its certification programs and from other applications.

With establishment of the Clinical Interoperability Council (CIC) and HL7's engagement with other activities focussed on clinical content, such as DCM (Detailed Clinical Models) and RCRIM/CDISC in the clinical trials area, the role of EHR TC as a focal point for engagement of generalist clinicians in HL7 standards is becoming concentrated on provision of expert input to EHR-S functional profiles for particular clinical areas. At the same time, the involvement of EHR systems vendors is increasing as they become more affected by requirements for certification to EHR-S FM profiles.

With rapidly growing world-wide interest in Personal Health Records (PHRs), the EHR TC is providing a focal point within HL7 for the definition of PHR systems requirements. Work on a PHR Functional Model is moving rapidly based on the experience (and framework) used for the EHR-S functional model. Some of those working on this in HL7 (notably John Ritter) are also contributing to a Technical Report on PHR requirements in ISO.

In the USA, so-called "PHR" approaches seem likely to fill the role generally proposed for "Shared EHR" initiatives in Australia (e.g. the NEHTA proposal and pilots under the former HealthConnect program). This makes the current PHR work particularly relevant to Australia.

Several other standards documents are being developed by EHR TC that have potential ramifications for the way in which EHR content is created, managed and processed. These include the EHR Interoperability Model (EHR IM) and the EHR Lifecycle Model, which have largely been driven by one person, Gary Dickinson, without necessarily attracting critical scrutiny, particularly from the international community.

As these new standards are developed and move into ISO, it is important that there is continuing effective input from Australia and other international participants to ensure that our needs are represented in the development of these standards, which have all originated with a strong US-domestic bias which, if not addressed, would become institutionalised under a harmonisation agenda based on the mantra of "one world-wide standard, one test, one certification".

10.4.2 General

1. Co-chair elections. Two co-chairs (one of which was a formal replacement for David Rowlands) were elected:
 - Patricia Van Dyke (Delta Dental Plans Association), and
 - Corey Spears (McKesson).

Gary Dickinson (US), Beatriz Leao (Brazil) also ran but were not successful.
2. Characterisation of the TC – should it become the PHR-TC, with an EHR working group? While debated at several sessions – along with alternatives such as a separate PHR TC (not supported) or the mid-way position of becoming the EHR/PHR TC – the matter was parked for consideration on another occasion.
3. Emergency Care (EC) Functional Profile. This profile is currently a stable product; however, Dr Don Kamens (Xpress Technologies) reported that there are plans for changes to the profile, which has been used by HITSP and CCHIT as the basis for EC requirements and in the development of associated certification criteria.

The EC group are also concerned about how Release 2 (R2) of the EHR-S Functional Model will relate to functional profiles built on R1.

10.4.3 EHR TC strategic positioning and direction

The session on Q1 Tuesday, 15 January focussed on strategic positioning of the EHR TC and changes in its strategic environment and drivers. Some of the matters covered in this wide ranging discussion included the following.

1. How EHR-TC with clinical/user focus relates to, and is impacted by, evolution of the HL7 technical architecture, other committee's technical activities (particularly in modelling clinical domains) and the newly formed ARB and TSC. Among the matters considered was:
 - Need to continue partnering closely with Structured Documents TC on CCD and Patient Care TC, which has become the umbrella for many clinical groups
 - EHR TC has always been an easy group for less technical people to join – but HL7 now has other ways of relating to clinical groups. Is EHR TC now more relevant as a pathway to their deeper involvement? Can it grow its focus as a clinical and not as a technical spec group?

- The separation of clinical and technical within the broader HL7 community is increasingly artificial. The TC's approach must support innovation without excessive technical prescription.
2. How has EHR-TC addressed its mission of "informing architecture"? The main role has been, and should probably continue to be, defining functional architecture and keeping those working on more detailed technical aspects informed of requirements for HL7 technical architectures, noting that:
- EHR TC does not have a technical experts across every domain needed to develop technical architecture (which is the role of other groups)
 - EHR TC's value is in profiling through partnership with customers (including many with expertise beyond the room), and
 - Possibilities of failure include allowing HL7 technical and vendor-centric perspectives to impede or overshadow the TC's clinically focused work.

In response to this topic, Gary Dickinson noted that, in the early days, the US Government (ASPE) and 3 sponsors were looking for a prescriptive model that would ensure interoperable exchange of records. With the TC's focus on the functional model, this has not been addressed but is the reason that he has pursued the notion of standards for persistent records unaltered and verifiably assured from point of origination to point of use. In his view it is time for the committee to focus on requirements for validation of EHR outputs - v2 and v3 messages and CDA documents and ensure that the underlying information models (being developed by others) support these requirements.

3. Measures of success. The measure of success for a TC is the extent to which its work has been adopted. While EHR TC seems to be successful by this criterion, it needs metrics and methods for measuring the uptake of its standards.
4. Customer relevance. How do the mission and efforts of EHR TC, HL7 and other SDO's deliver benefits to industry and users and help them achieve their missions? It was noted:
- EHR TC has provided certainty as to what an "EHR" [i.e. EHR system] is and a framework that enables the functionality required of an EHR system to be specified and assessed against the capability needed to improve and support healthcare
 - With others, EHR TC has identified standard functionality for creation and use and interchange of clinical information through EHR and PHR systems, messages and electronic documents
 - HL7 standards were tested and largely proven in situations such as facilitating recovery of health data in the aftermath of Katrina – the need to be able to respond to such events without loss of health information is now pushing the EHR/PHR standards agenda much harder
 - EHR TC has provided functional models and profiles being used by CCHIT to certify EHR systems – reducing the risk to purchasers of EHR/PHR capability, helping to promote the uptake of eHealth and the realisation of its benefits, and

- EHR TC is the SDO that has created most standards actually used for systems certification – with potential for much wider application in both the US and elsewhere.
5. The EHR-S functional model was originally commenced to answer the question “tell me what an EHR [System] is?” It did this by cataloguing and defining the required functions of an EHR-S (noting that ISO TS 18308 had set about defining “requirements for an EHR architecture’ – principally aimed at EHR information content). The PHR has now emerged as a partly-defined industry hot topic needing similar treatment. The EHR TC:
- Started its PHR work to understand and define requirements for interoperability between the EHR and PHR. How should an EHR exchange information with the PHR?
 - Later decided to develop a full PHR functional model and in process get interoperability between EHR and PHR.
6. On interoperability – the way to improve healthcare is via exchange of health information. If EHR/PHR systems can be made to conform to an interoperability standard, this will facilitate health information exchange as compliant systems are proliferated. EHR TC has had limited exposure to RHIO or HIE projects to date, but needs to understand what functions are needed to underpin interoperability profiles.
7. Themes from discussion in the context of future directions for the EHR TC:
- EHR TC found a gap and filled it with excellent work in creating a systematic framework for specifying EHR system requirements through the EHR-S FM, work that has been adopted, extended through functional profiles. A large part of this work is now being improved. It is now time for change:
 - the TC has gone from work that was strategic to maintenance, extension and refinement of a product
 - It needs to look beyond the HL7 world and find the strategic space again
 - The EHR TC strategic vision needs to encompass: *“a standards environment that ensures EHR/PHR solutions function effectively across the entire continuum of care”*
 - What should the EHR TC do next? How should it reach out and capitalise on its links and overlaps with other committees, clinical domain, structured docs, etc?
 - EHR TC needs to confirm whether functionality should remain its focus and consider how further work on functionality requirements should be structured, to resolve:
 - Whether the perfect world has 10 or 100 or 1,000 functional profiles and what these should be?
 - How to modularise profiles more effectively and provide controlled hierarchies with multiple levels of profiles – enabling users to seamlessly mix and match to address their needs (e.g. basic EHR functionality + ER services + neonatal services).

8. How EHR TC can help HL7 resolving needs through:
 - Defining how to progress from interoperability requirements to implementation
 - Working with Structured Documents TC as functional areas are profiled to ensure that data domains reflect the same requirements and capture them in CDA r2 form (including the generic end-to-end interoperability requirements needed to incorporate documents into managed electronic health records).
 - Mounting projects to develop profiles and sub-profiles in emerging areas already identified (collecting once and using many times as per EHR TC mission), including: (a) NCVHS profile (in pipeline), (b) Reporting, and (c) Population health.

10.4.4 EHR TC – current projects

The following matters were identified as currently being progressed by EHR TC (in most cases through identified Work Groups – RMES, BH, LTC, EC etc).

1. Records Management and Evidentiary Support (RMES) Functional Profile. [RMES was formerly known as the “Legal Profile”]. Sue Mitchell (Omnicare) and Beth Acker (US DVA) reported on progress of the recent RMES-FP ballot outcomes and reconciliation, noting that:
 - 56 signed up for ballot pool – 8 affirmative, 39 negative. At least another round of committee ballot will be required.
 - Very large response. About half of the 449 comment lines were negative major and minors. There were lots of worthy comments.
 - 110 major negatives (but likely to consolidate to a few major issues as there was a lot of commonality).
 - Siemens, VA, DoD, KP and some others submitted block votes.
 - Some of negative comments point back to holes in the FM, which have potentially led to too much being added into the profile, noting that the possibility of extending the FM needs to be addressed.
 - There is a philosophy that the EHR-S FM itself should recognise that all health records need to be kept as potential legal records.

The responses have highlighted early need to revisit the EHR-S Functional Model and rules for its application – and how continuous improvement should be built into the model to rectify its performance; however, proposals for such changes have raised issues of backward compatibility. Lyn Rosenthal (NIST), who prepared the guidelines for application of the model, is to be consulted but was not at the San Antonio Meeting.

An RMES break-out group did a lot of work on reconciliation of comments and, for some of the time, was assisted by Richard Dixon Hughes (who has current legal qualifications). AHIMA and health information managers practising in health services have a particular interest in this work.

2. Long Term Care (LTC) Functional Profile. Sue Mitchell reported on behalf of the LTC Group, noting that they had no work planned for the San Antonio Meeting. Customisation of LTC profile to nursing home care in the US Realm is being progressed to the following timetable:
 - 30 day internal ballot within LTC group in next few weeks;
 - Work on the draft of the profile at May WG meeting and register the profile as a ballot item in May/June for committee ballot in September cycle; then
 - Full membership ballot after September.

3. Behavioural Health (BH) Functional Profile. Jim Kresz (Centre for Mental Health Services/SAMSA) reported on the BH ballot, which closed in December. There were only a few negative votes - mainly from software developers.

As most of the BH group were not present in San Antonio, they had not planned work there but hoped to resolve the negatives without substantive change in March so that the document can proceed to full HL7 membership ballot for April; otherwise a further committee ballot will be needed. Plans are afoot to get the BH profile onto the CCHIT work program later in the year.

Like RBES, the BH group are also concerned about how later versions of the EHR-S Functional Model will accommodate functional profiles built on earlier versions.

4. Child Health (CH) Functional Profile. The recent ballot returned 100% affirmative votes with comments able to be reconciled by the CH group at the San Antonio Meeting. This profile covers all of paediatrics. A more granular profile will now be developed from it for neonatal care. This will be the first sub-profile to be developed and is expected to be an exciting instantiation of the original "derived profile" concept.

The following five projects (past and present) are part of a set of activities that are being progressed, primarily by Gary Dickinson, with a view to supporting the standardization of EHR interoperability and the EHR lifecycle.

5. The white paper *"Coming to Terms: Scoping Interoperability for Health Care"* was completed by the EHR Interoperability Work Group and published on 7 February 2007 (some 12 months ago). The aim was to define *"interoperability"* for use in the EHR context.
6. EHR Interoperability Model (EHR/IM). Became a DSTU in February 2007 and has now been submitted as a new work item request to ISO TC 215. [Uptake in the user community is unclear.]
7. EHR/IM CDA r2 Reference Profile for EHR Interoperability – passed ballot in January 2008. Expected to be approved for publication as DSTU in February following disposition of comments.
8. EHR/IM Legal Profile for EHR interoperability (not to be confused with RMES Functional Profile). The legal aspects team has only just begun its review of the preliminary draft.

9. EHR Lifecycle Model – passed ballot in January 2008. Expected to be approved for publication as DSTU in February following disposition of comments.
10. Alignment with ONC/ AHIC/ HITSP Use Cases. The EHR-S FM and PHR-S FM are being reconciled with various use cases being considered by ONC, AHIC and HITSP to identify their suitability to be recommended as specified standards to support related implementations. Of the following three, one has been done and two are in progress:
 - EHR/Lab Results Reporting (Y1 Care Delivery) - Completed
 - Demographics/Med History (Y1 Consumer Empowerment)
 - Biosurveillance (Y1 Population Health)

The work is being done by Gary Dickinson, who is also assessing alignment with the EHR Lifecycle Model and EHR Interoperability Model.

A presentation of the results to HITSP and ONC is coming soon. There is also work to be done on HITSP's approach of focussing on transient messaging requirements for interoperability, with a view to encouraging them to move toward an approach and strategy that encourages the establishment of persistent EHR records within a trust framework.

11 PHR-S Functional Model

The PHR-S FM is one of the EHR TC's biggest current activities. The DSTU was circulated for public comment in mid-2007 and went to formal DSTU ballot in October 2007. Although the threshold has been met, there are some 5 substantive items where the resolution will need to go back to the ballot pool for acceptance.

It is proposed that this take place in an out of session ballot planned to start on 14 February and closing on 17 March. All spare EHR TC breakout time in San Antonio was spent in finalising reconciliation of the three main sections (Personal Health, Supportive and Information Infrastructure).

Proposals are understood to be under consideration (to be largely resourced from outside the TC) for the following functional profiles on the PHR-S FM.:

- ED functional profile
 - Payer-based & Health Banking
12. Regulated clinical information interchange. A project for a profile is/has been put forward [Driven by RCRIM?]. No further detail was provided.

10.4.5 EHR TC – proposed new work

The following are proposed new work items or matters to be tracked for the EHR TC and its work groups; however, it should be noted that not every item proposed will necessarily be accepted or resourced.

13. EHR-S Vital Records (VR) Functional Profile

Ms Hetty Khan from the National Center for Health Statistics (NCHS)/ Centers for Disease Control (CDC) in Atlanta, Georgia, outlined the proposal for the establishment of a project to develop an EHR-S functional profile for reporting vital statistics events directly from the clinical interface. It was noted that:

- The project is about secondary data uses, such as using birth and death details for reporting to public health.
- The main objective is to leverage information held in EHR systems to capture and report vital records data as it arises at the point of contact or point of care. The VR profile will articulate the functions needed to achieve this.
- The work will have three main components:
 - domain analysis and creation of domain model
 - messaging specification, and
 - definition of the VR functional profile.
- The proposed project has broad support from relevant authorities in the US – NCHC Biostatistics, CDC, State Health Departments and Federal Agencies
- A Vital Statistics Working Group will be formed to progress the work, to be led by Hetty Khan and Michelle Williamson. Once the project is approved by TSC, there will be an open call for participation in the group, which will have a nexus with PHER SIG and need to collaborate with, and be guided by other TCs in the area.

The VR FP proposal was also featured in discussion with PHER SIG and PC TC at the EHR TC Clinical Salon reported in section 10.4.8 below.

14. HL7 gap analysis project.

HL7 is planning a project to use the EHR-S functional model as a framework to finding the gaps between the existing complement of HL7 artefacts and the potential need for standards projects as identified by the model. The aim is to ensure that HL7 has, or is working on, the full range of standards to meet health system needs. The review will involve surveying a wide range of HL7 working groups and classifying their work – including some of the more dynamic standards areas such as SOA/HSSP. Don Mon led discussion of the project with it being noted that:

- HL7 has issued an RFP twice for external consultants to assist in undertaking the work but without attracting a bid

[Richard Dixon Hughes and Klaus Veil both obtained copies but neither were in a position to bid – Don Mon and AHIMA are expected to bid.]
- The EHR TC is involved as the TC has carriage of the EHR-S FM which underpins the work.
- There is some concern as to the true scale of the project as it potentially involves identifying the information needs of every clinical specialty or type of service against each of the functional areas in the model.

15. Outreach – Support for Ambassador Briefing program. A brief for the HL7 Ambassador program has been created to support HL7 Ambassadors presenting the PHR and the PHR-S FM. The HL7 outreach team are now seeking assistance to create an Ambassador Brief on the EHR functional model and profiles. Modelling it on the existing PHR brief may reduce the effort required. Volunteers wanted both for preparing the brief and acting as Ambassadors.
16. Educational module on PHR-S FM. Now that the PHR-S FM is proceeding through to release as a DSTU, a 3 hour tutorial pack needs to be prepared for delivery (by the next WG meeting in May).

If based on the existing EHR tutorial (focussing on the EHR-S FM) and Advanced EHR Tutorial (focused on profiles and performance), preparation of the tutorial is not considered likely to take a lot of resources. The EHR TC is seeking a point person and faculty to lead and deliver this work.

17. Tooling to support profile ballot reconciliation. As previously requested through EHR TC teleconferences, Jim Kretz demonstrated a tool developed for reconciliation of functional profiles generated from the EHR-S FM, with the following features:

- Developed by ABT Associates (Cambridge, Massachusetts) for the Center for Mental Health Service/SAMHSA using US Government funds
- Used for collection of votes and reconciliation of both the Behavioural Health and Long Term Care profiles
- May become a freestanding utility to be put into the public domain. Funding to support it longer-term is in question (not a SAMSA responsibility)
- Supports voting and review and allows import from Excel.
- Still a manual process to ensure the profile doesn't break the rules.

The EHR TC supported the tool being available and would investigate and report back on how this might be achieved.

18. AHRQ/NLM - Clinical Interoperability Model

As part of the (US) AHRQ desire to have same quality measures, Ed Hammond has secured NLM funding for a joint project to define an interoperability model for clinical information needed to support healthcare research and quality with the objective of creating data once and repurposing it to all 128 agencies and medical societies required to report on healthcare quality in the USA. Activities include examining:

- Existing sources of quality measures and opportunities to streamline data collection, and
- The EHR functional model, to see where the data comes within an EHR.

The project is to be led by AHRQ (Agency for Healthcare Research and Quality) and involves PCPI, AHIMA AMA [and HL7?] as participants with AHRQ calling the initial meeting.

EHR TC's support was sought for guidance, monitoring and tracking the project on behalf of HL7 and to assist in application of the functional model.

19. AHRQ/NLM – Data elements for quality reporting

This is linked to the previous project (No. 18) and aims to identify and specify the master set of data elements needed to support the in the EHR-S FM including those necessary for quality reporting. Points raised during discussion included:

- Whether this should also look at the items needed to support the EHR Interoperability Model (as supplemented by the EHR LifeCycle Model)
- Concerns about keeping the scope of this project within reasonable limits and whether looking to current functions covered by the EHR-S model provides the required inputs. An alternative may be to create another function or profile on the model in quality specific to the quality needs.
- The outputs would provide another avenue to allow gaps on the RIM to be found.
- Whether the HITSP Quality Use Case is a useful input to this work?
- Whether this is best started as a pilot constrained by a single requirement – which Don Mon recommended be the needs of project 18.

10.4.6 Potential future work items

None of the following items have yet to be recorded on the HL7 PMO projects database; however, several need to be progressed as soon as reasonably possible.

20. Moving to Release 2 of EHR-S FM.

This is the most important of the potential future work items. There was considerable discussion of this proposed work item within the EHR TC at various times during the San Antonio Meeting, with the following being among the points made

- The timeline for R2 is not yet clear as CCHIT has inputs, the ISO ballot may have inputs, the legal profile also has inputs, as well as input from the experiences with other FPs.
- Other sources of input may include a review of VISTA within US-VHA (Hammond) and gaps arising from progress with the EHR Interoperability Model (Dickinson)
- There is a large (and growing) list of “parking lot” items waiting for inclusion in R2. It was suggested that the HL7 tool for Projects should be used to manage parking lot items as EHR TC may lose some.
- There is an ANSI/ISO requirement that published standards be reviewed at least every 5 years and be renewed, maintained or withdrawn so that they remain relevant.

- The concept of building on implementation experience (even if it does cause some pain with backward compatibility) is also supported by the current ISO strategic plan.
21. Translation of EHR TC standards into multiple languages for world-wide use.
 22. Distance Learning/Education. Development of distance education (web and/or telecom) curricula and materials for worldwide education on the EHR-S FM, EHR-S FM and the creation and application of related functional profiles. This may potentially be needed in different languages.
 23. Regulated Clinical Research is understood to be seeking approval to create a functional profile against the EHR-S FM.
 24. Public Health has expressed interest in creating a functional profile against the EHR-S FM.
 25. Suggested coherent feedback loop between CCHIT and EHR TC be formally established as a project.
 26. Joint work with SD TC on EHR data elements

Structured documents TC (SD TC) noted on 14 January that they would like to work more closely with the EHR TC. AHIC has approached HL7 SD TC to do some work on EHR data elements. It was agreed that the two TC's will work together on this project and, in particular:

- To form a joint project group comprising Crystal Kallem, Bob Dolin and Don Mon to work up the project proposal and identify EHR TC's roles
- The first task is to create a project plan to link the group into the TC work plans.

10.4.7 Technical Salon

The following matters were among those addressed during the technical salon:

Joint session with Structured Documents TC

1. CDAR2 Reference Profile for Interoperability. Gary Dickinson presented his gap analysis; however, there is not consensus between SD TC and the EHR TC that the 9 items (out of around 50) are valid gaps – rather there appears to be a difference in philosophy over the extent to which a CDA document should internalise its control information.

Technical Steering Committee and Technical Liaison

2. It was noted that the TSC was formed to hear all concerns on technical issues, with a view to giving the Board amore strategic focus. The new ARB will assist the TSC in its technical coordination and oversight role, dealing with technical architecture issues.

Issues of consistency and concern can be brought up for consideration at monthly conference calls. Calvin Beebe is the representative for one year.

First try to work through co-chairs so they can work through Steering Committee.

3. Structured Semantic Design Forum. A wiki page has been designed to support this activity and details can be obtained from the page.

10.4.8 Clinical Salon

The following matters were among those addressed during the clinical salon:

Joint session with Patient Care TC

1. PC TC is working on the following, which are likely to be of interest to EHR TC.
 - (a) Problem list.
 - (b) Care Plan. It presently exists as a [draft] model but lacks good documentation as to how it will be used. PC TC is developing storyboards to document its use and then use them to check the model and complement its application.
 - (c) Population Data.
 - (d) Liaison with CEN /TC 251 with a view to increased harmonisation. A meeting has been held with the initial project proposal to harmonise vocabulary used in the PC TC and TC 251/WG1 standards.
 - (e) Allergies Model is in DSTU status. PC TC are seeking comments, which should be announced on the HL7 site by early February – to be evaluated in the Vancouver WG meeting in September 2008.
2. Both TCs discussed how they (and other clinically-focussed TCs) would interact with, and participate in, tasks being progressed through the recently formed Clinical Information Council (CIC). In particular, what will be the process for moving projects forward from CIC to TCs. Don Mon agreed to report back following his attendance at the CIC meeting (on 17 Jan).

Joint session with Clinical Decision Support TC - Public Health Emergency Response (PHER) WG

3. The EHR TC outlined the proposal it is preparing for TSC approval to undertake a project to develop an **EHR-S Vital Records Functional Profile** (as outlined at item 13 in the EHR TC proposed work items above).

Once the project is approved the call for participation will be released and PHER input would be sought. The initial starting point would be a domain analysis. Salient discussion points included:

- Don Mon's concern that data should not be collected in the clinician's EHR system if it is burdensome to the clinician. If the information is generally collected outside the clinician's office, the clinician cannot be expected to put it into an EHR system just for Vital Statistics collection.
- Dipak Kalra (UK) asked about international involvement. If he could get a good description of the scope in clinical terms he would be prepared to

approach those he feels may be interested in international participation on this project.

[Australian note. While this FP is obviously aimed at facilitating the CDC and DHHS standards-based approach to its new PHIN (Public Health Information Network) for Biosurveillance in the US, is there value in Australian involvement, or should we look at the resulting profile as an exemplar for a later Australian development?]

4. Patient Care is hosting an effort on collecting patient data. Should this be a joint project plan between EHRTC and PC-TC and used to inform work on the VR profile?

10.4.9 Links between the work of EHR TC and CCHIT

In his role as EHR TC Co-chair and member of the governing body of CCHIT [Certification Commission for Health IT], Dr Don Mon responded to questions about links between the work done in EHR TC and the use of its standards for CCHIT certification. Specific questions raised included how CCHIT identifies the standards that it will use? How does CCHIT apply and/or modify the provisions of a standard? Where are the upcoming requirements and proposed timescales? In discussing these questions, he covered the following.

1. Requirements identification. CCHIT does not only look to HL7 standards. When it receives a petition to establish a certification regime for a particular functional area, CCHIT reviews the associated use cases and identifies what related elements are important in EHR systems. Factors considered include:
 - Improvement of healthcare in US patient care settings
 - Interactions with other systems and users of information
 - Ability to collecting information once – and use for many purposes
2. Environmental scan. CCHIT can only reference standards not develop them. Based on its identification of the required functional elements, CCHIT carries out an environmental scan to establish what standards might be candidates to be called up when it sets its certification criteria.

During its early environmental scans, that CCHIT picked up on the work being done in the HL7 EHR TC and resolved to adopt relevant EHR-S FM profiles and has continued to do so. Another major source of requirements is the Alberta security standard.

3. Selection of activity areas and formation of projects. The expansion of CCHIT's activities is driven by business cases submitted by the US health care industry. This was the basis for work in LTC, BH, ER, where relevant services made the business case to establish criteria for their industry. In addition to making a business case, the industry must also show it is ready, willing and able to work with CCHIT and do their part of the work.

In each case, it helped that a profile had been developed for the EHR functional model supporting the relevant area. CCHIT took the profile as an incoming deliverable from these industries and had been able to transplant expertise and

materials from the already established HL7 work group to form the related CCHIT workgroup.

4. CCHIT relationship to work of the EHR TC. Members of the TC had noted situations where CCHIT requirements had been added into profiles being done by the TC. Don Mon confirmed that the TC has generally taken the course of merging CCHIT requirements into working versions of the Functional Model and profiles and hoped that this process could be streamlined. David Tao of Siemens expressed vendor concerns at CCHIT adopting functionality criteria not accepted at ballot, including material sourced from outside HL7, such as material from IOM and AMA studies used in the Inpatient, ER and Ambulatory Care criteria. The Committee noted the desirability of feedback to identify missing functions for timely improvement of the model and the need for R2 changes.
5. Closer working relationships. Better alignment between CCHIT requirements and timelines and those of HL7 and the EHR TC was generally supported, along with some more formal recognition of the relationship. EHR TC needs to be ahead of CCHIT and, therefore, needs to know as soon as an area is being considered by CCHIT for inclusion on its schedule to allow closer synchronisation of work cycles.
6. An MOU between HL7 and CCHIT was established shortly after CCHIT was launched two years ago. The cross-over in membership of work groups in HL7 and CCHIT has also been noted. It was suggested that improving communication about requirements and timelines should be raised with the HL7 Executive / Board and its stakeholder relationship management team so that HL7 becomes more aware of CCHIT needs and feeds these back to the EHR TC.
7. Discussion of specific initiatives:
 - (a) Of the criteria set out in the initial ONC charter, CCHIT approved and published Ambulatory and Inpatient EHR criteria in 2007. For 2008, work is underway on updating these, as well as on initial release of ED, Cardiovascular Medicine and Child Health with certification of health information exchanges planned for release toward the end of the year.
 - (b) Behavioural Health is being planned for entry onto the CCHIT certification list in September.

From non-US delegates, some concern was raised regarding the US-centric nature of the EHR TC which is evident in the above discussion, and the potential implications for compliance of the resulting standards with wider international requirements in support of the WTO barriers to trade agreement.

10.4.10 EHR TC, ISO TC 215 and international relationships

There was lengthy discussion of EHR work going on in ISO TC 215 and its potential relationship to activities of the EHR TC.

Presentations were given by Audrey Dickerson (HIMSS, ISO TC 215 Secretariat) and Elizabeth Hanley (Standards Australia; ISO/CEN/HL7 JWG Secretariat) on the work of ISO TC 215 and the JWG. This intervention (arranged by Richard Dixon Hughes at

short notice) was timely because the EHR-S FM is currently being progressed as an International Standard and many members of the EHR TC were unaware of ISO TC 215, the JWG, their activities and processes.

The intervention also served to personalise these somewhat remote international activities for the Committee members and raise their awareness of needs beyond short-term US domestic requirements.

Some of the particular ISO activities of relevance to the EHR TC highlighted during the discussions and presentations included:

1. Links and potential overlaps between ISO TC 215 Working Groups WG1 (architecture and data structure) and WG8 (business requirements for EHR) and the EHR TC. The TC was given an update on the WG8 work program.
2. The current review of ISO TS 18308 Requirements for an EHR architecture, noting that this document addresses the nature and management of the underlying record (the information) - what US readers would see as "EHR records". It therefore complements the HL7 EHR-S functional model, which is effectively a specification of the services which surround the underlying records.

Dr Dipak Kalra (UK), who is leading this review for ISO TC 215 encouraged members of the EHR TC to become involved in the review.

3. The HL7 EHR-S Functional Model has been accepted as a work item by ISO TC 215 and is about to enter a 5-month ballot as a Draft International Standard (DIS). As noted elsewhere, this may result in feedback requiring HL7 to consider changes to the model. Gary Dickinson is leading the progression of this item within ISO for HL7.
4. ISO TC 215 WG2 (Data Interchange) also has work related to the HL7 EHR TC committee. In particular, Gary Dickinson suggested that ISO/TR 18307:2001 *Health informatics -- Interoperability and compatibility in messaging and communication standards -- Key characteristics* needed review alongside ISO TS 18308.

Richard Dixon Hughes advised the TC that ISO TC 215 WG2 would be meeting on Friday and Saturday at the San Antonio Meeting and that additional participants from HL7 would be welcome. WG2 is the venue through which most HL7 work is brought into ISO TC 215 for acceptance as international standards, with the MDF, normative HL7 v2.5 and HL7 CDA r2 (and also the IHE process) all currently in various stages of approval within WG2.

5. Collaboration with ISO TC 215 on PHR standards. ISO TC 215 has a task group working on a PHR Technical Report and is identifying potential needs for international standards in the area of Personal Health Records. Because of the early interest of device manufacturers, this work is being managed through ISO TC 215 WG7 (Devices). A draft deliverable is due for the ISO TC 215 meeting in Gothenburg, Sweden at the end of May 2008.

EHR TC members who have been involved in this work at various times include John Ritter, Gary Dickinson and Richard Dixon Hughes.

6. Dipak Kalra and Mark Shafarman covered the EHR-related projects being undertaken by TC 215 WG1 (Data Structure). In particular, the recent ballots for progression of the EN 13606 EHR Communication standard as a full international standard, which had been strongly opposed by some within HL7. These obstacles had now been largely overcome (at least at the inter-organisational level) with concurrent progression of the following activities:
 - A harmonisation initiative allowing 13606 Part 1 EHR communication standard to progress to ballot with a commitment to joint production of an HL7 Implementation Guide for the standard
 - UK NHS funding a proof of concept taking EN 13606 records ('compositions') and translating them into CDA document.
 - Collaboration between HL7 and others harmonizing the HL7 clinical statement as a representation of EN 13606 data and HL7 templates DSTU including a formalism for creating machine versions of clinical statements.
 - Internationalization of v3 data types, supports CEN point of view and the HL7 v3 point of view
 - As a standard process, both sides will continue to formally advance the harmonization process with ISO.

The strong support for the ad hoc collaboration meeting on Sunday evenings at HL7 was also noted as well as the plan to hold the JWG after the International Affiliates meeting at HL7 meetings where possible.

A small working group was set up to explore the EHR TC landscape and work plan, and make a set of recommendations to HL7 as to what this technical committee can contribute to the ISO/CEN/HL7 collaboration within the objectives of the TC. The WG will consist of Audrey Dickerson, Jaime Ferguson, Grant Gillis, Dipak Kalra, Mark Shafarman, Pat Van Dyke (as EHR TC co-chair) and Gary Dickinson.

Some suggested topics for consideration included:

- Review of work on CDA for health summaries (and see if anything was missed in the EHR-S FM)
- Review 13606 Implementation Guide
- Communication of nursing information to support transfer of care – coverage in the implementation guide
- Transfer of profiles, in the patient care domain.

EHR TC members attending HIMSS in Orlando, Florida were invited to take part in the next JWG meeting to be held on Saturday, 23 February.

10.4.11 EHR-S Functional Model in ISO

The HL7 EHR-S Functional Model has been accepted by ISO Technical Committee TC 215 (Health Informatics) for ballot as a Draft International Standard (DIS). This work item is being managed by TC 215/WG8 (EHR Requirements). While the timeframe for this work had still to be resolved, the document needed conversion from HL7 format to ISO format before going to ballot, which would run for 5 months.

[Note: The DIS ballot needs to go out by April 1 to allow comments back for review at the October ISO meeting planned for Istanbul].

It was noted that comments could be expected that would need to be reconciled with the existing HL7 position on the document and that some changes would likely be required. The EHR TC discussed the issue and noted the its intention to feed any ISO comments back into work on R2 of the EHR TC FM in HL7, even though this would mean the international version of the standard may then differ from both R1 and R2HL7 EHR-S FM.

10.5 Implementation & Conformance TC (IC TC)

IC TC is a high-level oversight technical committee formed in May 2007 from two other groups and having the following mission (subject to current review by TSC):

"The mission of the Implementation & Conformance Technical Committee (IC TC) is to support all post-publication activities of users of the standards. This includes the localization of HL7 standards to suit specific real-world situations, the creation of implementation guides and the mechanism to specify conformance."

The charter of the Implementation/Conformance Technical Committee (IC TC) includes providing a forum for users of HL7 standards to share best practices, success stories, and challenges related to the use of HL7 standards in specific real-world situations, in particular:

- During development of proposed standards the IC TC provides assistance to HL7 V3 implementers in conjunction with the applicable technical committees and special interest groups.
- The Committee is a conduit for end-users to give feedback into the standards development process and formulate proposed enhancements to the standards.
- The IC TC provides specifications related to the testing of conformance. To do this it produces normative specifications that define conformance based on the rules and mechanisms for constraint and localization.

Various members of the Australian delegation attended IC TC sessions at different times during the San Antonio Meeting with the following being among the matters noted:

Harmonising CDA implementation guides

1. Several Implementation Guides were displayed from various organizations and jurisdictions including IHE, Germany, Netherlands and Canada. These all had fairly similar component artefacts and also had some similarities to previously published IHE profiles.

It was agreed that an activity is needed to get a standard template for CDA implementation guides. This activity will be led by the Structured Documents TC and include members of the IC TC – with a draft framework to be ready for review at the May meeting.

Wiki.ihe.net/Patient_Care_Coordination gives examples of an implementation guide framework, which sets out common content for use in implementation guides.

It was noted that IHE has adopted an XML publishing approach for specifying CDA documents to be used for IHE referral profiles, in which a marked up template from the wiki is used to generate .pdf files by XSLT transformation of XHTML documents. There is a spreadsheet "Criteria for Messaging Implementation Guides" that defines standard content headers.

Frank Oemig agreed to upload a German template for Implementation Guides to the Implementation/Conformance wiki. [Subsequent review revealed that this appeared very useful and, following its upload, several other templates have also been uploaded. All are available for download.]

Dick Harding of Australia has volunteered to contribute to the small group producing a draft framework for Implementation Guides.

2. Frank Oemig went on to propose that the content of published V3 material should then be changed to reflect the artefacts included in the framework. This would then allow jurisdictions to develop their Implementation Guides by a simple constraint process against the published standard.

Harmonising conformance profiles with underlying v2.x standards

3. Attending a joint session of I&C and InM, Klaus Veil became concerned that I&C appears to be creating compliance profiles that effectively modify and re-state, rather than build on the underlying HL7 V2.x standards.

This impression was created when a notation for data item usage and cardinality was proposed without much consideration of the equivalent specifications in the V2.x Standards. He followed these concerns up through face to face discussions and subsequent e-mail conversations and understands that, as result of these representations, an effort to harmonise the I&C notations and content with v2.x is underway.

Proposal to replace mandatory field lengths in v2

4. A proposal to remove most mandatory field lengths from all HL7 v2 standards was put forward in IC TC and was one of the more controversial issues addressed at the San Antonio Meeting.

As the majority of the debate on this topic and the final resolutions were taken in the InM TC, an outline of the proposal, issues and outcomes are reported under the InM report in section 10.6 below.

HL7 v2.8 Conformance Roadmap

5. Rob Snelick detailed work that NIST are doing to develop a conformance roadmap for HL7 V2.8 which will be based on the following new profiling concepts.
 - Referencing table definitions
 - Providing individual field occurrence definitions

- Provisions for linking a regular expression with an element
- Profiling query messages
- Specifying and HL7 version at the segment level
- Profile version identifier
- Providing example messages

Other improvements to clean up v2.8 conformance requirements and assessment include:

- Updating the conformance profile schema
- Validation methodology
- Comparing sending/receiving profiles pair

The purpose of these changes is to:

- Align the standard with common practice and existing tooling
- Develop conformance requirements that support tooling efforts

Discussion of Messaging Workbench (MWB) v6.7

6. Pete Rontey summarised features of the new version 6.7 of MWB, which has just been released incorporating over 60 changes, including:
 - Extended help files
 - The ability to use value sets in test message generation (a major change)
 - New export features, including export of HL7 conformance profile from a file drop-down menu.
 - Enhanced value set management capabilities – Can define value sets to be populated into example messages
 - Improvements to end-to-end message testing.

Joint meeting of Tooling Committee with IC TC

7. The principal aim of this joint meeting (held Q2 Thursday and attended by Chris Lynton Moll) was to gather IC TC requirements for implementation tooling to inform the V3 Tooling project. The session noted that:
 - (a) There is need for a restriction hierarchy of V3 for conformance requirements as is currently present in V2.
 - (b) Currently there are no tools out there that can be used to produce an implementation specification for v3.
 - (c) There are also no tools available to test messages for conformance. There will be some available in approximately 12 months.
 - (d) Open Health Tools have some conformance testing capabilities.

- (e) Message instance testing needs to be against a normative standard in the first place before getting down to constrained implementations. MIF has some aspect of conformance testing.
8. Tooling support – Project Homepage.
- The HL7 Project Homepage site is intended to support HL7 Tool Developers (Toolsmiths), Technical Committees, and Special Interest Groups in managing their projects. All of the tools available on this Homepage are designed to support the development and publication of HL7 Version 3 Messaging Standards. Homepage may be accessed at:
<http://hl7projects.hl7.nscce.edu>

Other matters reported from IC TC sessions

9. Specification of HIPAA claims attachments. A joint session of IC TC, Structured Documents TC and Attachments SIG noted that:
- Attachments SIG was formed and commenced work some time ago on defining claims attachments in the form of CDA documents for use as claims transactions under the US HIPAA (Health Insurance Portability and Accountability Act, 1996)
 - Attachments SIG's initial focus was HIPAA claims attachments but, with that work being substantially complete, it has now moved on to define other attachments and transaction types.
 - However, as yet, HL7 CDA attachments have not yet been accepted by CMS (Center for Medicare Services), the relevant regulator.
10. Patient Identification with OIDs in CDA instances. Provider and patient identifiers need to be present in CDA claim attachments and are preferred to a local OID. A proposed approach is to provide a unique OID for patients by adding the patient's National Patient Identifier(NPI) as terminal digits to an OID assigned to the government body that assigns NPIs.
- A group has been formed to provide an informative document (white paper) on this.
11. Potential topics for next meeting in May 2008
- OIDs in CDA instances (real world acquisition of OIDs)
 - Harmonising the look and feel of CDA Implementation guides
 - Improving the ASIG publishing process
 - Optimising how we can create example files

10.6 Infrastructure and Messaging (InM) TC

InM (formerly Control Query TC) is a high-level oversight technical committee with the following mission (subject to current review by TSC):

"The mission of the Infrastructure and Messaging Technical Committee (IM) is to provide the infrastructural support required in order for systems to exchange domain content as specified by HL7."

With regard to v2, InM TC has principal responsibility for maintaining Chapter 2 (Control), Chapter 2A (Data Types), Chapter 5 (Query), Chapter 8 (Master Files) and Chapter 14 (Application Management) of the normative HL7 v2 standard.

With regard to HL7 v3 InM TC's responsibilities include:

- Transmission and Transport, including transmission wrappers, abstract transport specifications and transport protocol guidelines (e.g. ebXML, Web services, and MLLP), interaction patterns and trigger events
- Commonly used message types
- Implementable Technology Specifications (e.g. XML, UML)
- Abstract Data Types - the technical quality of the data type definitions, ensuring their utility across all technical committees, HL7's input to work on harmonised data types for ISO, CEN and HL7 [see section 10.2 above].

Various members of the Australian delegation attended InM TC sessions at different times during the San Antonio Meeting with the following being among the matters noted:

Proposal 476 to replace mandatory field lengths in v2

1. A proposal to remove most mandatory field lengths from all HL7 v2 standards was put forward but strongly opposed by many in the Australian delegation. The essence of the proposal, as reported by Chris Lynton-Moll is as follows:

HL7 v2.7 Minimum and maximum lengths - proposal

- In v2.7 lengths are being assigned to data types.
[See HL7 table 0440 – data types.]
- Specific fields will have their minimum and maximum lengths specified in the standard. For example – MSH-1 (1..1), MSH-2 (3..4), MSH-15 (15..15).
- The proposal is to move all other lengths to a profile. Thereby providing three significant advantages over maintaining the values in the standard.
 - Maintaining values in the profile will provide increased flexibility,
 - It will allow rapid changes when necessary rather than waiting for changes to the standard, and
 - It will allow values to be tailored to specific user or regional requirements rather than adhering to requirements that may be better suited to a different community
- If adopted, users will be able to make immediate changes when necessary, and the changes can be tailored to accommodate the specific requirements of the user community.
- Minimum values were not previously included in the standard but are added solely where they may assist the user. Otherwise they can be ignored by simply setting a minimum value of zero.
- If the null character is transmitting as "", it is deemed to conform to any minimum and maximum length specification.

2. Following discussion within the IC TC, which generally favoured Proposal 476 as outlined above, the proposal was taken to the InM Technical Committee where much more discussion was had over several sessions. There appears to be a significant section of the HL7 community that does not agree with this proposal or cannot see its benefits.
3. Klaus Veil noted concern among many members of the Australian delegation at the short notice to consider this proposal that would remove field lengths from V2.x Standards, in favour of specifying this material in profiles for individual implementation projects. He attended three sessions of the InM TC in connection with the proposal and noted the following disadvantages:

HL7 v2.7 Minimum and maximum lengths - disadvantages

- This proposal would jeopardise enforceability of the V2.x standards as a tool for procurement and force profiles to be created to specify the data item lengths.
- If the length specifications is relegated to profiles, formal profiles would need to be created and their adoption agreed for every application, thus duplicating the V2.x standards.
- For Australia, this would have the consequence of potentially weakening the AS4700.x standards.
- The need to have profiles as well as the standard and implementation guides increases the level of professional support and cost to implement v2.

4. When put to ballot at InM TC (with many IC TC members present) the proposal was accepted - 8 in favour, 6 against, 5 abstain, with most Australians opposing. The matter now will be taken back to IC TC for further action.

5. A compromise of having lengths as informative not normative was also put to the vote but was not successful.
6. Klaus Veil reports that, since the decision, there has been vigorous discussions about this on the relevant HL7 e-mail lists but, given the vote at the InM TC on this issue, some lengths may be removed when V2.7 goes to first ballot.

Expression of cardinality and optionality

7. Inconsistencies had been noted in the usage (wording) applied in various HL7 standards to express the cardinality and/or optionality of modelled relationships.

A motion was put and accepted to bring usage of (or words must, may, should, shall etc) into line with accepted practice. There now needs to be some editing of content

XPN family name datatype

8. It was resolved that the "Family Name" component of an XPN datatype is to be mandatory. This has an impact where the name is not known or only partly known. The impact and relationship to identification work practices, which vary widely needs to be considered. The matter was scheduled to be reassessed at an InM TC teleconference on 28 Jan.

10.7 Laboratory, Radiology and Pharmacy

Activity in the Laboratory, Radiology and Pharmacy TC meetings was monitored and progressed by Richard Harding, who noted that:

- The Pathology, Radiology and Pharmacy groups did not have any time allocated to V2 issues. This is a direct consequence of the very small numbers of people who are interested in working on V2 topics. However, there is an expectation that issues for V2.7 will be considered at the May WG Meeting in Phoenix.
- Pathology was mainly concerned with V3 ballot reconciliation. This work is somewhat tedious, but necessary to ensure that all comments are included, or at least considered, in the final standard. Pathology had missed the December 2007 ballot round. It was mainly concerned with preparing for the next (April 2008) Ballot round, and so focused on adding attribute-level descriptions to each attribute in each message, and resolving the remaining issues from the last ballot. This work is somewhat tedious, but necessary. Pathology expects to be ready for the April 2008 round of ballots.

[See notes at section 9.4.3 above in relation to the ICH Pharmacy messages being progressed by a joint Task Group of ISO, CEN and HL7 under ISO lead].

10.8 Patient Care TC (PC TC)

The work of the Patient Care TC is important as it develops models of clinical structures which are very relevant to Australian needs and are applicable across a range of messages and document types. These models are expected to become

increasingly important, irrespective of the particular EHR, document and communication modalities implemented in Australia.

The following matters primarily within the domain of the PC TC were noted by Australian delegates attending related sessions.

1. Overall progress. Parts of the Care Provision model have gone to DSTU ballot but the following five aspects are still being developed or tidied up: -
 - Representation of Problem/Problem List
 - Care planning
 - Assessment scales
 - Population data and queries (proposed new project) , and
 - Consistency of vocabulary.

There is a web site to capture comments on DSTU in the HL7 site. These will be reviewed in September. This site will become available any day now.

2. Allergy Model. This work is now very comprehensive, advanced and is nearing completion. It has been checked with Pharmacy TC and Patient Safety SIG and DSTU ballot is awaiting publication after minor fixes and improvements following committee comments. From a technical viewpoint, it still has some shortcomings in relation to null type information (no known allergies) and date last reviewed which will need further improvement.
3. Care Planning. Further development and refinement includes review against CEN model with view to harmonisation. Current work includes binding to concerns, linkage of Order Sets, and reviewing against Care Provision guidance documents for: Problem, Care Planning, Order List, Work List, and Allergy List.
4. Health condition. *Health Condition Update* is being done by HL7 Canada for inclusion in the 2008 v3 Ballot. The *Health Condition List* project is expected to be extensive and involve other groups (as happened for allergies).
5. History and Physical. This is a new work item coming via the Emergency Physicians group.

PC TC works closely with specialist clinical domains, particularly through the Paediatric, Cardiology, and Public Health/Emergency Response (PHER) SIGs and, in future, is expecting to get further new work items referred from the Clinical Interoperability Council [see section 10.18 below].

The v2 Referral and Collaborative Care message developed by the Standards Australia IT 14/6/6 Working Group is being progressed into HL7v2 through the Community Based Collaborative Care SIG [at section 10.1 above], which reports through PC TC.

Following a presentation to a joint meeting of CBCC SIG, Patient Care TC and PHER, PC TC will be taking on responsibility for balloting the functional model for HSD (Health Services Directory) which has been influenced by Australian requirements for a health care, community services and provider directory, in which Max Walker of DHSV has been involved as a CBCC co-chair.

10.9 Public Health & Emergency Response (PHER)

The PHER SIG comes under the Patient Care TC and holds many sessions jointly with other groups. The following are among the matters noted by attendees at PHER sessions.

Process for managing development of Domain Analysis Models (DAMs)

1. As HL7 looks to new tooling for v3 development, the processes for DAM development need to be both effective and easy to use while also being rigorous and delivering accurate, consistent models.
2. PHER is presently carrying out a domain analysis to produce a DAM and is concerned to ensure that the resulting outputs have the rigour and consensus needed to inform subsequent use for development of standard RIM artefacts, v3 messages and CCDs/CDA documents. In this process it has raised the following questions:
 - Where should the ultimate responsibility for DAMs reside in HL7? - SIG, TC, Steering Division, ARB, TSC or PMO
 - How, and by whom, should they be balloted to ensure their integrity?
 - Can/should they be balloted as informative?
 - If PC TC is ultimately responsible for submitting PHER DAMs to the TSC for approval, should the DAMs be managed and reside in the TC?

Vital Statistics Domain Analysis Model (DAM)

3. PHER was involved in a joint session with EHR TC and PC TC at which work on the domain analysis for vital statistics was being actively debated. This DAM will help inform stakeholders whether messages will need to be developed or whether CDA can be used.

The major point of the modelling work will be to capture and standardize Vital Record (VR) data collection requirements across both State and Federal agencies with the ultimate aim of establishing functional requirements and data specifications for capturing VR data from the point of care. Part of the job is to help determine where and what types of EHR systems exist in each State so that the information that they hold can be effectively leveraged.

[Note – more information on the EHR-S Vital Records Functional Profile project and associated message development is reported at section 10.4.5 above]

10.10 Publishing Committee

The main focus of the Publishing Committee is on the logistics of getting ballot material ready for publication and the systems and procedures used to achieve these ends – it is a Committee of the Board to assist it in fulfilling HL7 functions. The following are some of the matters related from Australian involvement in the work of this Committee.

Appointment of Dick Harding as Co-chair.

1. Subsequent to the San Antonio Meeting, the Board appointed Dick Harding as a co-chair of the Publishing Committee. His main interest in serving in this role is to improve processes and procedures and facilitate changes in publishing formats, tools and content that make publishing activities easier and more effective for work groups and HL7 to use.

Ballot publication checklist.

2. To raise the standard of published V3 material and to assist balloters, the Publishing Committee is also creating a checklist of issues that publishing facilitators should compare with their ballot material, before submitting it for publication. It is likely that many of the points on this checklist will be able to be checked by program and so lessen the load on the domain content creators and Publishing Facilitators.

V2.x Publishing Sub-Committee

3. Klaus Veil chaired a meeting of this group, which reviewed the less from the publication of V2.6 and planned the preparation for the first ballot of V2.7⁷.

One of the delaying factors getting V2.6 onto CD had been a gap in version control which necessitated a careful re-check of the upgrades from V2.5.

10.11 Patient Administration TC

The committee reviewed the V2.7 enhancements in chapter 3 of the HL7 v2 standard.

Heather Grain and Klaus Veil provided an update on the ISO Work Items on "Person and Provider Identification" to the committee. Examples of the mapping work in progress were given and a further update has been scheduled for the May 2008 WG meeting in Phoenix, Arizona.

10.12 Security TC

Chris Lynton-Moll attended a session of the Security TC held Q1, Thursday, 17 Jan which addressed the following matters:

Security management cookbook

1. The Security TC is undertaking a project to produce an HL7 security risk management process (or security management cookbook) that will set out a unified method and process for identifying, categorising and managing security risks using a standard, widely accepted risk management framework.

The project was approved in September, 2007 and the project proposal/plan has been prepared for approval in accordance with HL7 process.

⁷ Note that HL7 CEO Charles Jaffe publicly stated during his attendance at MedInfo in 2007 that HL7 will produce V2.8.

The output will be guide and training manual on which instruction will be offered as a tutorial at subsequent WG meetings. The guide will be referenced in the HDF and an executive summary included.

In discussing the plan, the following were suggested:

- Undertaking a pilot test of the proposed risk analysis methodology on people who are not familiar with security.
- Including means to monitor/gauge conformance as part of the risk analysis process.
- Including intent to make risk analysis a part of the HL7 standards development processes, but HDF content would be a high-level summary and reference to the detailed risk analysis process document.
- Including frequency of education in the overall plan.

Identity management terminology

2. The aim of this project (carried forward from May 2007) is to identify authoritative sources of identity management terminology whose focus includes identity credential management (e.g. terms like authentication, credentials, enrolment service). The purpose is to select standards developed specifically for this domain. The working group will not attempt to harmonize terms across SDO environments but will refer to the authoritative standards, including

NIST SP800-63
OASIS XACML

NIST FIPS PUB 201-1
ISO SC27 61191

NIST SP 800-103

10.13 Services Oriented Architecture (SOA) SIG and Healthcare Services Specification Project (HSSP)

One of the objectives of Australian attendance at HL7 Working Group Meetings is to track and report on HL7.org's approach to Service Oriented Architecture (SOA).

Various members of the Australian delegation (including Rowed, Dixon Hughes, Hanley, Walker and McCauley) attended sessions hosted by SOA SIG during the San Antonio Meeting with the following being among the matters addressed.

10.13.1 General

Focus of the SOA SIG and Australian interest

From its very foundation, the SOA SIG was primarily interested in developing and integrating the consensus procedures and software engineering processes needed to deliver an effective suite of Web Services components to the health industry.

Integral to this was the establishment and operation of the Health Services Specification Project (HSSP) as a joint HL7/OMG group to achieve the (sometimes difficult) task of using HL7 processes to define standardized service requirements and OMG's RFT process to have software components delivered by the ICT industry to meet these requirements. The vision was bold and appears to be yielding major

benefits for which recognition and many thanks should go to Ken Rubin (of EDS/DVA) who conceived and continues to drive this essential alliance and to provide advice and assistance to all who are interested (including Australian interests).

With the principles having been defined, documented and piloted with the Resource Location and Update Service (RLUS) specification, the SOA SIG's role has moved away from deep involvement in each individual SOA specification project. These are now in the hands of the relevant HL7 Technical Committees with the specific domain expertise needed to complete them.

The more general SOA SIG sessions therefore tend to be progress reviews of SOA projects being managed by other TCs, with SAO SIG members providing expert advice and guidance where appropriate. The more specialised solo sessions of the SIG are meetings of experienced SOA specialists and experts who manage the HL7 SOA development processes, tooling and architecture in collaboration with the TSC and ARB. While Australia is interested in, and is potentially a major beneficiary of this more detailed work, our opportunity to contribute is limited, given that we do not yet have much SOA capability or implementation experience within the health sector. Given that NEHTA has recommended Web Services technology, closer engagement of the relevant NEHTA experts at the detailed level with international work in the health sector would be of national benefit (it is understood that this may be occurring – but in private consultation outside the standards development paradigm).

In relation to work in its formative stages, it is considered that the Decision Support Service (DSS) and Common Terminology Services specifications are very important to Australian clinical care. These are being progressed by the Clinical Decision Support and Vocabulary TCs respectively.

Ken Rubin is keen to encourage liaison with Australia on SOA and established a link on the HSSP website to IT-014 during the San Antonio meeting. For more information on HSSP see http://hsspforum.org/bb_forum/.

More detailed information on work in progress is also updated on the HSSP wiki at: <http://hssp.wikispaces.com>.

Major SOA in Health Conference – April 2008

This conference/workshop is planned for 15-17 April 2008 in Chicago to present the work of HL7 and OMG through the HSSP and those looking to apply service oriented architectures (SOA) in health care.

The conference is being organised by Ken Rubin, SOA SIG and HSSP co-chair, who invited Andy Bond of NEHTA to present at the conference. Further details of the conference are provided in section 14 below or may be obtained from the conference website at:

<http://www.omg.org/news/meetings/HC-WS/>

10.13.2 SOA architecture and processes

The following are some of the matters in relation to SOA architecture, processes and organisation noted at the SOA SIG sessions attended by Australian delegates.

- HSSP is still a joint project of OMG and HL7 and even though it makes decisions, produces documents and needs to acquire goods and services to progress its work, it is still not a legal entity. It was noted that this may change.
- How the SOA fits into the HL7 Dynamic Model. This has arisen as an issue from the work on the EIS and PASS specifications and includes proposals to use WS CDL (Choreography Description Language) as means of expressing dynamic model concepts as they are evolving for SOA.
- These issues are being taken up with Modelling and Methodology group at HL7 but it is not clear how this fits into the established HL7 development framework (or alternative ways of approaching some of the needs in services-oriented environments – as perceived by W3C, BEPL, ISO and/or ebXML)
- More engagement of the SOA SIG with the EHR TC is considered important and should input to some of the work on further development of the PHR-S and EHR-S functional model and associated specialised profiles.
- Resolving Australian concerns with overlap of IHE work and HSSP work on harmonization and integration of service profiles. Ultimately the same information needs to be shared in a seamless fashion – whether in messages or documents or via services; however, the different groups tend to assume their own models of information content and workflow.

Dr Vince McCauley reported further on this issue and considered that the initial perception of and overlap between PIX/PDQ and IHE with HSSP had now been largely resolved

- Clarifying ‘Semantic Signifier’ approach to holding / stub point for various reference models which has been criticized by Australian EHR groups.
- In the session on Q2 Tuesday, Charlie Mead, chair of the HL7 ARB, discussed some of the issues surrounding the move to SOA in health noting the importance of HSSP relating to a wider group of organisations and that, from an architecture perspective, implementations of Web Services in Europe may be more advanced than those in USA. He also mentioned some particular approaches being considered for of engineering web services:
 - CRFQ, a way of specifying services
 - evolving SFM into more of a requirements analysis document to allow direct implementation by linking to an associated platform independent model (PIM).

10.13.3 Entity identification service (EIS)

Issues noted that need to be dealt at the EIS session included:

1. Operation names (eg do, create, update, find)
2. Possible re-invention of an existing OMG patient identifier specification with implications of reworking (a) existing definitions, and (b) spreadsheet mapping
3. XEIS implications (is this an issue?)

It was noted that the SOA group use the term "traits" for the identity data (the specification defines a set of base traits ie patient demographics, encounter). But the focus of work is around an identification service (focussed on "interfaces"), not a good set of traits, according to the group. There was a lot of discussion about traits, the extent of what these could cover, and whether the concept needed to be revisited at this time.

The group could benefit with input from the ISO identification standard for their future work on traits.

Allan Honey, the co-chair noted the variation in national use cases for EIS, and that the work done in SOA group needs to be able to handle this.

The group has identified a potential process failure in that agreements aren't always documented. They are therefore concerned about going over old ground to confirm agreements. Lots of discussion occurred around going back to the original submission to the OMG process, and resolving differences with the current version (which is not the final version).

Discussion also occurred on how the current version of the EIS functional spec will take input from the OMG process, leading to the technical specification and that an implementation guide may be done for the EIS.

The following way forward was identified to reconcile potential differences:

- 1.1 Compare initial submission and current version (v 6) and
 - (a) accept changes where there is no issue
 - (b) reject and add to issues list where this is conflict
- 1.2 Post spreadsheet which analyses PIDs compatibility
- 1.3 Read PIDS spec and IHE profiles
2. Develop work issues list
3. New issues / clarifications "what ifs" of behaving

10.13.4 Privacy access and security service (PASS)

Matters discussed in relation to the development of this specification included the following.

1. This is potentially a large project with the number of services to be defined likely to exceed 20 – and noting that the project encompasses Security Services, Privacy Services, Access Services integration with Identity Services. Most of the functions have been defined, but the interfaces have not.

This is a very new project with work only starting in December 2007. There is no definition yet of the services needed to be provided by the SOA environment.

The PASS project group are currently defining the scope and identifying problems for broader resolution (information is currently on Wiki). In overview:

- Privacy services consist of identification, consent services, disclosure services and audit privacy
 - Access services consist of authorisation, trust services and target dereferencing
 - Security services consist of encryption, digital signatures, audit-security, notification
 - Auditing is also in scope.
2. PASS is driven by requirements for privacy which implies access control which uses access services and requires security which uses security services (from PASS Concept Diagram 0.1).
 3. Access control – use case is sending a query from A (requesting entity) to B (access coordination) to handle access control using credentials (to identify person) which can be communicated in other services eg patient resolution, resource resolution and trust resolution.

Access control service needs a policy engine with decision points and polices and an access enforcement point

Max Walker pointed out and the group agreed that a policy engine is needed for every service in the PASS diagram.
 4. An issue was raised about getting subject matter expertise from security TC and involving them in SOA PASS. Discussion was then held about successfully getting the business area to sponsor and ballot the SOA project to get better domain knowledge and involvement in the ballot.

10.13.5 Human services directory project (HSD) and provider identification

The joint HL7/OMG HSSP project coordinating the specification of web services for use in health care has resolved to re-orient its "Services and Provider Directory" project to address the wider needs for a "Human Services Directory" and is re-naming its SPD project to reflect this shift in emphasis.

Max Walker (DHS Victoria and Co-chair of CBCC) has asked CBCC for use cases and its parent, the Patient Care TC, to ballot the HSD services project for approval with the revised scope. The project needs international use cases.

CBCC SIG and PC TC, which are the expert committees that are progressing the work, are examining the existing DHS Victoria HSD with a view to developing use cases that address a wider range of human-services needs for inclusion in the HSSP specifications. Max demonstrated the DHHS Vic Human Services Directory which has been available since 20004 (describes over 35,000 services).

Matters discussed in relation to the development of this specification included the following.

1. Max noted problems with resourcing this project and requested more help.

2. Ron Parker, Canada Health Infoway's Chief Architect stated that Infoway sees this as a key priority under the aegis of patient access to quality care, and has a resource that can be contributed to the project immediately. Canada needs to develop a service directory and do bookings and scheduling. Currently, Canada has provider registries for credentialing and identification, and need to set up services directories. Max noted that Australia will need to set up services directories after it sets up identification services.
3. Galen Mulrooney (US Department of Veterans Affairs) also agreed to help with the HSD project.
4. As a result of Max's presentation, there will be fortnightly conference calls for the SOA services directory project with Canada Infoway and Max, and other interested people from the United States.

[As a first time HL7 attendee with a professional background in standards development, Elizabeth Hanley observed that the HL7 between meeting process involves fortnightly calls to develop actual content (or perform offline ballot reconciliation) by experts and for delegating development activities around the group. This process is a key feature of HL7 standards development work enabling far more ground to be covered between face-to-face meetings. The disadvantage for Australia is that many of the teleconferences take place at family-unfriendly hours.]

10.13.6 Common terminology service (CTS)

The Vocabulary SIG is the lead group for this project and reports back to SOA SIG for technical input and advice.

Matters discussed in relation to the development of this specification included the following.

1. Members present reported that they had spent the last HL7 meeting working through actors – terminology user, provider, service, which helped them develop scenarios. Four main categories of scenarios have been identified
 - administrative service (loading to different formats)
 - search query operations for a terminology
 - associations service services – to create associations inter / intra coding systems, ie mapping
 - authoring and curation / maintenance service (some debate about whether to use the label "curation" or "maintenance")
2. During this work, the following issues have arisen:
 - Mapping uses cases dependant on ownership of the coding system
 - Creating different profiles for access and the need to work out access control (will discuss this with the PASS SOA project lead)
3. Next steps

- (a) Continuing with weekly teleconferences to define functionality and to determine to what level attributes should be defined in the SFM.
 - (b) Aim to pencil out the meta-model and to look at each scenario and develop the functional model, starting with a minimal model and then fleshing it out in more detail
4. Contact with IHTSDO. During discussion there was some uncertainty as to what IHTSDO was planning in various areas and how the CTS group could ensure that the final specifications were compatible with IHTSDO's activities.

To help HL7 resolve this problem Richard Dixon Hughes made email contact with Karen Gibson of NEHTA who represents Australia on the IHTSDO Board and Chairs the Technical Committee. In her response, she indicated that she would be happy to facilitate exchange of relevant information. Richard passed Karen's positive response on to a range of recipients for follow-up (including John Quinn as the official HL7 contact point for liaison with other SDOs). It appears that actioning this contact fell between the HSSP (Ken Rubin – who was heading off on leave) and CTS Group in the Vocabulary TC (who probably should have pursued it but did not appreciate the significance of the response). Richard Dixon Hughes will follow up with Heather Grain as Co-chair of Vocab TC.

10.14 Structured Documents TC (SD TC) and CDA (Clinical Document Architecture)

The SD TC had a very full schedule with a lot of work on detailed ballot reconciliation and modelling issues flowing from practical implementations of CDA R2, particularly through the increasing adoption of the Clinical Care Document (CCD) specification and use of both CDA and CCD in IHE profiles and CCHIT criteria. The planned agenda coverage was:

- HAI Ballot reconciliation (Mon Q4),
- Template tooling (Mon Q3)
- UML demo of CCD constraints (Mon Q3)
- CDA4CDT (CDA for Clinical Drug Trials) (Tues Q3)
To address publication schedule, confirm commitment to next ballot cycle for diagnostic imaging reports in conjunction with II SIG.
- QRDA (Quality Reporting Document Architecture) project
- scope review (Mon Q2)
- Schematron validation (Mon Q2)
- CDA R3 planning (Mon Q2)
- Certification exam passing requirements (Mon Q2)
- Medical Records and V2
- IHE use of CDA
- EHR Technical Salon – hosted by EHR TC (Wed Q1)
- Joint with Devices SIG (Thu Q1)

- Clinical Statement pattern – joint with joint with OO, patient care- Thur Q3/Q4clinical statement model

Various members of the Australian delegation attended IC TC sessions at different times during the San Antonio Meeting with the following being among the matters addressed.

1. A CDA specification for an Operation Note is to be developed for ballot next cycle.
2. HITSP now have an example of a constrained CCD (a conformance profile) – which needs to be reviewed and understood in further development of CDA.
3. CDA exams: 100% of the 50 persons who sat the CDA exam have passed yet the SD TC considered that this was not acceptable. Exam pass rate increased from 50 out of 70 questions to 59/70 which would have yielded a failure rate of 16% on previous performance.

Quality reporting document architecture (QRDA)

4. Originally requested by Paediatrics to record data for quality measures, the QRDA project potentially has much wider application, especially given the recent focus on clinical care quality measures sweeping across the US health care system.

The project seeks to find a mechanism to specify inclusion and exclusion criteria for document validity for import into the EHR and export from the EHR, which may leverage VMR concepts and possible be done using Clinical Decision Support. Document specification is intended to provide patient and population quality summary measures.

It was agreed that the initial ballot will be US Realm specific with later possible extension to International if resources are made available. However the project scope is not US Realm specific.

CDA R3

5. SD TC is canvassing proposals for CDA release 3. There was much discussion of mechanisms for doing this and the implications for existing work. A separate Wiki was suggested. There are already a lot of debates as to whether to make “essential” changes (mainly for US programs or IHE) now by amending R2 in a piecemeal fashion or parking them for inclusion in R3. In either case, backwards compatibility is looming as an issue.

Joint meeting with Templates

6. Potential implementation inconsistencies between the CDA specification (and its usual interpretation) and the Template (or Implementation Guide) specifications were explored, including:
 - Populating the Template ID in an instance of a CD should be an assertion that the instance complies with the constraints in the identified Template document (e.g. an implementation guide). This is not necessarily computable.

- Templates also define OIDs (HL7) for value sets and the value set members, whereas CDA instance contains the SNOMED code not the value set OID.

[In relation to this Vince McCauley noted that “an incomplete template” implies a constraint with no exceptions for part of a CDA only. This should be compared with section level templates etc. Template identifier can be asserted at the document, section or clinical statement level. There appears to be no difference between a profile and a template ID other than that a profile ID is a root level template but is not valid at sections etc.]

Tooling demonstration

7. As part of its approach to HL7 document constraints/templates, the US DVA has engaged contractors to develop a tool to integrate standardized UML representations and HL7 specifications. The tool has the ability to import a model in Model Interchange format (MIF) and then add constraints with documentation and then automatically produce a hyperlinked PDF with model diagram and documentation to become an implementation guide.

Joint meeting with Image Integration (II)

8. There will be a joint ballot of II TC and SD TC next cycle for acceptance of the Diagnostic Imaging report specification in CDA.
9. There was a detailed discussion about how to implement DICOM context changes (e.g. for previous film comparison) by blocking context in the choice box for the observation on the entry relationship class or the reference class. The context in the CDA header must apply to the whole document.

10.15 Templates SIG

With the Templates DSTU on its way to publication, and major potential users of template/constraint methodologies moving independently toward tooling-based approaches for template-style functionality, there was serious discussion at the San Antonio Meeting as to whether the Templates SIG needs to exist as an independent group, or whether its activities might be adequately realised by some combination of the ITS (Implementable Technology Specifications) SIG, InM (its original parent), the Modelling and Methodologies (MnM) TC, Implementation and Conformance TC (responsible for Implementation Guides), Structured Documents and the technical oversight functions performed by the ARB and TSC.

The practical ability to define interoperable message and document content more generally via the existing HL7 templates paradigm continues to be elusive and shows little prospect of being realised directly – at least in a standard way between different implementations in the US.

Strategic emphasis appears to be shifting toward better modelling and tooling to capture requirements and translate them directly into container structures, rather than using templates to constrain generalised representations.

Nevertheless, designated joint WG sessions co-hosted by Templates provided a good strategic overview of issues related to clinical modelling and representation and constraint technologies (archetypes/templates) relevant to implementation of interoperability for shared EHR and PHR environments.

The US VHA (represented on Templates SIG by co-chair Galen Mulrooney) has developed its own approach that enables two-way mapping between UML 2.0 models and an XML MIF.

UK NHS CfH (represented on Templates SIG by co-chair Ian Townend) is also working toward its own version of the HL7 Templates specification, to be supported by tooling that accelerates the production of HL7 message and document artefacts, with the time to production having been greatly reduced.

Role Clarification Motion

At the joint meeting of Templates, DCM and TermInfo in Q2 on Friday, 18 January it is understood that a formal motion was passed along the following lines [NB exact wording not available for this report]:

To bring the work on DCM to the TSC via the Domain Expert Steering Division with a view to sorting out responsibilities with:

- *Templates SIG to have responsibility for technical representation of clinical content including requirements for supporting metadata*
- *TermInfo to have responsibility for the and appropriate use of clinical information models and the principles for how they interact with terminology*
- *Patient Care TC, Structured Documents TC, (CDA), O&O TC and joint Clinical Statement group be responsible for formal definition and support for the actual use of clinical statements in messages (v2 and v3) and CDA*
- *The DCM Collaborative continue as a forum to develop, share and maintain actual instances of clinical content and bindings etc. granular, including assessment scales*
- *The PV group enlarging its scope from assessment scales to DCM at large, and*
- *The CIC being responsible for identifying clinical content and managing its progression through HDF.*

Further to this, the proposed work of DCM is to be put into a project proposal channelled through Patient Care TC to the Domain Expert Steering Division, noting that Patient Care are already preparing a proposal on assessment scales; however, some (Kevin Coonan) want a much broader and larger scale project on this. The DCM group will be guided by PC TC in this matter and will discuss on their on-going conference calls.

10.16 V2 issues – General

The following are some of the matters noted from the San Antonio meetings in relation to the development and future of v2.x messaging standards.

1. HL7v2.x – future role and direction. The leadership of HL7 now appears to accept an ongoing role for HL7 v2.x as part of the longer-term strategic 'Roadmap' - with v2.8 now solidly on the drawing board.
2. HL7v2.x Implementation Guidance There is also recognition that better v2.x implementation guidance is needed to provide consistency and address inter-version and backward compatibility issues. Australia needs to continue working to ensure that this is picked up and driven through by the IC TC and is also reflected in HL7 education and training programs.
3. Need for v2 profiles from IC TC to harmonise with v2.x standards. Klaus Veil identified, and subsequently stepped in to resolve, potential problems where the IC TC was creating a compliance profile infrastructure that was modifying and re-stating, rather than building on the existing HL7 V2.x standards. [Further reported under IC TC at section 10.5 above].

10.17 V3 Dynamic Model

Richard Harding has been following and participating in work on the V3 dynamic model. He reported that, once again, there was a lot of expectation that the V3 dynamic model would be developed more formally.

At this meeting, some agreement was reached that we should try to develop a common framework for implementation guides and to base the V3 Dynamic Model on the artefacts needed to populate this implementation guide framework. (see notes on Implementation Guides under IC TC at section 10.5 above)

More ambitious expectations include mapping new dynamic model artefacts to functions in the EHR-S.

To date, this is the most positive and credible initiative towards developing an agreed HL7 V3 dynamic model.

10.18 Vocabulary TC and TermInfo

10.18.1 Vocabulary TC

The Vocab TC had a very full schedule with an agenda that included:

- Update presentation on new vocabulary tooling by Woody Beeler (in joint meeting of Vocabulary Facilitators and MnM - Sun Q4)
- Vocabulary Implementation (Mon Q1)
 - An update from the NLM on all their current activities
 - Development of terminology implementation document to inform Implementation Guides - results of requirements survey
- Vocabulary Implementation Ask the experts (Mon Q2)
- New Terminology Binding Standard (Mon Q3/Q4)
 - conceptual frameworks and understanding with Russ Hamm

- US Realm session: Marital status; Lab Order codes (Tue Q1)
- Value sets: Process for adoption of representative and universal binding (development of proposal) (Tue Q2)
Joint with MnM for resolution(Wed Q1)
- Versioning of value sets (Tue Q2)
Joint with MnM (Wed Q1)
- Approval of names for V3 binding strategies (model based and realm based) (Tue Q2)
- CTS 2 with Russ Hamm (Tue Q3/Q4)
Review and comment on draft; Progress new functionality
- Implementation Case Studies (Wed Q2/Q3)
 - Canada Health Infoway Laboratory Terminology
 - Terminology services at Centers for Disease Control (CDC)
- Joint meeting with INM to discuss V3 issues and changes in R2 coded data types (Wed Q4)
- Joint meeting with Pharmacy on AFMS harmonization (Thu Q1)
- Marital status concepts - International Use (Bob Davis) (Thu Q2)
- v2 Coding System and Vocabulary identifiers (Thu Q3)
Extensions to V2.6 and V2.7 coded data types with InM.
- Forward work program for Vocab TC and TermInfo (Thu Q2/Q4)

The HL7 TermInfo Group which is related to Vocab TC also held meetings on Q1 and Q2 on Friday, 18 Jan, with the second of these being a joint meeting with the DCM group and Templates SIG at which a resolution on the respective responsibilities for clinical modelling and content was passed (see section 10.15 on Templates for details).

Heather Grain was the principal member of the Australian delegation covering the activities of the Vocab TC sessions at different times during the San Antonio Meeting. Other members also participated in some of the sessions and joint sessions with the following being among the matters addressed.

1. On Q2 Thursday, Heather Grain (Australia) and Beverly Knight (Canada Health Infoway) were elected as co-chairs of the Vocab TC for 2 years in a contested ballot. Ning Zhuo was the unsuccessful candidate.

There is also a vacancy for a Vocabulary facilitator but no candidate to fulfil the role at present; however, Sundak Ganesan may be interested in working as a vocabulary facilitator for Orders and Observations or for Emergency Care.

2. Marc Koehn of Gordon Point Informatics gave a presentation on Canada Health Infoway's pCLMN (Pan Canadian Laboratory Messaging and Nomenclature) on Wednesday Q2.

The relevant point for Australia is the potential benefits of having a uniform, well designed, universal national approach.

3. On Wednesday Q3, Sundak Ganesan presented on CDC Terminology Services and Jennifer Pienbrooke presented on the CDC Biosense Terminology.

In response to a question it was noted that the Environmental Protection Agency (EPA) maintain the EPA SRS (Substance Registry System) component of the terminology infrastructure.

4. Jane Curry is doing a user requirements document for tools in HL7. This includes a review of existing tools and their interdependence, strengths, weaknesses and additional user requirements for tools to support HL7 work. Jane will include the issues relative to vocabulary tools and web capacity.
5. The Glossary and the Style Guide need to be considered for update. These are part of the foundation documents required for V3 in the next ballot cycle.
6. Object identifier life cycle. Discussion will continue on the regular conference call.

ValueSet versioning

7. ValueSet versioning in relation to static and dynamic binding were identified as hot topics with the following being resolved:
 - (a) All ValueSets can be versioned. A ValueSet is not dynamic or static, the binding of the valueset to a model element is static or dynamic; and
 - (b) The version number in the binding statement refers to both the version of the value set definition and the version of the code system content.

Inclusion of value set version in R2 of the CD (coded data) data type

8. Two use cases were identified and discussed in relation to the inclusion of value set version in the R2 coded data types
 - (a) To know what value set version a new item in original text should be added. This applies in the situation where there was no code or code system.
 - (b) In the case of a quickly evolving value set as in a SARS outbreak.

In this instance there are multiple, fast changes to the value set to meet demand and emerging knowledge. There is a need to be able to identify at any given point in time the values that were available to an application.

This is essential to support know for later data analysis to accurately report the true frequency of use of each value, i.e. to be able to identify that in the first week there were 3 options available and in week 2 there were 5 and in week 3 6 options.

A change to the R2 specification was required to support the use case in (b), which requires the Vocabulary TC to:

- (i) Give notice to INM of Vocab TC's intent to re-discuss this issue
- (ii) Schedule this issue for voting on Vocab TC conference call, and

- (iii) Modify the data types to reflect the requirement that both the value set and value set version should be optional elements in consequence of this change.

It was resolved that the Vocab TC would:

“Review the CD data type and make a new definition for value set and value set version that satisfies the existing use case and covers the case when the value set is rapidly changing.”

Implementation of Terminology - Guidelines

- 9. The Vocab TC resolved to create a Terminology Implementation document to define the principles and function of terminology as it should be used by other committees in HL7 implementation guides

Universal and representative bindings proposed at harmonization

- 10. The international Affiliates Council (IAC) will now be responsible for approving Universal Bindings and Representative Bindings proposed at harmonization. The IAC is responsible for determining a timely process for approving these bindings.
- 11. This raised a question, “If there is an existing universal binding to a Value Set what is the process to make changes to that Value Set?”. The situation was clarified as follows:
 - If a change that is made to a value set is consistent with the domain definition then it is a new version of a value set.
 - If it is not consistent, then it is a new value set.

Implications of CTS2/HSSP specification project

- 12. The CTS2 (Common Terminology Service – Release 2) activity is part of the HSSP (Healthcare Service Specification Project) that is a joint activity between HL7 and OMG. The current draft of the document was reviewed and additions and corrections were reflected directly in the draft.

There was also discussion of the spectrum of items in the terminology server noting that the range includes:

- 30,000 drug concepts
- Over 1 million medical device, changing daily
- States of the union (not to mention internationally)
- People

The question was raised as to whether CTS is able to handle the complete scope of items?

A presentation by Senthil Nacumathu (3M and University of Utah) raised the question of how different terminology system models would be accommodated in the CTS specification.

Better names for Design Time and Run Time binding

13. The fundamental difference between the two kinds of binding is whether the attribute in a model is bound directly to the value set, or if the attribute is bound to a concept domain and then outside of the model the domain is bound to the value set.. After consideration of around two dozen candidate terms, the Vocab TC resolved that:
- Design Time Binding be replaced by the term Model Constrained Binding; and
 - Run Time Binding be replaced by the term Situation Constrained Binding.

OID for ISO 3166 (Country Codes)

14. HL7 would prefer that the ISO 3166 code set be identified by a universal (ISO or ITU) OID, rather than each person specifying or implementing the codes using their own locally derived OID. ISO was approached for advice on an appropriate universal OID for this purpose. Advice was received from Gerard Lang, who is responsible for ISO country codes at ISO who indicated that ITU-T had registered an OID for the 3 character country codes, and someone has separately registered under the CCITT tree an OID for the numeric code set of ISO 3166-1. The Vocab TC resolved:

"If by the May Working Group Meeting ISO has not assigned an OID for 3166 Code System, then we (the HL7 Vocabulary TC) will assign an OID under the HL7 branch for the ISO 3166 country code system. There would be a single OID for all three parts of 3166 (3166-1, 3166-2, 3166-3) and any synonym sets (2 letter codes, 3 letter codes, numeric codes) that exist for the sub parts of the standard. The value set machinery would be used to bind a particular sub set and/or synonym set to a coded attribute."

Action item: Representatives from Australia, Canada and Germany are to request that their national standards bodies request resolution of this issue from ISO. Ted Klein will prepare a statement that describes exactly the resolution required for the purposes of HL7.

Table 396

15. There is a desire to coordinate entries in table 396 with entries in the OID registry. However, Version 2.x does not have a value set mechanism so there is a discrepancy between what needs to be represented in table 396 to meet the requirements of version 2 as opposed to those of Version 3. Version 2 requires OIDs for value sets as well and code systems and Version 3 only requires OIDs. This item was deferred for lack of time.

International use of marital status codes

16. After Bob Davis made a presentation and this issue was discussed, the following decisions were reached:
- (a) Add a category for Registered Partnership.

- (b) Add a new category of Living Together (which addresses the US concept of "Domestic Partnership").
 - (c) Amend the definition for Never Married to, "The person's status is that a person has never been married or had a marriage annulled."
17. It was also noted that:
- The marital status code list should include all of the valid or definable states for marital states that exist anywhere in the world. This allows individual countries to make sub value sets as appropriate for their jurisdiction or particular use case and retain consistency across the set.
 - The definitions are the most important thing, and the labels that are attached cause some confusion because a term like "Domestic Partner" may have different meanings in different jurisdictions.
 - CDC will become the permanent home for this code system, and will maintain the content. [How does this sit with Australia?]
 - Living arrangement will be the next topic taken up for harmonization.

Harmonization questions from Patient Administration

18. The Patient Administration requirement to harmonize vocabulary between V2 and V3 for several value sets has raised the following questions: .
- (a) Marital status: what value goes into table 396 for Marital Status or will it be an imported table?
 - (b) Administrative sex table: what will the new table number will be?
 - (c) Race and ethnicity – currently have an externally maintained table at CDC (for the US).
PA TC has values that it would like to use for this attribute.

Binding Document Development

19. Documents with related material aimed at different audiences are being developed:

Document A: is for use within HL7 to cover the technical components supporting implementation.

Document B: A new document is intended for ballot within HL7 but for use outside and inside HL7 that describes the framework of terminology binding to information models. It will compare 11179, possibly OWL, *openEHR* and a variety of information models. The purpose is to stand as the conceptual framework for sharing of binding and value sets consistently in implementation guides irrespective of setting.

It is intended that drafts will be available for the May meeting and volunteers were called on to assist in the drafting.

Terminology Implementation Document

20. A terminology implementation document with a similar audience to the non HL7 specific binding document is also to be developed to explain the principles of terminology implementation and provide a reference to more detailed documentation. It is intended that drafts will be available for the May meeting.

Clean up of Vocabulary content, tooling and metadata

21. The following matters and complexities are hindering this clean up and conversion of the vocabulary database to lexgrid.
 - Vocabulary is no longer being in a relational database
 - Design models are only held in an xml data store
 - The technology is MIF, which is a set of schemas in xml to implement the model format design
 - The vocabulary MIF was only completed a few months ago and there are no tools that access vocabulary in the MIF model and can link it to the model designs that are in the xml technology MIF
 - Exports out of the relationship database are imported into xml and handcrafted to pull them together and generate the ballot.
 - Tools are planned to assist committee activities, but there are no tools to support publishing
 - The ballot process is currently hugely dependant upon manual work undertaken by Russ Hamm and Woody Beeler.

The effort and complexity of the task is difficult to maintain with dependence on volunteers with limited time availability

10.18.2 TermInfo

The TermInfo document is now quite stable having passed ballot at the September 2007 Working Group Meeting.

Current TermInfo issues (Vocab TC)

There was a discussion in Vocab TC to identify and plan major issues that need to be addressed within by the TermInfo group, including consideration of the following.

1. Problems with postcoordinational expressions have arisen in datatypes R2. There are different approaches in different systems and information models leading to a need to describe how postcoordination can be handled in different information models.
2. Microbiology and Laboratory would appreciate discussions to support implementation guides for expressions using LOINC and SNOMED together. Eg: organism and associated result requirement where detail is required in one place. This item was brought forward by Beverly Knight and represents real world issues in implementation in Canada.

3. Pathology – need to publish a non coded text modifier to a SNOMED code. For example: when reporting cancers there are often text modifiers to a SNOMED code and there is a requirement to be able to represent this appropriately in V3. This item was brought forward by Beverly Knight and represents real world issues in implementation in Canada.
4. US realm project to apply the CHI standards to assessment instruments required by the US government. This involves LOINC questions and answers as well SNOMED. In the MBS people are working with survey questions and there is a need to know the SNOMED relationships to support reasoning. Rita Scichilone brought this item forward for consideration.
5. Germany are developing a discharge letter working with ICD10-GM and there is a requirement to display/bind diagnoses using V3 representation. Guidance on the communication of ICD10 in HL7 V3 has been requested. (Sylvia Thun).

TermInfo Meeting

The TermInfo meeting was planned as two sessions (scheduled for Q1 & Q2 Friday, 18 January) with the second being joint with Detailed Clinical Models (DCM) and Patient Care. The following were the more substantive issues addressed at the meeting.

1. Managing responses to the existing DSTU and preparing for release of an updated normative version continues to be a significant piece of work for the TermInfo group. TermInfo and the Vocab TC have also identified other important terminology/HL7 information model boundary topics that could be examined and addressed, potentially including:
 - Managing LOINC and SNOMED within HL7
 - ICD 10 in HL7 v3, and
 - AOB

Managing LOINC and SNOMED within HL7

2. Attempting to support a number of clinical and laboratory representations using both LOINC and SNOMED CT codes in the same specifications causes major problems in practical implementation of HL7 standards and in interpretation of clinical information. Guidance appears to be needed on which terminology to extend when (1) gaps were identified and (2) both terminologies had released content for common areas of representation.
3. It was noted that the IHTSDO and LOINC were in discussions with regard to optimal co-working arrangements, and any TermInfo work in this area would need to collaborate with and be sensitive to these ongoing discussions.

Consistency of design decisions would only be realistic and scalable once common design models were agreed between the relevant standards development organisations.
4. The group agreed that political/organisational considerations (and clear evidence of support and cooperation by the involved organisations – HL7,

LOINC, IHTSDO) must be a pre-requisite to any work beginning. A such, it was resolved:

"To draft a joint letter to HL7, LOINC and the IHTSDO indicating the group's interest in the development of an appropriate implementation guide, and exploring what steps we would need to take to ensure support of each group to this end."

ICD 10 in HL7 v3

5. DIMDI and the HL7 user group in Germany have developed an approach to the standard communication of ICD-10 coded diagnoses in HL7 v3 messages for a number of clinical, epidemiological and business use cases, noting that a number of alternative design representations are possible to achieve such communication, in particular regarding ways to indicate 'diagnosis types', as well as various ways to communicate dual code assertions (e.g. dagger/asterisk combinations).
6. As with the LOINC/SNOMED discussions above, it was concluded that providing standard implementation guidance on ICD-10 in HL7 v3 would be a very useful move, the initial step should be a joint letter to senior staff at the WHO and HL7 indicating a willingness for the TermInfo group to coordinate the creation of an implementation guide, provided it had the full support of each organisation. It was agreed:

"To draft a joint letter to HL7 and WHO indicating the group's interest in the development of an appropriate implementation guide, and exploring what steps we would need to take to ensure support of each group to this end."

Delineation of roles - DCM, TermInfo, PC TC, CIC, Templates etc

7. See Templates SIG at section 10.15 above for report on this topic as discussed in joint session.

Other matters dealt with in joint session

8. Some of other matters relating to clinical modelling brought up in the joint session (particularly in relation to the Goossen presentation on assessment scales and model transformation) are covered under the report of the DCM meeting in section 12 below.

Planned approach to managing DSTU issues

9. Jane Curry gave a brief presentation on the TermInfo DSTU Project Homebase used to manage feedback. the site can be found at:
<http://hl7projects.hl7.nscee.edu>

With the TermInfo DSTU work at
<http://hl7projects.hl7.nscee.edu/projects/terminfo/>

There is also a section in the latest version of the HL7 Development Framework that describes the recommended change control process at:
http://hl7projects.hl7.nscee.edu/frs/?group_id=44&release_id=247

The proposed approach would be to gather feedback initially by the lighter approach offered at:

<http://www.hl7.org/dstucomments/index.cfm> (as well as to the list)

and then progress more complex topics to Project Homepage.

11. Clinical Interoperability Council (CIC)

11.1 CIC Organisation, Role and Activities

The Clinical Interoperability Council (which first met in May 2007) is a clinical group established by HL7 in an attempt to bridge the gap between HL7's acknowledged technical expertise in clinical informatics and those who practise in various clinical domains. Some key aspects of the CIC's foundation, organisation and role discussed at the San Antonio Meeting included the following.

- The CIC has a non-technical focus and is responsible for providing clinical expertise and defining clinical requirements – such as those needed by HL7's Patient Care TC and other groups.
- It is intended to provide outreach beyond HL7 and the ability to mentor new clinical groups as they come into the organization.
- It was noted that HL7 has gaps in areas where it has not been able to make appropriately informed decisions – clinical data elements, terminology, universal identifiers; and in other areas closely related to clinical process and practice (particularly specialist practice). Much work has been done on models – but where do these fit in? and are clinicians getting sufficient benefit from HL7's modelling and standards development activities?
- As experts in the clinical domain, the CIC will advise on: flow of data in the clinical setting, data element definitions and terminology, clinical information retrieval/presentation clinical trigger events, clinical knowledge (clinical guidelines, disease/condition management protocols, decision support content), and other clinical issues.
- CIC membership has developed significantly since previous meetings. The CIC now has a wiki and three co-chairs - Ed Hammond (HL7), Brian McCourt (Duke Clinical Research Institute) and Crystal Kallem (AHIMA), who was elected at the San Antonio Meeting. Another co-chair will be elected at the May 2008 WG Meeting.
- Domain Analysis Models (DAMs) and master data elements are among the early tasks proposed for the CIC and were discussed at some length at the San Antonio Meeting.

[Nevertheless, many observers still consider it is very much an open proposition whether most clinicians who are primarily engaged in clinical practice are able to contribute effectively through DAM development. Whilst much simpler than RIM-based models, DAMs are still technical abstractions.]

- HL7 is still resolving the CIC's role and activities in the development of DAMs, requirements formulation, application of the HDF methodology, and the definition and maintenance of clinical data elements.
- Meredith Nahm (Duke) introduced DAMs and led the CIC in a discussion about the potential value and difficulties of DAMs in describing clinical practice. Issues were raised that are important to the application of informatics in a clinical contexts, such as the need for models of meaning (for clinical interpretation) as against models of use (which have underpin much of HL7's focus on information flows); and the need to allow individual flexibility while building on best practice and avoiding duplication and overlap – a searchable registry of DAMs is needed.
- A measure of CIC/HL7 success is when HL7 standards deliver the interoperability that clinicians require in a way that is completely transparent to users of clinical information systems.
- The CIC needs to assist the new HL7 executive team and organisation ensure that bottlenecks holding up projects inside HL7 are cleared. An example was given of a request to HL7 for an immunization record to rationalize the different systems used in each of the 50 (US) states. This took HL7 4 years because it had to go through so many different TCs and SIGs to get the work completed.
- It was noted that efforts in the groups external to HL7 are proliferating (e.g. CCD/CCR document development) and have outpaced HL7's ability to leverage them. The risk is that HL7 will be irrelevant to the clinical community if HL7 does not have an effective way to incorporate the work that is happening outside HL7.
- There was a lot more discussion about the CIC's role and how to achieve HL7's goals for much stronger clinical interaction and the needs for a clinically oriented work program, but no substantive actions in this regard flowed from the meeting – other than that the Patient Care TC should connect with the primary care clinicians to see how they get requirements and examine opportunities to work together and see what the overlaps are.

In reviewing CIC outcomes, Dr David Rowed noted that an important aspect of the CIC's role is to take pressure off Patient Care TC, which was gathering innumerable SIGs for clinical specialities. It was noted that PC TC is gaining an important role as the "inside" group with primary responsibility for working with the CIC.

Some delegates privately expressed concerns after the meeting that the proposed CIC work program may lead to further divergence in the development of standards in the clinical domain and compete for resources from other clinical content work, including the established work being done by others, such as the DCM collaborative, EHR-TC, SD-TC, PC-TC and their SIGs (and from those defining clinical requirements using other approaches – archetypes or terminology).

Despite HL7 attempting to ensure that the CIC is internationally inclusive, its detailed activities, proposed work and leadership have all become very US-centric.

Dr Vince McCauley noted the importance of Australia being active within the CIC as it will assist us in the task of ensuring HL7 meets Australian clinical needs.

11.2 CIC Presentations

11.2.1 ePCRN - Electronic Primary Care Research Network

The segment on the Electronic Primary Care research Network (eCPRN) was presented by Dr Kevin Peterson MD, from the University of Minnesota, who is chair of the Health IT Working Group of the North American Primary Care Research Group (NAPCRG) and holds several other positions in the US and UK. The following are some of the key points arising from his presentation.

- The eCPRN project is funded by the National Institutes of Health under its "Re-engineering the Clinical Research Enterprise" program and has the ultimate aim of improving clinical research through advanced technology.
- Under the earlier US \$9M "The Future of family medicine" project, the Committee for the Advancement of the Science of Family Medicine made the following recommendations in relation to a roadmap for health IT:
 1. Define a clinical practice
 2. Provide a common language
 3. Capture the concern of the patient
 4. Track problems over time.
- Many more patients are seen in primary care than inpatient hospital settings so there should be more research conducted in primary care facilities.
- A clinical discussion of the network for research showed for clinical research enterprises to remain successful, new partnerships need to be developed with primary care providers. These partnerships should enhance the ability of investigators to conduct research and deliver better tools (and feedback) to clinicians to assist in care provision.
- Randomized controlled trials (RCTs) are a fundamental clinical research tool but primary care practice has not traditionally been used for many RCTs, despite being potentially rich sources of patients and data.

Reasons include: - difficulty identifying subjects, delivery of complex interventions, privacy and confidentiality; however, emerging technologies and methodologies can now overcome these obstacles.

- A Practice Based Research Network (PBRN) is a collaborative of clinics and experienced physicians committed to performing research of importance to their clinical practice, with the following key characteristics:
 - The network exists beyond the needs of a single study
 - The network has research-oriented primary care physicians as members and a representative governance structure
 - The network services diverse populations in diverse locations, through multiple delivery systems
 - Its patients closely resemble the demographic of the general population seeking medical care.

- Its principal goal of the ePCRN project is the development of an electronic architecture that facilitates the recruitment of subjects and the performance of RCTs in primary care practices anywhere in the United States, allowing the rapid integration of new research findings into primary care.
- It achieves this through provision of open source, standards-based facilities for access to distributed data sets to provide a searchable virtual clinical registry. It is deployed to 20 clinics and is growing rapidly. More details are available at: www.epcrn.org.
- The ePCRN project also facilitates change in the primary care community that enables their wider use of contemporary eHealth solutions through:
 - Increased uptake of electronic medical record systems and high-speed broadband access
 - Instituting standardized XML-based record export capabilities using CCR (ASTM) and CCD (HL7) documents and secure (PKI) infrastructure
 - Compilation of logical data repositories based on XDS Affinity domains, and facilitating development of RHIOs, and
 - Application of other standards and technologies - SOAP-based grid services, OGSA-DAI grid access middleware, Globus Toolkit, BRIDG/CTOM (PCROM) and UML modelling.
- The ePCRN technical architecture has two main components:
 - ePCRN Portal (researcher), which hosts applications supporting: design and management of research trials, eligibility searches and registration, conduct of virtual pilots, and maintenance of standardized data elements
 - the NIH Gateway (clinician) which hosts the clinic research support applications and clinical tools
- Modelling and design aspects include:
 - UML use cases to ensure functionality reflects diversity of primary care studies
 - UML logical models for consistency with HL7 (RIM model) and CDISC
 - UMLS (National Library of Medicine) mapping for standard language interface with SNOMED-CT.
- The main challenges have been: - Domain specific requirements; Overlaps and gaps in domain expertise; Getting ownership; Getting consistency; Management of revisions and change as the program evolves.
- Other points covered during discussion included:
 - 40% of primary care practices have EHR systems according to the American Academy of Physicians.
 - 80% of content overlaps with content in BRIDG repository.
 - A [Gartner Research?] scale for information systems support of critical decision-making identifies five steps or maturity levels:
 1. Generator, 2. Documenter, 3. Collector, 4. Colleague, 5. Mentor.

The ultimate aim is to get clinical systems to level 4 or level 5 and this is one of the longer-term objectives of ePCRn.

- A suggestion that OWL is a way of overcoming the exponential complexity of state analysis of clinical content by allowing assertional statements to be defined and used to constrain specific patient information

11.2.2 caBIG™ – Cancer Biomedical Informatics Grid

John Speakman from the National Cancer Institute (NCI) gave a presentation on caBIG™, an information network launched by the NCI in 2004 and available since 2007 as an open community resource to enable all constituencies in the cancer community – researchers, physicians, and patients – to share data and knowledge.

- The Goals of caBIG™ are to:
 - Connect cancer research communities through a shareable and interoperable infrastructure
 - Develop standard rules and a common language to more easily share information
 - Build or adapt tools for collecting, analyzing, integrating, and disseminating information associated with cancer research
- caBIG™ has developed a range of open-source software tools that support cancer research efforts, and has established a common grid computing infrastructure (caGrid) that can be used to share data and applications between organizations.
- Grid computing is seen as an essential aid in dealing with the tsunami of data now starting to flow from work on proteomics and genomics and its correlation with the susceptibility of individuals and biological processes to particular types of cancer and cancer treatments.
- The approach has potentially broader application in relating the genetic makeup of individuals to pathogens, therapies and adverse reactions – but that is for the future (or others).
- Main objective is to share data, tools and resources amongst cancer researchers – connected via the caGrid, a service-oriented architecture and federation that connects caBIG™-compatible systems together regardless of where they are installed, facilitating:
 - Query across data resources installed in different locations
 - Automatically integrating comparable data from different sources
 - Creating workflow pipelines for data retrieval and analysis using resources across the grid
- Users have several options for connecting to caGrid:
 - Selecting and installing an existing caBIG-enabled application (available free of charge) to perform required functions
 - adapting your existing tools and applications to plug into the grid (takes longer and requires more expertise)

- Selecting and installing an existing caBIG-enabled application and adapting it to meet your needs, or
- Developing software applications to plug into the grid.
- Interoperability is multi-dimensional and flexible from basic to advanced (gold) level, depending on the needs of the user. At the gold level, a user's grid-enabled tool:
 - Re-uses caBIG Common Data Elements (CDEs) in its services and functions
 - Enforces caBIG CDE standards
 - Uses standard caBIG vocabulary and value sets, and
 - Has its interface logical information model fully harmonized with relevant caBIG UML models.
- This level of interoperability is only required for sophisticated participants (such as a cancer registry sharing data for virtual trials). Basic data interoperability allows retrieval from Clinical Trials Data Management System (CDMS) products that use the caBIG Common Data Elements (CDE's) and standard Case Report Forms (CRF's).
- Metadata (information about an application or user's stored data) is deposited in a "Grid index service" that can be queried by grid users (via standard web service advertisement and discovery processes).
- caBIG also provides access to a range of central information resources and products, such as:
 - Cancer Central Clinical Database (C3D)
 - caArray: Microarray data management system
 - CaTissue: Biorepository management system
 - caGWAS: Cancer Genome Wide Association Studies
 - NCIA: National Cancer Imaging Archive
 - geWorkbench: Microarray gene expression and sequence data management
 - CTODS: Clinical Trials Object Data System
- Key standards include:
 - Biomedical Research Integrated Domain Group (BRIDG) model for data interchange between healthcare and bio-research organizations (includes some HL7-compliant formats and there is active collaboration with CDISC on data interchange).
 - Objects and information models are defined in UML and registered with metadata as ISO/IEC 11179 Administered Components in the Cancer Data Standards Repository (caDSR)
 - Object definitions draw from controlled terminology and vocabulary registered in the Enterprise Vocabulary Services (EVS), and their relationships are thus semantically described

- XML serialization of objects adheres to XML schemas registered in the Global Model Exchange (GME).

Products, tools and services used to deliver caGrid include:

- [Globus Toolkit](#): Provides the core Grid infrastructure for service deployment, service registry, invocation and secure communication
- [Mobius GME](#): Provides grid repository for XML Schemas of strongly typed objects transferred on caGrid
- [Cancer Data Standards Repository \(caDSR\)](#): Provides repository for Common Data Elements and UML models
- [Enterprise Vocabulary Services \(EVS\)](#): Provides controlled vocabularies
- [ActiveBPEL™](#): open source workflow engine following BPEL standard
- [Grouper](#): Management of group information across integrated applications and repositories

- In response to the question, “What work has CaBIG done with HL7?” it was noted that the EHR-TC has approved work on the RCRIM functional profile: supporting CaBIG.

11.2.3 caDSR - NCI Cancer Data Standards Repository

Dianne Reeves, RN from the Center for Biomedical Informatics and Information Technology (CBIIT), National Cancer Institute (NCI) gave a presentation on caDSR, the NCI Cancer Data Standards Repository, which was briefly introduced in John Speakman’s earlier presentation.

caDSR, which has been operating since 1999, is designed to address the problem confronting the biomedical data management community caused by the wide variety of different ways that similar or identical concepts are described. Such inconsistency in data descriptors (metadata) makes it nearly impossible to aggregate and manage even modest-sized data sets in order to be able to answer basic questions. Key features of caDSR include:

- It is one of the three information management legs of the Cancer Common Ontologic Representation Environment (caCORE) served out of a secure web-based environment and comprising:
 - caBIO – repository of Bioinformatics Objects
 - EVS - Enterprise Vocabulary Services
 - eDRS – repository metadata (and semantics) on Common Data Elements (CDEs), clinical case report forms and UML Models.
- It is based on an implementation of the ISO/IEC 11179 metadata standard, a flexible model for describing metadata (also used by AIHW for Australian collections).
- It presently holds some 31000 Common Data Elements (archetype equivalents) and the North American Cancer Registry association has just added all their data definitions to caBIG.
- It also has tooling with capacity to that facilitates:

- Defining concept archetypes with defined metadata and then template onto a form.
- Loading a UML model class diagram to create a web browser template
- Comprehensive online training courses are available.
- From discussion it appears that there is no provision or plans to make use of SNOMED-CT to underpin the concept base as the EVS component has been built around LOINC.
- caDSR Home Page may be found at:
http://ncicb.nci.nih.gov/NCICB/infrastructure/cacore_overview/cadsr

12. Detailed Clinical Models (DCM)

The DCM sessions (run jointly with Templates SIG at HL7) review progress in the modelling of clinical information and seek opportunities for sharing standardized models of clinical information at the detailed, or atomic, level (e.g. Blood Pressure, Alerts, Barthel Index). It also provides a forum for exchanging information on tools and methods for capturing, representing and exchanging detailed clinical information. The original goal of the DCM group was the creation of a shared library of clinical models in a common form that could be centrally maintained and shared between implementations. Issues of governance, resources, tooling, methodology and, also, the local pressures faced by participating programs militated against the achievement of a single shared library. The group now focuses more on facilitating the exchange of models, tools and techniques between participants while looking toward longer-term convergence on more uniform, compatible approaches that integrate well with different underlying standards and implementation technologies.

Several members of the Australian delegation, including Dr Vince McCauley, were present at various times during the joint DCM/Templates (and TermInfo) sessions held on Q1-Q3 on Friday, 18 Jan, with the following being among the matters noted.

12.1 UK NHS Connecting for Health - DCM Update

NHS Connecting for Health (CfH) has been funding a major program to model clinical content for use in its Care Records Service and for standardized communication between NHS applications across the NHS Spine. Ian Townend provided a quick overview of current activity, touching on four key topics:

V3/openEHR/13606 transformability

The content modelling and transformation project started with a pilot in 2006 and, following evaluation in mid-2007, was expanded to address more clinical areas through Q2 and Q3/2007. This NHS projects is one of the largest and best resourced efforts at identifying clinical requirements and modelling clinical content by direct interaction with many clinical personnel from across a health system.

Information requirements were captured in the form of *openEHR*/EN 13606 archetypes. The UK also has a firm commitment underpinned by contractual obligations to implement HL7 v3 messaging as the cornerstone of its health information exchange. The project has therefore also involved the development of techniques and tooling to enable these models to be transformed into a UK variant of HL7 V3 templates that are then used to define and validate practical message and storage structures for use in implementations. The results should be of considerable interest to Australia, which has also used *openEHR* and variants of archetypes in its main clinical modelling work and is also looking to CDA documents and HL7 v3 Clinical Statement as the means of exchanging clinical information in future.

The most likely next stage in the UK work will be to investigate, define and demonstrate a (generic) discharge summary using the defined data content.

An interim report on the results of this latest phase of the work was expected to be available for comment in February 2008, with a final report in March/April 2008.

Developing design guidelines

The development of design guidelines is still in its early stages, but key principles being discussed include:

- being guided by requirements for data retrieval, and
- investigating detailed guidelines (and tools requirements) for binding to SNOMED-CT, an activity which is being led by Dr David Markwell (well known as a co-chair of the HL7 TermInfo Committee)

Early draft documents related to SNOMED CT binding may be reviewed on request to Laura Sato. Complete draft documents were expected to be available in March for DCM comment.

Developing governance processes

Early discussions are in progress with the NHS Information Standards Board concerning the process for NHS-wide quality assurance and approval of content models. These activities need to operate on both a clinical and technical level.

NHS CfH is interested in considering opportunities for DCM or other international groups to participate in its formal review roles.

Ongoing data capture (forms) 'requirements' modelling

Work on capturing requirements and design of clinical forms is continuing in close association with applications development for the English North / Midlands / East (NHS) Programme for IT. Recent subject areas include:

- ENT – focused on paediatric acquired hearing loss
- generic Discharge Summary
- Learning Disabilities assessments

Pilot users of NHS content models are in discussion with the London and Southern Programmes for IT, likely focusing on the 'translatability' of current (e.g. Cerner) clinical data models and developing NHS ones. It is understood that there may also be documents on transformability of Cerner clinical models available to approved organisations and individuals on request.

NHS CFH is considering sponsoring tooling development to support rapid (commercially-neutral) user interface prototyping and generation from content models to aid in clinical review of the models and also to provide richer user interface requirements specifications to vendors (if this progresses, the output would be open source).

Discussion

The following are among the points made during discussion of the NHS work.

- NHS have developed a prototype tool to map archetypes to v3 templates.
- Availability of review documents. CfH is prepared to share information with international experts involved with the DCM collaborative who are able to provide useful and constructive feedback. Requests for information should be addressed to Laura Sato at: Laura.sato@nhs.net
- The "CEN/ISO 13606 Pilot Study Final Report" published in October 2007 is available online at:
http://www.ehr.chime.ucl.ac.uk/download/attachments/3375121/NHSCFH_13606-Pilot-Final-Rpt_v1-0.pdf

12.2 DCM Milieu

1. On-going role of DCM Group. At the joint meeting of Templates, DCM and TermInfo in Q2 on Friday, 18 January it is understood that a formal motion was passed for consideration of the TSC recommending roles for the DCM Group, Templates SIG, TCs involved with clinical content, TermInfo Group and the CIC [more detail reported under Templates SIG at 10.13 above].
2. Report of Brisbane Workshop – August 2007. Dr William Goossen stated that he had completed the report on the Brisbane workshop and was in the process of posting it to the DCM wiki. He spoke to the report later in the meeting outlining the need and a proposed approach for action on: *Quality criteria for care information models*. The final version is available via the HL7 Templates SIG email list server (as an attachment) to the message at:
<http://lists.hl7.org/read/messages?id=120875>.
3. Following a comment from Andrew Perry (UK), it was noted that:
 - Under the current *openEHR* approach, more generic archetypes can be constrained as they are put into an *openEHR* template.
 - Using this approach, *openEHR* templates could be quite large collections of clinical concepts and Template as

- It wouldn't be necessary to have tight governance and harmonisation of templates, providing that the underlying archetypes are harmonized and controlled
 - A HL7 CDA implementation guide could operate similarly to an *openEHR* template by containing component clonical statements.
4. Mark Shafarman suggested that, to avoid confusion:
- An HL7 template corresponding to an *openEHR* archetype should be called an "atomic template"; and
 - An HL7 template corresponding to an *openEHR* template may be called a "clinical template".
5. David Rowed reported on some of the work being done for NHS by Ocean Informatics. This included work in migrating legacy formats to CDA and back to Legacy by transforming it via *openEHR* archetypes. One advantage of the approach is that it gives more flexibility and control over the mappings on the way through.
6. Validating conformance of CCD models and templates. Mark Shafarman outlined how the CD TC were approaching conformance of CCDs to the specifications in the CCD Implementation Guide, noting the final version had to address the needs of HL7 (CDA) and ASTM.
- A Schematron schema is provided as part of the CCD Implementation Guide and is available to be used for validating conformance
 - Validation needs to occur at both the technical level and the clinical level
 - The process is based on creation of XSDs, use of Schematron to validate and extract Schematron XML ITS generated from static models in V3
 - A large collection of "templates" is expected at XML schema level
 - Once the schema in the implementation guide has been created and validated, people who know XML can use the templates without much detailed knowledge of the underlying HL7 models
7. Further information on the work of the DCM collaborative may be found on the DCM wiki at: <http://Detailedclinicalmodels.org/wiki>

12.3 IHE constraint profiles for CCD

Larry McKnight gave a presentation to the meeting about IHE's work on constrained profiles for CCD, as follows.

- The detailed CCD profiles are on the IHE website at: Wiki.ihe.net but the individual profiles are easiest found by their OID. These can be found at: http://wiki.ihe.net/index.php?title=PCC_TF-2#CDA_Release_2.0_Content_Modules
- Patient care section. Example was given of CDA specifications for Discharge Summary with accompanying Schematron schema for validation of the templates. This will be tested in Chicago. LOINC is used to encode observations.

- Constraints are documented as specific assertions.
- Schematron is given as a set of rules, although wiki is not complete in terms of all rules.
- Does not do as good a job as archetypes in terms of user interface for valid choices at each point.

12.4 Transforming HL7v3 care provision message

William Goossen presented the latest work that he had been doing in the Netherlands developing detailed clinical models for care provision, in particular Vital Signs and Assessment Scales, and working with others (notably Sam Heard) on transforming the resulting models between representations.

He has developed models and HL7 v3 messages in accordance with the Clinical Statement pattern RMIM modelled by Heath Frankel and forming part of the Care Provision DMIM. During discussion

1. William suggested that clinical requirements should be represented through a three level process:
 - (a) Sort out what the clinical requirements are at a business level using tools that can be readily understood by clinicians
 - (b) Express clinical requirements in a technology-agnostic format (a space is where *openEHR* archetypes are moving – also DAMs).
 - (c) Translate from the into required technologies via ITS, mapping tables etc – be the resulting product an IHE CCD/CDA specification, HL7 v3 HMD, *openEHR* template or other representation.
2. It was noted that HL7 HDF is really the first two levels based on use of UML.
3. From his experience with the Barthel Index, William had found that most of the work was sorting out the details with clinicians and getting their agreement.
4. McKnight (IHE) expressed concern at an approach based on pumping out *openEHR* archetypes in collaboration with clinicians and trying to use them in a system that only knows HL7 via a transform. Each transform is lossy unless there is a 1-1 correspondence between the representations. This view was disputed and was not supported by the UK experience; however, it was noted that the schematrons used in IHE are specific to particular technologies, notably CDA.

[During private conversation with McKnight it appears that in the US-realm there is an assumptions in HITSP, HIPAA, that information is RIM-based and Schematron is to be used to represent it. So, it is unclear how archetypes fit in – are they a distinct type of constraint or (as appears) or merely a duplication of what can be done using alternative approaches.]

13. ISO TC215 WG2 (Data Communication) Meeting

The ISO TC215 WG2 meeting attracted a core attendance of around 20 delegates, with around 40 in the 3-way sessions with the HL7 Imaging Integration (II) TC and representatives of DICOM at which DICOM standards. Some of the topics addressed included processes and current issues flowing out of workflow (Substance Administration), the extension of RIS/PACS and imaging technologies across a range of specialties including pathology.

Progression of harmonized data types for information interchange (ISO 21090)

From an Australian perspective, the most important issue was gaining a commitment from those who are heavily involved in ISO and CEN that they would support the timelines for the joint balloting of the ISO Harmonized data types work being carried out by Grahame Grieve, primarily within HL7 (which is where objections are most likely to arise, because of the extent to which the previous HL7 data types had been implemented. At the request of Richard Dixon Hughes, Grahame came and briefed the meeting on progress.

There was some objection from several European/UK interests at having the main reconciliation event in conjunction with the September HL7 Working Group meeting in Vancouver but these are understood to have been overcome and a resolution passed to hold a special ISO TC 215 WG2 meeting on this topic in Vancouver.

A strong personal commitment was received from Melvin Reynolds (UK), Vice-Chair of CEN /TC 251 to ensure that this work is progressed within both CEN and ISO in a timely fashion.

Other matters

- Genomic Sequence Variation Markup Language (GSVML) – progress noted.
- An invitation to contribute and collaborate in work on "The Categorization And Nomenclature of Medical Devices". This work is being conducted by Tom Marley in the UK who is collecting and analysing requirements from a medical device directory and registry for the NHS and proposing the underlying framework as a joint work item for ISO, CEN and HL7, noting the complexities and differences in the types of details needed in the supply chain, statistics and in the clinical context.
- IHE Integration Profiles. The following activities were noted to progress ISO/TR 28380-02 (Part Two).

In San Antonio the global structure for Part 2 was reviewed along with examples of:

- (a) IHE domain description,
- (b) list of profiles and
- (c) specific profile overviews,

The review group agreed the content of these components with the results to be communicated to IHE by Charles Parisot and Kevin.

IHE is to be asked to provide completed descriptions of all three items by 18 April 2008 so that the draft of Part 2 will be reviewed and issued for TR ballot in May at the meeting in Gothenburg, Sweden.

- Meta-Data-Model for Standardization of Class Models - HL7 Version 2.5 – progress
- ISO 17113 – Methodology for Development of Messages - progress
- HL7 CDA Release 2 – progress (formatting and release of DIS). The project lead is Woody Beeler (USA) who reported that the document was issued for DIS ballot in HL7 format with an ISO cover. This process has been completed but there is, as yet, no report back from ISO on the ballot result or comments received.
- Common Healthcare Information Components – progress
- Registry Framework of Clinical Document Architecture – detailed discussion of Korean proposal followed by general agreement to allow the item to proceed based on a draft being prepared in Korea.
- WARM (Web Access Resource Manifest). Project lead is Nick Brown (UK), who advised that the initial draft was distributed to interested parties for comment.

It has been accepted that the draft is not to include details of wrappers but is to include use cases at user level. A number of other useful comments were received which will lead to some revision.

CD to be prepared in time for the May meeting.

- New/Other Business – New Work Item Proposal(s):
 - NWIP Quantities and units – Telebiometrics related to Telehealth and World-wide Telemedicines (arising from liaison with ITU-T and IEC /TC25 and IEC /TC12).

14. Upcoming Conferences/Events Supported by HL7 and Affiliates

April 2008 - "SOA in Health Care: Realizing Quality of Care, Business Value, and Delivery on IT's Promise"

This conference/workshop is planned for 15-17 April 2008 in Chicago to present the work of HL7 and OMG through the HSSP and those looking to apply service oriented architectures (SOA) in health care.

The event targets a US audience to align with current interest in health care quality measures but with some international participation. The program has now been published and is available at:

<http://www.omg.org/news/meetings/HC-WS/>

It features some 45 speakers, organized as follows:

- The first day will be an "executive summit" consist of industry case studies in a single stream
- The second and third days day will have a technical stream and a business stream with the focus for each being:
 - Wed , 16 April - Planning to Execute: Preparing for SOA
 - Thu, 17 April 17 - Doing SOA: Techniques for Success

May 2008 HL7 Working Group Meeting

The May 2008 WG meeting is to be held from 4 to 9 May in Phoenix, Arizona, USA.

2008 ISO TC 215 Plenary and Working Group Meetings, Gothenburg

These meetings are scheduled to be held in Gothenburg, Sweden over the weekend from 31 May to 3 June 2008, immediately after the European Medical Informatics Conference.

CEN /TC 251 will hold joint meetings in conjunction with the ISO meetings.

The next meetings of the ISO/CEN/HL7 Joint initiative and Joint Working Group will also take place in conjunction with the ISO TC 215 meeting.

2008 HL7 Annual Plenary and Working Group Meeting in Vancouver.

The 22nd HL7 Annual Plenary & Working Group Meeting is to be held at the Sheraton Wall Centre Hotel in Vancouver, British Columbia, Canada from 14-19 September 2008.

9th International HL7 Interoperability Conference (IHIC 2008)

The 9th International HL7 Interoperability Conference (ihic2008@hl7.org.gr) will take place from 9-10 October 2008 at the Aldemar Knossos Royal Village resort on the

island of Crete in Greece. ([http://www.aldemarhotels.com/EN_Crete-Knossos Royal-Village.html](http://www.aldemarhotels.com/EN_Crete-Knossos_Royal-Village.html)). The dates have been chosen to adjoin the TC215 WG Meeting scheduled to commence in Istanbul, Turkey the following Sunday.

As with previous IHIC conferences the focus will be on HL7 v3 message standards and Clinical Document Architecture (CDA) with a view to sharing implementation experiences including successes, issues, lessons learnt, strategies and the way forward. Moreover, the conference will examine the challenges faced by HL7 as it addresses the needs of personal health records and individualized care. With keynote speakers examining these themes in the context of national strategies, transnational projects and HL7/ISO/CEN cooperation, specific themes for learning, cross fertilization and collaboration will be developed around:

- HL7 implementation experience from regional, trans-regional, or national implementation, including:
 - Use of CDA documents, and HL7 v2.x and 3.0 messages
 - ePrescription and eClaims
 - Collaborative use of standards, HL7 in IHE profiles
 - Terminologies, ontologies and coding systems
- Business Models for reimbursement & large scale deployment
 - Global initiatives beyond HIPAA and the European Health Insurance Card
 - Electronic Healthcare Record: from strategy to implementation.
 - Knowledge deployment processes for education, certification
 - Legal and regulatory issues
- HL7 standards for Security, Confidentiality and Trust
- Beyond HL7 messages and documents. - Challenges ahead
- HL7 in consumer health:
 - HL7 v3 for PHR and health plans
 - environmental and personal health warning (e.g. pollution, allergies)
 - HL7 CDA for Personal health devices, smart appliances, health cards
- HL7 in population health and decision support
 - epidemiology, disease surveillance and control, GIS for population health
 - disaster medicine, emergency management and public health
 - clinical genomics and family history

Papers are sought by 31 March 2008, with notification of authors by 31 May.

The early registration fee will be €350 for those registering by 31 July 2008, with normal registration costing 400€ and student registration €150.

A copy of the call for papers is being obtained for circulation to the HL7 list.

2008 ISO TC 215 Working Group Meetings, Istanbul

The second set of TC 215 meetings for 2008 are scheduled to be held in Istanbul, Turkey from 12 to 15 October 2008.

7th Asia-Pacific HL7 Conference, Taiwan

Following a request from the Taiwan Department of Health, this conference is now being planned for 19-22 November 2008 in Taipei, Taiwan. The Department is keen to ensure that the conference will provide a lot of information and experience on how to effectively use CDAr2 for electronic discharge summary.

Limited details have been provided to date; however, further information is understood to have been posted on the HL7 Taiwan website (in Chinese). The address is: <http://www.hl7.org.tw>.

January 2009 HL7 Working Group Meeting, Orlando

The January 2009 WG meeting is to be held from 11 to 16 January in Orlando Florida, USA.

2009 International HL7 Working Group Meeting and IHIC 2009 in Kyoto, Japan

The May 2009 HL7 Working Group meeting will be held from 10 to 15 May at the Kyoto Convention Center (in the same hall where the Kyoto Agreement on Climate Change was executed).

HL7 Japan has proposed holding IHIC 2009 in the same venue, commencing on Saturday, 16 May and concluding on Saturday, 16 May; however, it is understood that this proposal has yet to be accepted by HL7.

2009 HL7 Annual Plenary and Working Group Meeting

The 23rd HL7 Annual Plenary & Working Group Meeting is to be held at the Sheraton Atlanta Hotel in Atlanta Georgia, USA from 20 to 25 September 2009.

15. Useful resources and links

The following sources of information and links were noted:

1. CDA Examples (42MB)
http://www.ringholm.de/download/CDA_R2_examples.zip
2. V3 message examples
http://www.ringholm.de/download/NE2006_examples.zip
3. Final Report of NHS pilot of use of *OpenEHR* Archetypes and Templates (CEN 13606):
http://www.ehr.chime.ucl.ac.uk/download/attachments/3375121/NHSCFH_13606-Pilot-Final-Rpt_v1-0.pdf
4. DHS Victoria Human Services Directory:
<http://humanservicesdirectory.vic.gov.au>.
5. Center for Ageing Services Technology (USA)
<http://www.agingtech.org/index.aspx>
6. HL7 publishing schedule
http://www.hl7.org/documentcenter/public/schedules/pubs_schedule_2008.pdf
7. HL7 Tooling Resources - Project Homepage:
<http://hl7projects.hl7.nscee.edu>

16. Conclusions

Overall, satisfactory progress was made towards the achievement of Australian objectives for international standardization.

Australia continues to influence HL7's strategic positioning as a global SDO and encourage its collaboration with other global SDOs through:

- Its membership of the ISO/CEN/HL7 Joint Initiative Working Group (ISO TC215 WG9 – with Elizabeth Hanley of Standards Australia as the Secretariat),
- Klaus Veil's continuing attendance at Board meetings as a non-voting invited observer in his role as Affiliate Liaison and recent Board member,
- Richard Dixon Hughes' membership of the HL7 Board Advisory Committee,
- Grahame Grieve as a member of the reconstituted Architecture Review Board,
- The work of Klaus Veil, Grahame Grieve, Heather Grain, David Rowed, Dick Harding and Max Walker as co-chairs and/or facilitators of Technical Committees and SIGs, and
- Active Australian participation across a wide range of Technical Committees and SIGs, as well as via informal channels.

Major policy issues discussed at the January 2008 HL7 meeting included:

- Collaboration between HL7, ISO and CEN and other major SDOs to harmonise global health informatics standardization
- HL7's key initiative to build (and maintain) an "HL7 Strategic Roadmap"
- Increased international interest in the adoption and implementation of HL7
- The maintenance of local Implementation Guidelines which is a major task for some international Affiliates
- Closer alignment of HL7 work with a broader spectrum of clinical requirements - through the formation of the Clinical Interoperability Council
- Enhancement of HL7's technical capabilities, in particular:
 - Renewal and strengthening of successful alliances with other organisations both in the US and internationally
 - Supporting the foundation of the OpenHealth Tooling group
 - Building new relationships.
- Continuation of work on HL7 V2.7, V2.8 and rebuilding and rebranding V3
- Personal health records
- Disagreement between the conformance community and the HL7 v2 standards development community over continuing some mandatory field size restrictions in the v2 standard.

- Role of the Clinical Information Council (CIC) in relation to other groups within HL7 concerned with clinical information content and processes.

As stated in previous Meeting Reports, participation at the HL7 Working Meetings requires exhausting travel, hard work and long hours. However, it is one of the most productive activities for those involved in the Australian HL7 standards effort.

It is difficult to over-estimate the focus and the resulting progress that is created at an HL7 Working Meeting. Australian participation is vital, as HL7 continues to grow its influence as the leading eHealth standards organisation worldwide.

This influence is being extended by international IHE support and from eHealth governing bodies in the US, notably HITSP, CCHIT and more broadly, the US government, though its endorsement of HL7 CDA as the standard for its clinical documents. With the extension of the steering group responsible for planning under Mandate M/403 in Europe to include HL7 and IHE, and approval of HL7 standards in ISO, the way is opening for HL7 to achieve official recognition in the EU. HL7's relevance is further strengthened by the recent inclusion of people with technical leadership roles in major HL7 v3 stakeholders – the UK NHS and Canada Health Infoway - as key external appointments to the HL7 Board.

With many Australians having leadership positions with HL7, Australia has continued to build its substantial influence, which allows us to effect changes that are important to Australian stakeholders. This influence is a direct result of our continued and committed participation in the development of HL7 standards.

The issue of removing normative content from V2.x is an example. This could significantly weaken the usefulness of the V2.x Standards for compliance. With many discussions in the committee, but also "in the corridors" we were able to clarify the risks of this approach to many of the stakeholders while still at the meeting.

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Annexure A – Draft HL7 Strategic Roadmap

Roadmap 2008

Version 0.6

General Principles

The HL7 strategy will be supported by a Roadmap that clearly defines both the standards and technologies that we will develop and use and those we will not.

- The Roadmap shall be tightly coupled to a timeline for deliverables and it will be harmonized with the medical, financial, organizational, business, biomedical technology, and information technology developments within the healthcare community and in the interest of our global stakeholders.
- HL7 must measure success through the users of HL7. This includes the relative rate of adoption of a product when measured against the potential user pool. It also includes the frequency of use within a user's organization and comments and feedback to HL7 on how they see HL7 as "fit for their purposes". HL7 will not be measured solely on the volume of Standards and other Technologies that are produced or balloted within a given period of time
- Continued evolution of the Roadmap is critical. Review will be undertaken annually supported by a group of internal thought leaders and external stakeholders.
- Ballots continue to be excessively time consuming and are often delayed. What measures must HL7 utilize in order to balance the reconciliation of negative comments against the "good enough" approach to draft standards creation?
- Does HL7 need two divisions? By example, one group dedicated to the creation and maintenance of mainstream products (the standards) with the other focused on innovative solutions (e.g., V4).
- ANSI has recommended that HL7 streamline its interpretation of ANSI requirements. This approach would potentially reduce development delays and improve time to market. What can be done to manage this philosophical course correction?
- Some organizations (e.g., W3C) rely upon paid staff for project management. Is this a philosophical shift or a practical necessity?

Standards

Architecture

Principles

- HL7 Standards and Technologies are founded and managed by a set of Architecture principles that help to assure that they are internally congruent, consistent with appropriate measures of quality and have been prepared according to the appropriate approved HL7 associated methodology. (Note: the term "goal architecture" originates in documents created by the Strategic

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Initiatives Task Force. It is possible that the more familiar IT industry term “reference architecture” might substitute for this less familiar term. The ARB will decide on the future nomenclature for HL7.)

- HL7’s Architecture Review Board (ARB) keeps and manages the HL7 architecture(s). The ARB defines and documents both the “goal architecture” for the suite of current HL7 products and the gaps that exist between this “goal architecture” and the current or *de-facto* architecture as it currently exists. The HL7 “goal architecture” is consistent with both the HL7 Mission and the current HL7 Strategic Plan as defined by the HL7 Board.
- The ARB provides recommendations to the Technical Steering Committee (TSC) and Chief Technology Officer (CTO) that move the HL7 organization and products towards the current “goal architecture”.
- The ARB works to improve the consistency and effectiveness of committee operations relating to overlap of committee scope or gaps where no committee is working

Objectives:

- Reorganize and establish a new ARB based on the above mission by (Date: xxxx).
- Create a defined set of Architecture principles associated with each HL7 product by (Date: xxxx).
- Position the ARB to work with all relevant committees of HL7 to proactively champion the adoption of an approved HL7 Reference Architecture and establish a process for its continuous review and update by (Date: xxxx).

Version 2

Principles

- The continued development of the Standards, implementation guides and other technologies of the V2 family are critical to the maintenance and continued effectiveness of the legacy systems of our stakeholders. V2 development should be harmonized with the evolving requirements of realm-specific domains. Both this harmonization as well as the intended development of V2 products should be defined in the Roadmap. This process will be global and not only US-centric.
- We expect demand for the evolution of V2 to continue over the next five years. Any specific plans for “sunsetting” or retiring any technologies or other portions of V2 will be noted in the Roadmap.
- Business requirements and established methods and techniques for the migration of V2.X to V3 will be established and timelines for achieving these goals and identified limitations will be articulated.

Objectives

- By (Date: xxxx), publish the completed normative edition of HL7 Version 2.6
- By (Date: xxxx), publish a first DTSU for v2.7
- By (Date: xxxx), complete the normative ballot process for 2.7

Milestones

- By (Date: xxxx), complete a successful first ballot for DSTU 2.7

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Version 3

Principles

- The development of V3 will continue to maintain its current global trajectory across all realm-specific domains and will not be focused on the specific requirements of any single constituency. Realm-specific requirements and development should be incorporated into and harmonized with the global V3 standard.
- Products and services to support V3 will be incorporated into the Roadmap. These will include, but are not limited to, balloted implementation guides; tools to support harmonization (e.g., RIM) and publication of V3 products; tools to support the development of templates, tools to support the publication and validity testing of V3 implementation guides and example messages, etc. (We need to develop a position here on our plans to support conformance testing as well).
- The Clinical Document Architecture (CDA) shares many of the constituent artifacts of the Version 3 Architecture and our existing V3 Messaging Standard. HL7 will further develop CDA under global sponsorship and document the use of CDA by our user community. HL7 will develop clear business cases for CDA and substantiate recommendations for its implementation.
- HL7 recognizes that some stakeholder communities are concerned about the “appropriate balance” between document-focused solutions and messaging. We will work with our user community and other interested organizations to document regulations where they exist and best practices on this subject as they emerge.
- RIM development will proceed within specified timeframes and with strategically aligned domain experts. RIM harmonization will be achieved through tighter collaboration with supporting stakeholders and contributors and will support the activities of other standards development organizations (SDO) who wish to partner in this activity.
- Tightly scoped development of the RIM must support a more focused definition of the HL7 architectural objectives.
- Services Oriented Architecture (SOA) will evolve with dependent technologies. This process must be defined within the Roadmap and aligned with the principals and practices developed by other standards development organizations.

Objectives

- By (Date: xxxx), complete a successful normative ballot for (Date: xxxx) Version 3

Milestones

- By (Date: xxxx), deliver the V3 (Date: xxxx) DSTU
- By (Date: xxxx) publish a normative ballot for V3 (Date: xxxx)

Other Existing Standards / Implementation Guides

- EHR5
- CCOW
- HL7 Claims Attachments Specifications
- Arden Syntax

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- GELLO
- CCD Implementation Guide
- Other Implementation Guides

Evolving Standards / Implementation Guides

- PHRS
- SOA

Objectives

-

Milestones

- Meet with the committees responsible for all of the existing and evolving standards and establish milestones and objectives for each of them for (Date: xxxx) by (Date: xxxx).
- Create a Board appointed task force to review ANSI requirements and to suggest changes in the balloting process to improve efficiencies and streamline standards delivery.

Services

Certification

Principles

- Potential varied approaches to systems certification will become a valuable business-centric and education-based opportunity. Development of certification models will be defined and tracked within the Roadmap.
- Strategic partnerships (e.g., CCHIT, IHE) will be nurtured to develop certification requirements and processes.
- HL7 Committees and specifically the ARB must define the internal requirements for our products to support conformance testing where applicable.
- As HL7 turns more towards developing Implementation Guides for HITSP and others, conformance testing and the means to support conformance testing must be considered and included as appropriate.

Objectives

- Create a task force to evaluate the potential for certification, including but not limited to certification types, partnerships, models, obstacles, expenses and revenues on or before (Date: xxxx)
- Task force to render their report to the Board during the (Date: xxxx) Retreat

Implementation Services

Principles

- Provider needs have historically never been well-articulated. Vendors will not invest in standards which their clients do not demand. HL7 has an opportunity to become a voice of the solution purchaser. How might this conflict, as it has in the past, with its relationship with the vendor community?
- Standards should not reach normative status prior to successful implementation. DSTUs will be used to provide opportunities to prove the implementability and correctness of Standards and Implementation Guides.

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- Implementation guides will be developed in conjunction with clearly enunciated partnerships (e.g., IHE). Development of these guides should be strategically defined and articulated with other milestones within the Roadmap.
- Strategic partnerships should be reaffirmed and broadened to accelerate implementation processes.

Objectives

- Create an advisory committee composed of Board members and stakeholders to investigate opportunities and obstacles for developing an implementation entity and/or partnering with an external organization. Report to Board during the (Date: xxxx) Retreat.
- Finalize Memorandum of Understanding with the newly incorporated IHE organization by (Date: xxxx)

Tooling

Principles

- Tooling activities will receive appropriate emphasis and funding to meet stakeholder needs
- Cooperative efforts with tool-development organizations will be prioritized
- HL7 will create commercial quality tools for our standards developers and user community. These tools must:
 - Be supportable and sufficiently documented that qualified users can understand and use them without assistance
 - Automate the process of publishing HL7 Ballots and Standards so that they are produced without syntax errors and preventable (wherever possible) semantic errors
 - Assist users in the creation of implementation guides for both HL7 Messages and CDA Documents that conform to the HL7 Standards and properly use the current associated HL7 Implementation Technology Specification (e.g., XML).
 - Assist HL7 in creating or editing conformance profiles and executable rules that can validate an HL7 message or CDA to an Implementation Guide.

Objectives

- Open Health Tooling (OHT) Group shall receive organizational and fiscal support through (Date: xxxx).

Milestones

- OHT deliverables will be defined and reported to the Executive Committee monthly
- By the (Date: xxxx) Working Group meeting a report will be created that:
 - Evaluates the suitability and capability of the OHT Eclipse platform and the proposed IBM publishing application to support HL7's needs
 - The MIF interface documentation for our existing tools will be completed
 - A set of user requirements will be generated for tools that:
 - Support the creation of V3 XML Message implementation specifications
 - Support the creation of CDA R2 implementation specifications
 - Support the publishing of V3 and CDA Standards

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- Support the publishing of V2 Standards

Vocabularies and Ontologies

Principles

- Increasing emphasis will be placed on the relevance of vocabularies
- Vocabularies and the modeling and other infrastructure required to support them will become one of the foundation pieces of HL7s “goal” Architecture.
- Vocabularies will be specifically represented through a Vocabulary Expert from the Vocabulary SIG.
- Greater efforts will be made to collaborate with SDO partners and domain experts to facilitate the effectiveness of interoperability specifications

Objectives

- Develop specific Memoranda of Understanding with two or more SDO active in the vocabulary domain (specifically to both leverage the prevalent expertise and derive value for our stakeholders) by (Date: xxxx).

Evolving and emerging Technologies

Principles

- Careful measurement of evolving and emerging technologies (e.g., Personal Health Records, HL7 Dynamic Modeling and Service Oriented Architectures (SOA)) will improve Roadmap prioritization
- Monitoring of these opportunities should be an activity shared by internal domain experts and stakeholders

Objectives

- Include coherent and complementary static and dynamic modeling concepts in the HL7 “goal” Architecture.
- Work with the HL7 SOA Committee to develop SOA through the HSSP collaboration with OMG
- Deliver a first balloted reference architecture document to include a services delivery approach as a means of using HL7 Standards in SOA by (Date: xxxx).

Organizational Development

Technical Services

Principles

- Transition to policies that support top-down management will be timely. Partnership of the CTO and TSC is a strategic success metric.
- The CTO role will rapidly mature with focus on:
 - Liaison of HL7’s Roadmap to tactical projects within the TSC
 - Communicating requirements and needs identified in the TSC and its constituent committees back into the Roadmap and the project management, harmonization, and gap remediation.
- The TSC will continue to evolve with appropriate re-alignment of Technical Committees as needed.
- The TSC will promptly develop a model to vet all specification development. This is particularly critical in the coordination of initiatives that span technical

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committees as well as those needing harmonization among standards development organizations.

Objectives

- The TSC and CTO will publish new TSC communications and reporting processes by the close of the (Date: xxxx) Working Group Meeting

Milestones

- The Project Services Committees of the TSC will be established in (Date: xxxx)
- The TSC and CTO will propose an updated HL7 Product Strategy at the (Date: xxxx) Working Group Meeting
- The HL7 Project Tracking tools will be brought current with actual work taking in progress by the close of the (Date: xxxx) Working Group Meeting

Operations Management

Principles

- The financial and functional requirements for development of new employee roles will be tracked within the Roadmap.
- The compensation model for HL7's management group (AMG) shall be evaluated. A more equitable system for estimating and rewarding achievement is required.

Objectives

- Create a task force to evaluate management schema in other standards development organizations and recommend to the Board its finding and management options by (Date: xxxx). Task force members will include Board members, the management team, and external experts.
- Create a committee to evaluate the compensation model for the existing management structure and report to the Board (Date: xxxx).

Project Management

Principles

- Role of salaried project managers (e.g., W3C model) will be reviewed, tested and introduced
- Coordination of project management is the shared responsibility of the CTO and the Technical Steering Committee, and defined within near-term tactical guidelines.

Objective:

- Research the W3C model and create a report to the Board by the (Date: xxxx) that explains W3C's approach to organize and fund salaried project managers.

Marketing/Communications

Principles

- Marketing will take a higher priority and increasingly focus on promoting HL7 among diverse stakeholder communities.
- The Marketing Committee should transition to a Marketing Council to reflect a broader constituency and a more global approach to communications.
- Marketing management will evolve into full-time salaried staff.
- The stakeholders and leadership should entertain the concept of an HL7 User Group to promote greater participation of implementation experts.

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- A clear definition of the “HL7 brand” should become a priority. The Marketing Council should immediately develop an “elevator pitch” that explains what HL7 does and why its role is so important.
- The Marketing Council must contribute to the content development of the newly created web site and publicize its value and features. The web site must have a highly valued external face as well as newly created internal utility.
- The Marketing Council should supervise the collation and harmonization of public presentations. Our outward facing communications should reflect a common point of view, whenever possible.
- Opportunities for external support for marketing and communications (e.g., Harris Interactive) should be exploited wherever possible.

Objectives

- The Marketing Council will provide recommendations for funding and governance of an enhanced role for Marketing by the (Date: xxxx). The Council members will be supplemented by Board members and outside expertise as the need and resources permit.
- The Marketing Council will recommend other outreach activities, including but not limited to an
 - Ambassador Program (of dedicated domain experts for speaker venues and publications)
 - HL7 User Group

Industry Advisory Council

Principles

- The Advisory Council role should be strengthened. New communities of expertise should be added to the existing panel.
- Advisory Council activities must be tethered to the evolution of a Stakeholders’ Roundtable, to be held annually.
- Leadership of the Advisory Council should be transitioned to a council member, and the chair should stand for election, while the committee remains both dynamic and flexible.

Objectives

- The new IAC chair will be seated by the January 15 Board meeting.
- The IAC will prepare recommendations to the Board for its expanded role, transition and governance by the IAC meeting preceding the (Date: xxxx).

Financial Development

Funding sources

Principles

- Deriving new and innovative revenue sources will increase in priority. Competition for a dwindling resource pool will increase both tension and visibility.

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- Plans for changes in dues structure and participatory costs will be defined and timelines established. Successful change management is predicated upon an effective communication plan.
- Greater emphasis will be placed on the vendor community and in its role as a funding resource. Direct marketing opportunities should highlight the contributions of HL7 to the success of individual vendors as well as the for-profit entities at large.
- Governments and government agencies will be increasingly relied upon for funding of specific needs and organizational support.
- The payer community, previously largely ignored, will transform into relevant funding sources. This approach should be closely aligned to tactical marketing opportunities and aggressive public relations activities.
- Business case development will be more critical to successful fund raising. Partnerships with credible evaluators of business value will become more critical

Objectives

- New funding equal to or greater than the funding of the Marketing Director will be generated by that office by (Date: xxxx).
- Additional funding sources will be identified in conjunction with the evaluation of an independent HL7 Foundation.

HL7 Foundation

Principles

- Foundation concepts and models are critical opportunities and will be evaluated for viability

Objectives

- A report of an initial evaluation of the potential legal, strategic, and operational implications of an HL7 Foundation will be reported to the Board on (Date: xxxx).
- Recommendations for further action on the viability and potential for success of a Foundation will be made to the Board by (Date: xxxx).

Affiliate Development

Principles

- One-member-one-vote: Solutions will be sought that support business viability
- US Realm: Development of US-centric products and services will continue, but will be managed under an evolved organizational plan which may or may not include the creation of a US Affiliate.
- These previously topical issues are becoming more strategic. They must be addressed with solutions that meet both governance mandates and business reality.

Objectives

- Convene a Board-appointed task force, comprised of both US and Affiliate members, to address the organization's ability to satisfy Affiliate concerns but provide a tiered approach, both supporting and sustaining business viability.

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Milestones

- Develop an HL7 Management position on these issues for presentation at (Location & Date: xxxx).

Outreach & Relationship Development

Associate Charter Agreements

- New groups will be added to strengthen contribution of SDO and professional societies.
- Opportunities for new relationships (e.g., Clinical Interoperability Council) and new approaches to existing relationships (e.g., HL7 User Group) should be exploited.

Memoranda of Understanding

- Renewal of contracts with existing organization must be a priority. These agreements must be supported by sound business cases, rather than simply reflecting co-marketing arrangements and/or publication requirements.
- Development of new relationships (principally among stakeholders) will become vital in the very near term.

New partnerships

Principles

- Rapidly improving relationships with entities that could obviate HL7 standards development (Google, Microsoft) will become increasingly important. The market impact of these organizations cannot be underestimated.
- Relationship development should become a greater priority for the CEO and Marketing Council, and should become a non-technical component of the Roadmap

Objective

- Create a shareable set of web pages that documents all current formal relationships including current activities, designated liaisons, existing agreements, and stated mission and goals for the relationship. A process will be put in place to keep it up to date and a summary report generated for Board Review at least once a year. This objective will be in place by (Date: xxxx) and the first report given to the Board (via email) before (Date: xxxx).

Annexure B - Minutes of HL7/CEN/ISO Harmonisation Meeting

Minutes of HL7 / CEN / ISO Harmonisation Meeting 13 January, 7.30 pm to 9.30 pm At HL7 Working Group Meeting January 2008, San Antonio

Minutes by Elizabeth Hanley and Mark Shafarman, 15 January 2008

1 Welcome

Mark Shafarman, Convenor, welcomed attendees, and stated that the most important outcome of this meeting will be communication on joint projects that people are engaged in.

2 Current Status of Joint Initiative on SDO Global Health Informatics Standardization

Audrey Dickerson reported that the Joint Initiative Council (JIC) held two teleconferences in December 2007 to discuss the development of policy and procedures for joint projects. A policy document and form for project details have been drafted for JIC agreement, and trialling.

This policy document addresses a number of matters including:

- Policy statement
- The list of agreements currently held by ISO TC 215
- Identification by JIC of the need for a joint task group; and the host SDO.
- Identification of the project lead from host SDO, with co-chairs from each of the participating SDOs.
- Project timelines
- Copyright issues.

Elizabeth Hanley noted the Joint Initiative website at:

<http://www.e-healthstandards.org.au/cat.asp?catid=43>

This website has several important documents including the Joint Initiative Charter, the Joint Working Group (JWG) Terms of Reference, and the JWG Work Program, as well as minutes from the JWG meetings.

Issues raised by those present included:

- The need for a process for scheduling out of cycle meetings for joint project task groups
- Do projects included in the joint work program need to have already gone to ballot within one SDO?
- The need to avoid duplication of projects i.e. if a work item has been established in one SDO, then it should not be established by another SDO.
 - In the case of standards with overlapping, duplicative content, and/or which also support overlapping use cases, and which have already reached normative status in more than a single SDO, and which already have significant stakeholders, joint harmonization projects must be

initiated and supported. It is realized that this is not the ideal solution, but one that is necessary at this time, and that as the JIC continues, an important goal will be not to initiate overlapping projects in multiple SDO's.

- The need for the joint work program to include a scope statement for each project
- The need to coordinate the ballots. Ideally, the dates should be the same for each SDO. The ballot reconciliation should also be coordinated, and done only once with participation from each SDO during the same coordinated (agreed-upon) time interval.
- The importance of continued open, transparent communication among all the participating SDOs was affirmed. Such communication will allow a sense of trust and collegiality to develop, which is necessary for the success of the JIC.

Note that some of the above bullet-points are discussed below as related to the ISO datatypes project.

3 Project Updates

3.1 Data types

Graham Grieve reported that there has not been a lot of progress since August, since there was a decision to complete the next version of the abstract data types specification before completing the ISO document. The current abstract datatypes ballot had over 270 comments needing reconciliation. The group plans to continue the ISO datatypes ballot in the next HL7 ballot cycle, when it will be coordinated with the HL7 abstract data types ballot. Graham acknowledged the help from task group members and the support from NHS to bring the project forward.

Issues were raised as follows:

- The need to synchronize ballot cycles.
There is a single community commenting from different perspectives; comments are handled in different SDO committees in different timeframes; problems can occur when changes to documents are made during comment resolution, so that different documents are out for comment. There is a need to have a single ballot cycle with one version of the document.
- Different ballot cycles: i.e. there are 90 day ballot cycles for ISO and CEN, whilst for HL7 there is a 30 day ballot cycle. It was reported that the HL7 TSC has discussed this issue and may extend their ballot cycle.
- The need to harmonize processes for resolution of comments
The HL7 process is that the committee/work group goes through comments one by one for resolution, whereas ISO TC 215 working groups create a disposition of comments document which goes out for approval.
If the project team/experts review all comments as a single group, then there would be no need to repeat comment review in another forum i.e. have a single open process for submission of comments and review.
It was suggested that most issues can be resolved virtually, with a face to face meeting held to resolve difficult issues to finish and approve the resolutions. This could occur at any SDO meeting, but HL7 meetings may attract the most people. It was noted that it is important to engage all communities of interest in the resolution of comments.
- Editorial issues
Editorial / style differences between HL7 and ISO were noted, in regard to document formatting, and placement of normative and informative provisions in documents.

- Communications about joint projects
Communication about joint projects is seen as important – how does this information go out to SDOs?

3.2 Electronic Health Record Communication: 13606, parts 1 to 5

Dipak Kalra reported on the current status of 13606

	CEN	ISO
Part 1	published February 2007	currently out for FDIS
Part 2	published July 2007	currently out for DIS
Part 3 ballot	currently out for Formal Vote	about to be released for DIS
Part 4 ballot	published in March 2007	about to be released for DTS
Part 5	currently out for informal comment period in both SDOs	

Dipak raised several points of collaboration with HL7, including the following:

- An NHS sponsored project to develop implementable transformation between 13606, parts 1 and 2 and particular templated CDA documents, starting with discharge summary.
- An NHS sponsored project to represent clinical information in *openEHR* archetypes.
- 13606 data type profile requirements contributed to the HL7 data types work via CEN comment process.

Mark Shafarman noted that following the Joint Working Group meeting held at the October 2007 CEN meeting, a letter was provided to ISO member bodies with the FDIS ballot of 13606, part 1, to make the ISO community aware of current and planned harmonisation efforts. For future ballots needing harmonization (or with existing harmonization projects), it is intended that this information on harmonisation will be added directly to the ISO ballot documents.

3.2 ICH and related pharmacy projects

Stephen Kay reported that Ian Shepherd, convenor of ISO TC 215 Working Group 6, is the project lead for the pharmacy projects raised by ICH. The intention is to work in the Joint Initiative framework, and this was related to the pharmacy meeting today. That meeting looked at the process for developing the six work items on identification of medicinal products in ISO TC 215; looked at project scopes and identified ISO project leads. There are a number of harmonization and scheduling issues still to be addressed. HL7 will be asked to provide co-chairs.

It was noted that Ed Hammond has identified that John Quinn is the HL7 contact point for joint projects and he will identify co-chairs.

There was some discussion about the ISO TC 215 WG6 Individual Case Safety Report projects. There seems to be a need for further information about these projects, their current status and HL7's role.

3.3 HL7 CDA

Audrey Dickerson noted that HL7 CDA and HL7 v 2.5 are opening through ISO for DIS ballot, and advised that HL7 members should participate in the ISO balloting process through their national member bodies.

3.4 Detailed clinical modelling group

William Goossen stated that he has completed the report on the August 2007 workshop of the detailed clinical modelling group, and that this report will be tabled at the next Joint Working Group meeting. William noted that the report contains a number of recommendations for consideration.

3.5 CEN HISA

Mark Shafarman reported that he has done a mapping from the CEN HISA information model to the HL7 RIM. This mapping is accessible on the CEN TC 251 website.

4 Other Business

4.1 Other participants

Grahame Grieve asked whether there are any other SDOs that should be involved, and whether IHTSDO should be invited. It was reported that Martin Severs, Chair of the IHTSDO Board, had attended the first Joint Working Group meeting in Brisbane. Bernd Blobel suggested that ATSE, who have established an e-health group, and also OASIS, are potential participants.

4.2 Future meetings

It was noted that there is now considerable interest in collaboration and harmonisation, with over sixty people at the current meeting, an increase from eight people at the first meeting held at HL7 three years ago. However, scheduling the joint meeting in the evening, following the day-long Affiliate's Council meeting has been less than optimal. Since much of the information presented at joint meeting has also been presented at the Affiliate's Council meeting, there has also been unnecessary duplication. If we were not to present the information twice, the Affiliate's Council meeting could be shortened, which would allow future joint meetings to take place in the late afternoon rather than the evening. This change has been arranged for the next HL7 Working Group meeting.

4.3 Email lists

The email list for this meeting is being transferred to the Joint Working Group, and will be administered by Elizabeth Hanley.

Participants

Mark Shafarman	United States	Ana Estelrich	France
Charlie McCay	United Kingdom	Nicholas Canu	France
Gary Dickinson	United States	Vincent McCauley	Australia
Bernd Blobel	Germany	Ron Parker	Canada Grant Gillis Canada
Sylvia Thun	Germany	Audrey Dickerson	United States (ISO TC 215 Secretariat)
Klaus Veil	Australia	John Ritter	United States
Jim Foss	United States	Melvin Reynolds	United Kingdom
Ian Townend	United Kingdom	Elizabeth Hanley	Australia (JI/JWG Secretariat)
Rik Smith	United Kingdom	Ed Hammond	United States
Tim Ireland	United Kingdom	David Rowed	Australia
Dan Anderson	United States	Dipak Kalra	United Kingdom
Robert Worden	United Kingdom	Gaby Jewell	United States
Paul Knapp	Canada	Andrew Hinchley	United Kingdom
Kristi Eckerson	United States	Stephen Kay	United Kingdom
Anja van Haren		Catherine Chronaki	Greece
Randy Levin	United States	Thomas Norgall	Germany
Mary Ann Slack	United States	Masahara Obayashi	Japan
Garry Cruickshank	Canada	Ken Toyoda	Japan
Larry Callahan		Michio Kimura	Japan
Gary Meyer	United States	Lenel James	United States
Jos Baptist	The Netherlands	Richard Dixon Hughes	Australia
Lisa Stevens	United States	Heather Grain	Australia
Pat Van Dyke	United States	Shirin Golyardi	The Netherlands (CEN TC 251 Secretariat)
Amnon Shabo	Israel	Terry Hardin	United States
D. Walker	United States	W. Gregory	United States
Julie James	United Kingdom	Bill Rosen	United States
Peter Goldschmidt	United Kingdom	Andrew Marr	United Kingdom
Kai Heitman	Germany	Kaori Nomura	Japan
Robert Stegwee	The Netherlands	Kostas Kidos	United States
William Goossen	The Netherlands	Karen Cuthbert	United States
Grahame Grieve	Australia	Tim Buxton	United Kingdom
Russell Hamm	United States		
Hugh Glover	United Kingdom		
Sarah Knoop	United States		

Annexure C – Summaries of Other Presentations

AHIMA Presentation to HL7 Board

Don Mon, CEO of the American Health Information Management Association (AHIMA), gave a presentation along the following lines to the meeting of the HL7 Board which was held on Tuesday, 15 January.

The Mission of AHIMA is to be the professional community that improves healthcare by advancing best practices and standards for health information management and the trusted source for education, research and professional credentialing.

The AHIMA Vision statement is quality healthcare through quality information. The preferred future is the EHR Electronic Environment

Strategic goals for EHR

- standard functionality, data content, data definitions, high data quality across the continuum of care for EHR systems
- EHR systems helping CDOs maintain a legal record for business and disclosure purposes
- Collect once, repurpose many times
- EHR systems reaching a critical mass so that health information can be exchanged between EHR and Personal Health Records (PHR) systems and across HIEs
- Protecting the privacy of the individual and the confidentiality of health information

Strategic goals for PHR

- Consumers are able to make good health decisions
- Consumers understand their roles and responsibilities in maintaining a PHR
- Standard functionality, data content, data definitions, high data quality
- PHR systems reach a critical mass so that health information can be exchanged between EHR and PHR systems, and across HIEs
- Protecting the privacy of the individual

Strategic goals for vocabulary & classification

- Help vocabularies and classification systems become more mature
- Vocabularies, terminology, classification, and coding systems are part of data standards and are widely implemented in E.H.R systems

Strategic Goal for Data Content

Under the governance of groups of expert stakeholders (Medical Specialty Societies) harmonise disparate data standards into a single set of standards

managed by an SDO (HL7) which is then harmonised amongst other standards (HITSP) and used for certification of EHR systems (CCHIT).

[**AHIMA's interest in personal health records (PHRs)** was particularly noted. AHIMA has a website about personal health records, <http://myphr.com/>, with links to 75 vendors who provide personal health records.]

Microsoft HealthVault

Presentation of HealthVault to HL7 Board

The following is a summary of the presentation on Microsoft HealthVault to the HL7 Board by Bert Van Hoof of the Microsoft Health Solutions Group.

Traditional health in the United States is focussed around the needs of the provider, employer, payer or supplier but not the consumer.

There has been a shift in the past two years with the consumer now placed at the centre of various healthcare strategies. This has led to interest in personal portable health records to support health and wellness, encounter management, lifestyle, condition management, search, education and communication.

Microsoft launched Health Vault on October 4 2007. Problems that they are trying to solve are:

- Healthcare is an information problem
- But healthcare is fragmented

HealthVault is a private, secure data storage and sharing platform that will enable seamless data exchange between hundreds of different health applications and devices and put the consumer in control of their healthcare. HealthVault is not a PHR but a way for individuals to collect, store and share their health information. It is a shared data platform.

It has three components – Web Health Search, HealthVault Account to create records and HealthVault Connect (to devices).

The Web Health Search is a private site and precautions have been taken to protect privacy and confidentiality – no data can go in and out of an individual's account without their consent. Sensitivities to privacy vary across the spectrum from wellness to chronic care, and it was reported that a lot of emphasis has been put on ensuring privacy in the Microsoft HealthVault. Data can't be forwarded to another provider without the individual's consent.

The system is inclusive of industry standards (i.e. it conforms to Microsoft's view of open platform systems).

There are no fees or charges to use the platform.

In future there are plans to do more with devices – measurement, portable and interface devices.

It was noted that Health Vault supports HL7 CCD but that Microsoft may have some reservations about the direction of the HL7 PHR work items (such as the PHR-S Functional Model).

Discussion of HealthVault at EHR/PHR Birds of a Feather

Further to the above, the presentation of HealthVault at the Monday evening BoF Session included:

Results of research into the information needs of Health Consumers

- Microsoft research has identified that overworked mothers perform the role of family health manager; not just for themselves but often for children, parents, elderly relatives and even the family dog. They are the primary target for improved access to family health information.
- The typical activities being undertaken by consumers when seeking health information include:
 - encounter management
 - health and wellness
 - education (including specific knowledge)
 - condition management (including lifestyle management)
 - social networking and collaboration, and
 - searching for information.
- Health care is an information management problem but health care delivery is also fragmented and critical information is locked away in silos. Consumers therefore receive sub-optimum care.

Nature of the solution

- Microsoft does not see HealthVault as a PHR or PHR-S, which it characterises as silo solutions. It is promoted as a secure communications structure through which users can collect, store and share health information.
- HealthVault Connection Center is a desktop utility for users to upload information from their health and fitness devices and applications to their HealthVault "account", as well as to view the information locally.
- HealthVault also has a Search feature that allows users to search for information on health topics within HealthVault and on the Web.
- Microsoft application partners provide applications that access and store their customer's health data in Microsoft's HealthVault with privacy control.
- Only US residents can currently become HealthVault users.
- Both US and non-US companies can develop applications that use HealthVault information, or create device drivers for HealthVault desktops.

Monetisation

- In response to questions about monetisation, it was noted that access is free to both users and application partners. While the business model is still under

development, it is likely that Microsoft revenues will include some from advertising (e.g. Pharmaceuticals) associated with the search function.

For more details:

www.microsoft.com/hsg

<http://msdn2.microsoft.com/en-us/healthvault/bb663039.aspx>