

**Report on the
HL7 Working Group Meeting
held in
Boca Raton, Florida,
9-15 September 2006**

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

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31 October 2006

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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
CEN	Comite Europeen de Normalisation
CMET	Common Message Element
DCM	Detailed Clinical Model
DICOM	Digital Imaging and Communications in Medicine
DMIM	Domain Message Information Model
DoHA	(Australian Government) Department of Health and Ageing
DSTU	Draft Standards for Trial Use
HER	Electronic Health Record
EHRS	Electronic Health Record System
HISO	(New Zealand) Health Information Standards Organisation
HITSP	Health Information Technology Standards Panel
HL7	Health Level Seven
HTTP	HyperText Transfer Protocol
IHE	Integrating the Healthcare Enterprise
ISO	International Organization for Standardization
ITS	(HL7) Implementation Technical specification
LOINC	Logical Observation Identifiers Names and Codes
NCI	(US) National Cancer Institute
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

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 awareness of the status of international standardisation is important to standards developers, the health ICT industry and the health sector generally. The contributions from Australian delegates to the Boca Raton meeting to this report are therefore gratefully acknowledged.

Executive Summary

The third HL7 Working Group Meeting for 2006 was held in Boca Raton, Florida from 9 to 15 September. Ten Australians were present at the meetings out of some 540 persons attending from 19 different countries.

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 Australian organizations and personnel are leading efforts within both HL7 and the UK NHS to enhance V3 to ensure its sustainability.

Actions flowing from the HL7 Strategic Initiative occupied a significant amount of the informal and administrative discussion at this meeting. Fundamental changes associated with HL7 becoming a more professional organisation include a full-time CEO with a strong representative role; competent technical support for standards development; and an enhanced funding model.

Recruitment of the CEO for HL7 has reached the short-listing stage with an appointment expected prior to the January 2007 working group meetings.

The Strategic Initiative has identified the importance of HL7 as a global SDO, but the challenges of obtaining and assimilating more effective input from global stakeholders and influencing global agendas remain significant. The substantial contributions of Australian representatives in helping HL7 to address these issues is strongly appreciated.

Recent research by HL7 mirrors the results of similar studies by Standards Australia in indicating that the major cost of standardization lies with organisations that contribute the time and expertise of their personnel to support standards work (in return for knowledge and influence in the standards process). Like other SDOs, HL7 needs to optimise the return that its activities provide to these organisations.

Although not part of the HL7 Working Group meetings, a preliminary convention of invited experts in clinical modelling from around the world met for two days and resolved to pursue a detailed clinical modelling (DCM) initiative to investigate:

- collecting clinical information models (viz. data groups, archetypes, local domain models) being developed by different organisations;
- expressing them in a canonical form (initially using the *openEHR* reference model, archetypes and tooling); and
- comparing and classifying them and storing them in a repository for re-use and to avoid duplication.

If the promise of sharing detailed clinical models can be realised via the DCM initiative, this will greatly assist interoperability and avoid duplication of effort. It therefore deserves support. The initiative has resolved to trial the approach on adverse events and reaction models but progress will depend on whether the organisations involved can commit the level of scarce health informatics resources needed.

Significant implementation of various forms of HL7v3 is now occurring throughout the world. There seems little doubt that various combinations of HL7v3 messaging and/or CDA r2 documents will be increasingly deployed over the next few years with

organisations such as the US government (and its NHIN projects), the UK, France, Canada, the Netherlands, Finland, Mexico and, now, the NATO forces and IHE investing in these technologies – which themselves are beginning to adapt and mature in the light of practical experience.

As indicated by the investigation and development work still continuing in the United Kingdom (which was presented to the HL7 Board) and the experiences of other early adopters such as the Netherlands, considerable effort and some fundamental changes are required to ensure HL7v3 and its associated tooling become a practical, usable interchange technology that can be used widely and consistently across a health system and its vendor community. Nevertheless, these challenges are being addressed in a collaborative manner and many are expected to be resolved within the next 12 to 18 months.

While high levels of semantic interoperability may be the ultimate goal, practical shared EHR implementations are giving higher priority to getting clinical information flowing in a usable form, rather than restricting information flows to that which is machine interpretable.

HL7v3 documents and message structures appear to be emerging as a preferred means of defining and expressing clinical content. The Health Services Specification Project (HSSP) and close ties between HL7 and OMG (and IHE) are helping to ensure that HL7 is part of the evolution toward SOA in healthcare, and HL7 (with its existing clinical terminology associations) is likely to remain a major forum on interoperability of health-related content.

After a period of limited progress, the Templates SIG is moving to formalise the functional requirements of HL7 templates as informative content for the next ballot cycle. These functional requirements are based on analysis of template use cases and CEN 13606 with the aim of harmonising the core requirements of HL7 templates and CEN archetypes (and allowing machine translation between them).

The HL7 v3 ballot is also to be updated with respect to best-practice approaches to template creation, template definition, and implementation of templates as a wire protocol within the XML ITS – including appropriate use of 'template id' within instances of HL7 v3.

Based on work by Grahame Grieve, the possibility of simplifying the HL7 modelling hierarchy with greater use of constraint techniques (archetypes/ templates) and using ADL (against the RIM) as a means of expressing HL7v3 templates was debated. It was noted that other approaches are also possible including work by the UK NHS, which needs a workable approach for transporting a wide variety of clinical content using common message formats and expects to realise its preferred interpretation of HL7v3 templates by the end of the year.

The UK NHS team and Grahame Grieve presented the results of their joint work on new Implementation Technology Specifications (ITS) and on mapping and harmonisation of data types, which is needed to support unambiguous rendering of HL7v3 content (and harmonisation with other standards). Adoption would involve changes in the way HL7 represents some information in HL7v3 structures and may therefore be subject to some push back from vendors that are already committed to (their own) implementations of HL7v3 data types.

Standardised translations of v2 material to CDAR2 and v3 (and back) are increasingly being sought to enable gradual transition to new information sharing networks in a world dominated by legacy systems.

In the United States, some of the National Health Information Network (NHIN) prototypes appear to be making significant progress with shared EHR interoperability on a local scale and are now well into some of the harder issues. In presentations and follow-up on these projects, it was noted that:

- Significant investments have been needed to realise some level of consistent interoperability
- Interoperability is predominantly based on using HL7v3 frameworks (including CDA r2) coupled with web service technologies,
- Several (but not all) use IHE XDS to assist with clinical document sharing
- The different NHIN prototypes appear to be progressing at different rates, with those having stronger health sector backgrounds being further into implementation
- Political and policy issues including identification of individuals and providers, establishment and realisation of privacy, consent and access control regimes, consumer contributions to the EHR and the longer-term role of the PHR are all hot topics that have delayed or had some impact on NHIN implementation
- The practical need to dynamically, reliably transform between HL7v2, HL7v3 and back is of concern to an increasing number of these projects
- There is no clear-cut best model for implementation of shared EHR systems; however, the results of NHIN work due for completion in mid-2007 will help inform decisions about some approaches.
- Projects of different types in various countries are increasingly adopting multi-level CDA r2 implementations as a means of handling the mix of structured and unstructured information encountered in practical shared EHR implementations – there is growing acceptance that it will be quite some time before the majority of clinical data will be in a semantically interoperable form.

1 Introduction

The third HL7 Working Group Meeting for 2006 was held in Boca Raton, Florida from 9 to 15 September. This plenary meeting was notable for its sizeable attendance, with over 540 registered attendees, 111 of which were from 18 countries outside the USA. There were substantial delegations from national implementation programs in the UK, The Netherlands and Canada comprising both managers and technical experts strongly committed to implementing the next generation of HL7 standards based on HL7 v3.

The Australian delegation comprised ten people. David Rowlands, Richard Dixon-Hughes, Brett Esler, Dick Harding, Klaus Veil, Chris Lynton-Moll and Sam Heard were subsidised via funding from the Department of Health and Ageing; while Max Walker, Grahame Grieve, and Heather Grain were supported by the Department of Human Services, Victoria, Jiva Medical and Latrobe University respectively.

2 Background

Health Level Seven is a leading, global, accredited standards development organization (SDO) operating in the healthcare arena. Health Level Seven's domain is clinical and administrative data. . Other SDOs produce standards (sometimes called specifications or protocols) for healthcare domains such as medical devices, imaging or insurance transactions

HL7 is a not-for-profit, volunteer based organization. Its 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 - develop the standards. Like all accredited SDOs, HL7 adheres to a strict and well-defined set of operating procedures that ensures consensus, openness and balance of interest.

HL7 develops specifications, the most widely used being a messaging standard that enables disparate healthcare applications to exchange keys sets of clinical and administrative data.

Members of Health Level Seven are known collectively as the Working Group, which is organized into technical committees and special interest groups. The technical committees are directly responsible for the content of the Standards.

HL7's Mission is to be an international community of healthcare subject matter experts and information scientists collaborating to create standards for the exchange, management and integration of electronic healthcare information. HL7 promotes the use of such standards within and among healthcare organizations to increase the effectiveness and efficiency of healthcare delivery for the benefit of all.

"Level Seven" refers to the highest level of the International Organization for Standardization (ISO) communications model for Open Systems Interconnection (OSI) - the application level. The application level addresses definition of the data to

be exchanged, the timing of the interchange, and the communication of certain errors to the application. The seventh level supports such functions as security checks, participant identification, availability checks, exchange mechanism negotiations and, most importantly, data exchange structuring.

Standards development in HL7 is undertaken via 16 Technical Committees (TCs), which are listed in Attachment 1, some of which have subordinate Special Interest Groups (SIGs) to address new areas that may need coverage in HL7's published standards. There are currently 23 active SIGs. Draft standards developed by these groups 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. As for 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 the commenter.

HL7 currently also has seven administrative committees, a Technical Steering Committee comprising all TC and SIG co-chairs, an Architectural Review Board and several Task Groups.

HL7 Working Group (WG) Meetings are held three times per year, shortly after each ballot cycle. Their primary purpose is to enable the progression of draft standards through the balloting and publication cycles - TCs and SIGs meet to draft and/or edit standards, prepare material for balloting, reconcile ballot responses, etc. TC, SIG and administrative committee meetings are generally held concurrently, which requires significant coordination 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, and its (ballot package) drafting and publications group meets bi-weekly. During the reconciliation of over 3,000 comments on the conformance criteria for the EHR Systems Functional Model, breakout groups on the components of the Functional Model (Direct Care, Supportive Information and Information Infrastructure) were also meeting weekly by telephone.

The Working Meetings also provide opportunities for the HL7 Board, Technical Steering Committee, International Council and other standing committees and task groups to meet.

3 Objectives

Australia participates in international standards development activities in accordance with its obligations under World Trade Organisation treaties. The overarching objectives are to promote free trade and its benefits (by lowering the cost of integrating and implementing health information systems, many of which are imported, and by reducing costs to Australian exporters – both 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 to improve Australian capacity in health informatics and

health standards development by expanding domestic knowledge and experience based on international best practice.

Specific objectives for international standardization via HL7 during 2006-07 include:

- Monitoring and influencing HL7's strategic positioning as a global SDO, encouraging its collaboration with other global SDOs and the assessing the strategic positioning of its key products (HL7 V2x, V3, CDA, EHR Models, etc.) so as to maximise Australia's capacity to ensure that our health messaging and related requirements are supported unambiguously by international standards.
- Negotiating the inclusion of Australian healthcare messaging requirements into HL7 V2.6, 2.7 and V3 specifications for:
 - Patient administration
 - Diagnostics (pathology, radiology), and
 - Collaborative care.
- Negotiating the inclusion of Australian health sector requirements into the conformance framework for the HL7 EHR-S Functional Model and the proposed EHR Interoperability Model DSTU; negotiating towards harmonisation of CEN/ISO 13606 and HL7 V3; and negotiating international standardization of the terms and definitions used in EHR related standards.
- Assessing HL7's approach to and compatibility with service oriented architectures, as input into Australia's national direction setting; and negotiating the inclusion of Australian health sector requirements, and in particular those described by NEHTA, into service specifications being jointly developed by HL7 and the Object Management Group (OMG).
- Assessing the positioning, development, implementation, utility and effectiveness of HL7's Clinical Document Architecture (CDA), for input into Australia's national direction setting.
- Assessing and exploring approaches to the carriage of archetypes in HL7 V2 messages for referral, diagnostic results and collaborative care, for input into Australia's national direction setting.
- Negotiating towards the international harmonisation of common data types 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 International

Nineteen countries (including the USA) were represented in Boca Raton. HL7 currently has 27 recognised International Affiliates (listed in Attachment 2), and negotiations with 5 other countries are in process. Poland's affiliate ship has lapsed.

Twenty eight percent (28%) of HL7 membership is US based and 45% is European (UK and Germany being the largest). However, the US accounts for 53% of HL7's revenue.

A communication strategy is being developed, led by the UK, aiming to generate more information exchange between people developing and using HL7, and V3 in particular. Several Affiliates struggle to develop and maintain a web presence.

More detailed information on V3 implementation projects will be collected by interview and survey to enable a more detailed picture of implementer profiles. This will also include seeking out implementers that do not attend working group meetings.

Renewed Affiliateship Agreements (for 2 years, commencing January 2007) were distributed for signing at Boca Raton. These incorporate substantial fee increases, and a number of Affiliates expressed concern to the Board about lack of consultation in developing the new agreements.

As usual, updates presented to the HL7 International Council Meeting provided an overview of the state-of-play across the HL7 community.

4.1 International Affiliate Activities

Argentina

HL7 Argentina has developed a website and is currently developing a V2.6 claims implementation guide. They have also developed training materials in Spanish and are planning for an HL7 conference targeting Latin America and Spain. Education efforts will focus on Clinical Document Architecture (CDA) and Version 3 (V3).

Australia

HL7 Australia continues to focus on Standards provision, Education, Support and certification. It has established strategic alliances with the openEHR organisation as well as AHML, which has been able to expand the range of HL7 V2 messages it tests and certifies and now services 32 countries. NEHTA has developed an Interoperability Framework (available on NEHTA's website) and a strong interest in service oriented architectures (SOA); acquired a national license for SNOMED; and is working on personal and provider identifiers and clinical data sets.

Canada

An Infoway Standards Collaborative has been established to support Canada's HL7, ISO, DICOM, IHE etc initiatives in a coordinated way. HL7 Canada has completed a chronic disease management ballot (see HL7 Canada site), and is defining realm localization and Object Identifier (OID) registration processes. They are also attempting to develop a coordinating approach to managing the HL7 artifacts developed via disparate projects.

China

HL7 China has been reorganized and has gained government support. It will be developing a comprehensive set of activities in the near future. It has already held an orientation to HL7 session; is translating HL7 documents; and is looking at localization processes, priorities and documentation. China's focus is on V3, and several trials are now underway. An EHR Steering Committee has been established.

Finland

CDA R2 implementations are advancing in Finland. New laws supporting e-prescribing and EHRs are going to Parliament next month. The roles of V3 messages and services in the national architecture are being considered. V3 efforts include death notifications to the national person registry; regional scheduling; and the national messaging service, connecting all providers, is to be based on V3. Prescribing will be a combination of V3 messages and CDA. Finland is also commencing work on certification and conformance issues

France

HL7 France is conducting education and training activities focusing on V3 and CDA. Most implementation projects in France are still using V2. A national PHR project is being developed – this will be document based, using PDF and CDA R2. Laboratory reports are being developed in CDA R2, based on IHE specifications.

Germany

Germany's national telematics project includes doctors' reports and e-prescribing, based on CDA R2. HL7 Germany has been very active in conference representations.

Netherlands

Membership of HL7 Netherlands has grown significantly. Two new SIGs have commenced, on patient care and pharmacy; and a focus meeting on transfers of care has been held.

National initiatives include a national switching point; a medication record; and an out-of-hours GP summary. These will roll out in 2007. Other developments (including perinatology and cardio-vascular accident) are underway, and others are being initiated (including pathology and an electronic child record).

Issues include the need for discrepancies in domain developments to be harmonized; OID registry management; the relationships between local and international developments; and IHE collaboration.

New Zealand

HL7 NZ's main stakeholders are the Ministry of Health and HISO. E-prescribing and electronic discharge projects are underway, as is development of a "forms server", which will house a store of information artifacts for reuse. NZ is determined to use CDA, but there has been a local backlash against V3 on the basis of perceived problems internationally (these perceived problems including project risk due to long message development times, and lack of skilled practitioners.). HL7 NZ is concerned

about the impacts of these perceptions, and notes that while the HL7 Board regards V3 as technically rich, rigorous and fit for purpose, it has failed to communicate this.

Romania

Romania is a new affiliate. An initial workshop will be undertaken in Romania to build a presence for HL7 and identify priorities, and international input is sought.

UK

Wales is now beginning its national program, and Scotland is likely to follow soon. Interoperability with England is important, so HL7 UK is looking to develop UK profiles (Connecting for Health profiles being just for England). Management of OIDS is also an issue.

4.2 HL7 International Conferences/Events

The HL7 Interoperability Conference was held in Koln in August 2006 and focused on exchange of international experiences with HL7 Version 3, including CDA in particular. Conference proceedings are available at <http://ihic.hl7.de/proceedings.html>.

Venues being considered for this event in 2007 include New Zealand, Crete and Stockholm.

4.3 Collaboration with other major SDOs

Senior HL7 representatives confirmed their desire to collaborate with other international and global SDOs.

ISO TC215 report

The HL7 RIM has been successfully balloted and published as an ISO standard (ISO 21731). There have been some administrative delays in progressing the message development framework, but it is proceeding through balloting processes and is now ready to go to Final Draft International Standard (FDIS) status.

Data types for use in health care data representation will be addressed in the 13606/HL7 harmonisation process – see below. CEN13606 Part 1 will be balloted in October 2006.

Seven new work items were submitted by HL7 via the US delegation in Korea - Version 2.5; Clinical Document Architecture (CDA) Release 2; Clinical Terminology Service (CTS) Release 1; structured product labelling; individual case safety report; electronic submission of stability data; and annotated ECG for clinical trial submissions. Of these, the first three were approved to proceed, but the other four have not yet been approved, having passed ballot but with insufficient experts nominated to work on them.

ISO TC215 and CEN TC251 will be holding joint meetings in Geneva in October 2006, contiguous with the 2nd Global Health Information Technology Summit and the inaugural HIMSS Europe meeting.

CEN TC251 report

A new draft business plan is being developed, in response to realization that changes are needed to the way CEN TC251 operates. Desired directions include greater collaboration with other SDOs; greater engagement with suppliers; and more pragmatism - standards must be implementable. The draft plan, will be discussed by the TC's management group in late September, and presented to the TC215/TC251 joint meeting in October. The section on the benefits of standardization is still under development.

CEN's preference is to produce ISO standards. All work items in future will start with business requirements and finish with implementation guides.

Balloting toward acceptance of EN 13606 (and archetypes) within CEN and probably ISO appears to be proceeding – with hold-ups being more due to administrative and editing delays, rather than issues with the underlying technical content and its political ramifications (despite perceived negative implications for Norway and the Netherlands, which have made significant commitments to different approaches).

Balloting of the EN HISA (Health Informatics Services Architecture) standards is proceeding but recent negative votes and comments from the Netherlands have indicated some inconsistencies and a need for better quality in the products – a matter Australia may wish to have addressed, if using the HISA approach or voting on these documents as ISO standards.

ISO/CEN/HL7 Coordination

A Coordination Meeting is now held at every HL7 meeting. This was attended by about 30 people who are active across the three SDOs. Key topics included CEN13606/V3 harmonisation, which was discussed at some length; detailed clinical models; two important initiatives being undertaken by the NHS's Connecting for Health program; and a draft paper from ISO TC215 about processes for ongoing harmonization.

- 13603/V3 harmonisation.

Arising from the last HL7 WG meeting, a proposal has been prepared to develop an implementation guide for CEN13606 that shows how to implement 13606 in an HL7 V3 environment. This has previously been discussed as forming CEN13606 part 5, but CEN is uncomfortable with this. CEN's issues are that there may be several implementation guides, not just an HL7 V3 one; and that an implementation guide is unlikely to be normative whereas CEN13606 is designed to be normative. Dipak Kalra (UK) will be scoping Part 5 soon.

Nevertheless, there remains very strong commitment to the harmonisation project. There is growing international interest in EHR interoperability and the standards that support this. Vendor representatives present at the Coordination Meeting strongly expressed a desire for convergence of standards, in order to realize economies of scale in software development, and they are concerned that this is not happening, or not happening quickly enough. They expressed strong support for this project.

CEN13606, CDA and Clinical Statements are all specified at high levels of abstraction, and require detailed implementation guides. There are existing pieces of work that can be built upon for this development.

The proposal was presented to various TCs and SIG meetings at Boca Raton, with the aim of actively seeking resources (both \$ and volunteer) to enable the project to be undertaken with speed.

Issues discussed at the Coordination meeting included how this work should be published – as normative or informative? By whom? Via which balloting processes, in which time frames?

- Detailed Clinical Models (DCM).

A select group of leading clinical information experts met independently for two days prior to the WG meetings to examine common approaches to creating and sharing clinical information models. This group included representatives of some of the most influential producers and users of clinical information standards, many of whom have teams defining clinical content on a full-time basis. There is considerable concern among these key players at the potential loss of interoperability and long-term benefits because of complexities of approach and need for more effective collaboration between standards developers working in clinical informatics and terminologies.

The group resolved to continue working toward more effective collaboration in the definition of clinical content by:

- Progressing a “Detailed Clinical Models (DCM)” project with active engagement and ownership by relevant groups within HL7, CEN, and *openEHR*;
- Establishing a DCM repository based on common formalisms – initially representing clinical information as *openEHR* archetypes using the *openEHR* reference model and tools;
- Evolving common approaches to the definition of clinical content for use in EHRs, clinical information interchange and clinical decision support;
- Improving collaborative processes for defining and representing clinical information – based on more editorial review and fewer “full consensus” processes; and
- Establishing the activity as a set of transparent processes and then rapidly expanding it to support the full range of potential stakeholders, which were identified as including:
 - Major US health informatics users, researchers and developers – including, Kaiser Permanente, InterMountain Health Care, Mayo, Partners Healthcare;
 - National programs: US-VHA, US-NIH/NCI, UK-NHS, NEHTA, Canada Health Infoway, The Netherlands;
 - The main health informatics standards bodies – HL7, CEN, ISO; and
 - In the longer term, clinical professional bodies and experts.

Hopefully, this work will provide focus to efforts to provide a recognised means of constraining clinical content within the HL7 V3 community – and a pathway to more consistent representation of clinical content within CDA

documents. NEHTA's Clinical Information Initiative would appear to have a great deal to offer this project.

Greater detail concerning the DCM project is provided at Attachment 2.

- Connecting for Health projects.

Two important pieces of work are currently underway, led by Grahame Grieve (Jiva Medical):

- Grahame has built a new implementation model for data types, in UML. This maps V3 to *openEHR*, and suggests that a combined/unified standard could be developed, with effort on both sides; and
- Grahame has also built a tool for converting V3's Visio models into computationally valid archetypes. He will be developing the reverse functionality in the near future.

- SDO harmonization.

A draft paper proposing a model for harmonising standards between the major health informatics SDOs including ISO, CEN and HL7 has been prepared by Don Newsham, Convenor of ISO TC215 WG1. This is not yet for circulation but limited copies were distributed for comment. The paper will be discussed in Geneva, along with a draft paper on changes to TC215's business model, prepared by David Rowlands.

There was no opportunity to discuss this item in Boca Raton.

5 Organisational Issues

The major item of business, and of concern, of an organisational nature was the HL7 strategic initiative.

5.1 Strategic Initiative Task Force

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, funded by a grant from the Robert Wood Johnson Foundation. The overall goals are to:

- 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 Task Force (SITF) report approved by the HL7 Board in March 2006 in principle as the basis for on-going implementation planning recommends as follows:

- HL7 will implement a new business model and organizational structure;
- HL7's Board will formally approve a product and services strategy that is reviewed annually;
- HL7 will optimize the effectiveness of its volunteers and other resources;

- HL7 will develop a brand hierarchy that helps the marketplace understand the relationship of its products to each other and to the overall organization;
- HL7 will develop consistent organizational messages and a communications strategy to disseminate those messages;
- HL7 will implement a product-oriented project management approach to ensure development of high-quality standards and associated products in a committed timeframe; and
- All standards will undergo quality testing at key stages of the development process.

HL7's Advisory Committee (of which Richard Dixon-Hughes is a member) reviewed the SITF report and advised that it felt that some of the changes to be excessive. This was considered at the Board's August retreat, where the core recommendations of the Strategic Initiative Task Force were discussed at length and accepted.

Key activities include:

- A US Affiliate will be established with careful consideration of the political and financial implications;
- The search for a full-time Chief Executive Officer (CEO) is underway, and it is hoped the CEO will be in place for the January meeting. There will also be a Chief Operating Officer and Chief Technology Officer, with a subordinate Technical Director. There will be other professional staffing, including project managers, technical editors and others; and
- Governance structures will change will commence during 2007.

The financial impacts of these changes will be significant, and will result in increases in membership fees and meeting registration fees of around 30%, plus increases in International Affiliate fees.

Consultation is being undertaken now, with organisational changes to be implemented in 2007. However, a number of concerns were expressed throughout the WG meeting, and in particular at a large consultation meeting held specifically to discuss the strategic initiative. These concerns include the impacts on international activities, and many important questions (eg re the role of CEO) were left unanswered. As a result, a number of documents have now been placed on the HL7 website.

It was noted that HL7's growth has brought with it difficulties in the time required to gain consensus as well as the responsiveness and coordination of the activities. Improved information flow and balloting processes are required to deal with this.

Australia is represented in key strategic initiative activities by Klaus Veil and Dick Harding.

5.2 Board Meeting

The HL7.org Board convened on the 11th of September, with the Affiliate Chairs and other invited guests in attendance. Considerable time was spent at the beginning of the Board Meeting reviewing the initial presentation of the Strategic Initiative Task Force outcomes to the HL7 Membership at the consultation meeting referred to above. The Board re-affirmed that the transition will result in very substantial

changes to the way HL7.org is structured and operates; and that the rationale and process of these changes must be communicated well to members and stakeholders to ensure buy-in and minimal disruption to standards development. It was agreed that expanded presentations and discussions of the changes needed to continue during the week and need to be very open and member-focused.

The HL7/CEN/ISO Implementation Guide project was outlined and supported; and reports regarding organisational relations with ADA, ASTM, CDISC, CEN, DICOM, eHI, IEEE, IHE, MedBiquitous, NCPDP, OMG, SNOMED and X12 were received. New agreements with WEDI and Liberty Alliance, CAQH, Oasis and the International Conference on Harmonization are being worked on. A formal alliance with NATO is also being worked on.

HL7's initiative for eLearning is progressing well. The goal is to produce a CD containing a general introduction to HL7 for distribution at HIMSS 2007.

The Tooling Initiative is also moving forward well, with support from the Eclipse Foundation, NHS, Infoway US DoD, Intel and others. Lloyd McKenzie is in an HL7 Architect role and HL7 is strongly supporting the work in cash, with IP and in kind.

In its continued efforts to implement e-working, the HL7 Board reviewed the use of electronic voting for co-chairs. Electronic voting for the Board and electronic balloting has been in place for some years as has electronic balloting. As from September 2006, the preferred communications method to members is by electronic means; paper is only available on an opt-in basis.

A team from the NHS reported on their work to review the HL7 V3 ITS. They have found that the V3 implementation problems that the NHS is facing go beyond what can be achieved by an improved ITS – see 7.3 below. The team will continue its investigations and will report back to the Board at the January Working Meeting.

5.3 Other organisational issues

The Community Based Health SIG (co-chaired by Max Walker) has changed its name to Community Based Collaborative Care and amended its terms of reference slightly to better convey the inclusion of behavioural health services.

The Medical Records TC was disbanded as of this meeting. This TC has not achieved a quorum for two years. Its work will transfer to the Structured Documents TC.

A resolution was passed asking message developers to research existing work for reusable artifacts prior to beginning new work, in response to growing concerns about duplication and variation.

HL7 is at an advanced stage in negotiating an MOU with the OASIS organisation which, along with other activities reported above, should bring HL7 closer to the IT mainstream, particularly in relation to security and electronic signatures.

Ed Hammond is the new Chair Elect of HL7. This will be Ed's third stint as HL7 Chair.

6 Plenary Session

The Plenary commenced with "State of the Union" addresses by Dr Kai Heitmann (International) and Chuck Meyer (HL7 Chair), covering a wide range of topics that are covered elsewhere in this report.

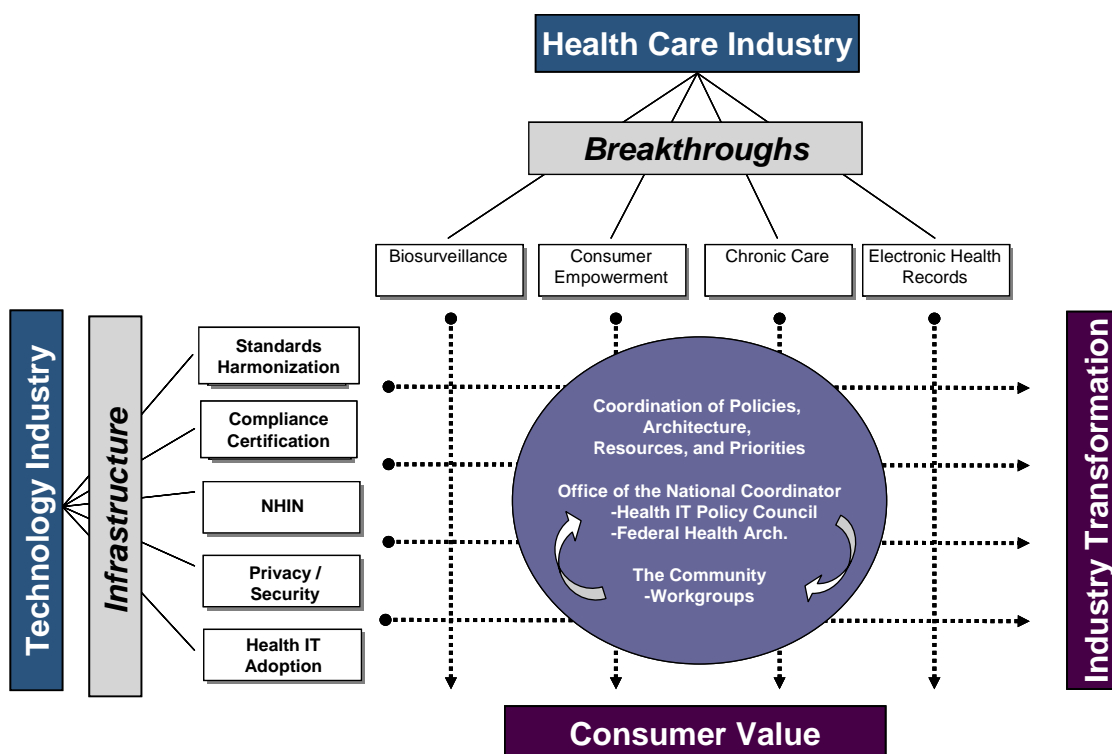
The keynote address was delivered by Sam Shultz, founding Chair of the HL7 Board of Directors in 1987. Dr Schultz has a distinguished career as an academic, CIO, researcher, educator and consultant in areas of health care information science and now predominantly works as a consultant. In charting an HL7 odyssey, he distilled some key principles for success in standardization:

- Get a good design that is workable to market and evolve it, rather than trying to design the theoretically perfect product - and recognise that standards continuously evolve. (in this he compared the success of TCP IP with ISO/OSI);
- Work in an open way, consulting widely on requirements; and
- Make sure vendors are part of the solution rather than part of problem.

Among many messages for the future, he recognised the importance and challenges of being a truly international organisation, of ontological clarity and purity and suggested that HL7 needed to embrace contrarianism and critics to help it to evolve its RIM-based products.

USA National Health IT Agenda

John W Loonsk, MD, Director Interoperability and Standards within the Office of the National Coordinator for Health Information Technology (ONCHIT) spoke on Standards and the National HIT Agenda in the USA outlining how standards and interoperability fit into the overall matrix of the National Health IT (HIT) Agenda as depicted in the following diagram:



He then discussed the five key information infrastructure activities (on the left hand side of the above diagram), which are being pursued through public private collaboration to drive fundamental transformation of healthcare industry processes to produce consumer value. These are:

- **Health Information Technology Standards Panels (HITSP)**, on which over 200 participant organizations from different industry sectors are represented with the aims of harmonization, filling gaps in standards coverage and achieving specificity. HITSP's outputs are sets of criteria that name standards and interoperability specifications to address priority use cases.
- Certification of compliance through the **Certification Commission on Health Information Technology (CCHIT)**, who establish compliance criteria, testing processes and manage certification marks with the aims of
 - Ensuring safe investment in systems and technology, and
 - Reliably determining functionality, security and interoperability.

Criteria for various components of Ambulatory Care EHR systems are being established during 2006 and 22 products had already been certified as meeting the compliance criteria for ambulatory care logs.

Criteria for Inpatient EHR are scheduled for adoption in 2007 with Networking to follow in 2008.

- The **National Health Information Network (NHIN)** comprises network services to facilitate the accurate, appropriate, timely, and secure exchange of health information.

Its current outputs are the trialling of four prototype architectures (discussed by later speakers); refined functional requirements (being finalised by NVHCS for October 2006 delivery); and the identification of business, operational and security service models, all with a view to presentation and discussion of initial outcomes at public forums in January 2007.

- **Security and confidentiality** – to ensure of patient information and confidentiality are protected by appropriate technologies & policies. Variations in regulatory requirements between States/Authorities are being evaluated, and recommendations are expected to flow to a **Security Privacy and Confidentiality Working Group** concerning practical implementation.

Future security and confidentiality will be based on architectures from NHIN, standards from HITSP and testing from CCHIT.

- To drive adoption, the HIT Agenda is also pursuing policy initiatives to identify blockages and find “breakthrough” areas needed to ensure that consumer value can be delivered through prioritization, incentives, removal of barriers, and regulation. In addition to formation of ONCHIT itself, specific measures include:
 - An Executive Order to ensure that the Federal Sector will use the defined standards in its next generation of purchases;
 - Providing relief to anti-kickback regulations that prevented interoperability between healthcare provider organisations and clinicians (previously banned to avoid the use of technology incentives to harvest referrals);
 - Making compliance with interoperability standards a condition for ambulatory care reimbursement;
 - Pushing the envelope on interoperability to achieve patient-centric rather than organization-centric information in the healthcare system;
 - Addressing difficulties in certification of a large installed base of legacy systems; and
 - Policy initiatives to harmonise data standards and health industry processes.

The American Health Information Community (**AHIC**) is responsible for the overall quality framework for the HIT Agenda and is considering the next set of priorities, which should include laboratory result reporting; and consumer empowerment – registration, medical histories, etc

Other priority needs for standards include security infrastructures and networking support; record location, access control, consumer centred information access, inter-organisation auditing, data persistence and the medico-legal record.

These presentations were followed by a panel session focusing on *HL7 and International, National and Regional Interoperability*, with the first four presentations providing an update on each of the NHIN consortium projects in the US.

NHIN Projects

Roberto Ruggeri, Senior Healthcare Technical Strategist of Microsoft presented on behalf of the **Computer Sciences Corporation (CSC) Connecting for Health (CfH) Prototype**. Features noted included:

- Health partners: - Mendocino HRE, California(3 health networks);
- Indiana Health Information Exchange (IHIE) (6 health networks);
- MA-SHARE, Boston Massachusetts (4 health networks)
- Prominent technology partners: Microsoft, Browsersoft, CITL, CfH, eHealth Initiative (eHI), EHRVA, Regenstrief Institute, SiloSmashers, Sun Microsystems.
- The Messaging Architecture comprises health industry application-messaging built on a web services-oriented interoperability stack:
 - Clinical Data Layer: HL7v3, NCPDP (pharmacy), X12 (HIPAA claims), ASTM CCR
 - Metadata Layer: XML Schema 1.0
 - Message Layer: SOAP 1.1
 - Transport Layer: HTTPS 1.1
 - Web Services Infrastructure: WSDL 1.1; UDDI 2.0; WS-I Basic Profile

Some lessons to date have included:

- HL7 v2.xml provides easier transition to v3 for leveraging existing investments;
- HL7 CDA is a good pathway into v3 for document-based clinical data (but CDA/v2 translation is required for PHR and EHR/Labs);
- More implementation support is needed for HL7 v3 standards, particularly:
 - Guidance on v2.x/v3 translation to leverage legacy investment; and
 - HL7 v3 implementation testing to improve compatibility of (XML) toolsets;
- Interoperation with standards other than HL7 is also needed in US settings; and
- The CfH framework calls for a minimal level of standardization – so individual markets have a choice as to how far standards need to drive their applications.

For more detail see:

<http://blogs.msdn.com/rruggeri/archive/2006/09/13/752651.aspx>

John Quinn, Senior Executive, Accenture presented on behalf of the **Accenture Appalachian Prototype**. Features noted included:

- Health partners serve large rural communities:
 - CareSpark in NE Tennessee and SW Virginia (5 health networks);
 - West Virginia eHealth Initiative (5 health networks); and
 - Eastern Kentucky RHIO (5 health networks)
- Prominent technology partners: Oracle, Apelon, Cisco, CGI-AMS, Lucent Glow, and Quovadx (Cloverleaf);
- Hospital/provider systems are different with few using federal health standards. Existing messaging is predominantly customized v2.x;
- Existing RHIOs lack information infrastructure for sharing health data (requiring this to be provided by the consortium);
- Key architectural principles:
 - Prototype to support three key use cases:
 - * EHRs to allow aggregated view of patient data (via EMPI/RLS etc)

- * Consumer Empowerment (→ new governance + flexible data locations)
- * Biosurveillance (→terminology/messaging services and standards);
- Must be scalable and have the capability to support future requirements such as clinical research and care management; and
- Must be component based and use SOA principles;
- Approach comprises a flexible v3 implementation in which:
 - 4 Oracle HTBs consolidate EHR information (3 “thick” RHIO HTBs linked via a “thin” summary HTB repository for the NHIN + RLUS);
 - Each provider application set connects to NHIN via a localized HL7 converter that converts non-standard messages & data to/from standardized v3 forms; and
 - Access to the NHIN repositories is via a web portal;
- Federal Health Architecture standards supported for HTB outputs include:
 - HL7, HL7 CDA, NCPDP (pharmacy), IEEE 1073, DICOM, X12 (HIPAA); and
 - Terminologies: LOINC, SNOMED CT, RxNORM/NDF-RT

Some implications of the approach include:

- Heavy emphasis on data standardization is critical for public health, care management, and clinical research ... BUT: this is hard to do, particularly when data isn't created or delivered as needed.
- Sophisticated information governance is critical for obtaining patient trust ... BUT: this needs common business rules to be established, which is difficult; and impacts on usability.
- Flexible architecture allows for increased control of where data resides (Federated vs. Centralized) ... BUT: this increases technical complexity and impacts performance.

Dave “Casey” Webster, Chief Architect NHIN at IBM, presented on behalf of the **IBM Prototype**. Features noted included:

- Health partners (which happen to serve large populations of IBM employees) are:
 - Taconic Health Information Network and Community (THINK), NY;
 - NCHICA (North Carolina Healthcare Information and Communications Alliance)
Research Triangle, North Carolina
 - NCHICA Rockingham County, North Carolina.
- Technology partners: Argosy Omnimedia, Business Innovation, Cisco, HMS Technologies, IDL Solutions, Ingenium, and VICCS
- Key architectural objectives and approaches include:
 - A community-centric approach in which information sharing communities are first built, then interconnected via lightweight, secure hubs providing basic services and flexible data storage location (central, local, or both);
 - Building on the IHE XDS interoperability framework and Java/J2EE with clinical events stored as HL7 CDA r2-compliant documents. CDAR2 was selected over transactional HL7v3 formats as it allows structural representation of a broader range of material;
 - Anonymous/pseudonymous data can be re-identified to provide security and privacy without sacrificing usability or research value;

- Seeking a practical solution that is scalable and cost-effective at every level of practice; and
- Point-of-care performance is critical to adoption
- The architecture is SOA compliant, with community hub services including:
 - Patient Identification (PIX for ID cross referencing and PDQ demographics);
 - Document Locator (simple URI-based registry service);
 - Access Control (Authorisation, authentication and patient consent) ;
 - NHIN Interface (Cross-community search, retrieval, security; Network admin)
 - Support Services (Audit, clocking and logging); and
 - (Proposed) Community Services (Biosurveillance, PHR Portal, Community XDS);
- Services at hospital/practice interface integrating with legacy applications include:
 - Data services (Patient lookup, CDA transform, Data gateway); and
 - Document services (XDS-referenced document storage and retrieval).

Lessons to date suggest the proposed technology is relatively simple to implement, but consumer readiness, politics, lack of universal standards, and issues surrounding patient/provider identification, access rules and regulatory differences between local authorities are much more problematic. It is also difficult to effectively separate policy from functionality, so a flexible architecture is to be preferred to cater for policy change.

Wendell Ocasio MD, Principal Clinical Systems Architect, presented on behalf of the **Northrop Grumman Prototype**. Features noted:

- Health partners: Santa Cruz RHIO, California; HealthBridge, Cincinnati, Ohio; University Hospitals Health System, Cleveland, Ohio;
- Technology partners: Air Commander, Axolotl, Client/Server Software Solutions, First Consulting Group, SphereCom Enterprises, and WebMD;
- Architectural approach:
 - A "federated" model without a central data repository and using a record locator service to find information at a local level;
 - Allowing different RHIOs to have different internal standards (e.g. HL7v2.x, HL7 CDA, proprietary XML and others), and employing gateways to join them networks using a NHIN canonical interoperability standard; and
 - HL7v3 has the features required of a NHIN canonical standard: enabling computable semantic interoperability; enabling interoperability across domains; and based on an overarching information model.

The main drawback identified with HL7v3 is its lack of widespread adoption within individual networks; however, the gateway approach proposes it be adopted now as a NHIN canonical standard for connectivity between regional networks, without "rip & replace" within networks, but with the expectation this will lead to its being increasingly adopted within individual networks.

- Northrop Grumman uses the following HL7 v3 structures for the NHIN:
 - Patient identification: Patient Registry Find Candidates Query/Response (PRPA);
 - Metadata registry: Find Act Reference Registry Entries Query/Response (MFMT);

- Consent registry: Currently: Masking Topic (MFMT), and in future Medical Records Data Consent Topic (RCMR);
- Personal Health Record: CDA (awaiting CCD specs);
- Medication History: Pharmacy Generic Patient-Related Query (PORX); and
- Laboratory Results: Laboratory Result Topic (POLB).

Work to date has identified a need for HL7 committees to develop an RMIM for resource utilization (specifically number of beds available in hospitals) to assist with biosurveillance and replace the current HAVE (Hospital Availability Exchange) standard, which has its own XML-encoding schema and wrapper (EDXL-DE).

International Projects

Robert Stegwee PhD, Chairman of HL7 in **The Netherlands** then discussed how that country is pursuing a vision of HL7 interconnectivity, with the following being noted:

- HL7 version 2 is used for integration within health services based on NEN standard implementation guides, which are similar to the AS4700-series in Australia, and have been progressively developed since 1992.

The Netherlands is currently at v2.4, based on NEN 7504:2004 with some extensions to cater for local Diagnostic Codes (DBC's). Some EDIFACT is also used, particularly in primary care sites;
- HL7 version 3 is being implemented for collaboration between health services. V3 work commenced in 2000 with strong medical (including GP) and nursing input leading to a perinatal pilot that has informed the v3 Patient Care models; and
- HL7 version 3 implementation is continuing with work on two domains, originally considered relatively simple: GP out-of-hours record access and Medication reporting. After much discussion, pilot implementations are underway.

His observations included:

- The initial pilots have revealed some problems with HL7v3 tooling and methodology;
- Advancing the interconnectivity agenda involves extended, continuing discussion of associated policy issues, including: when and what to communicate? roles, activities, necessary information, privacy, authorisation and doctor/patient "trust". Key outcomes are that:
 - Healthcare professionals retain stewardship of their own records;
 - Record references are published nationally;
 - Authorization is based on roles of healthcare professionals; and
 - Patients can constrain authorization;
- Improved ways of collaborating in the efficient development of standards are needed, including having the right people sitting at the table.

Dr Ken Lunn, Head of Communications and Messaging, **NHS Connecting for Health (CfH)** then discussed progress with the NHS CfH program and implications for HL7, noting that:

- Over 250,000 NHS staff are now registered to use the NHS Care Record Service;

- The electronic prescription service (ETP) has handled over 3 million prescriptions;
- Nearly 1 million bookings have been made using Choose and Book;
- 44 picture archiving and communications systems (PACS) have been installed and are now holding over 53 million diagnostic images;
- Fast, reliable broadband access (N3) has been provided at some 15,000 locations supporting over 800,000 staff. Universal e-mail is being progressively rolled out;
- All patients need a unique identifier, which is being implemented as an essential element of the program;
- Service providers are grouped into Clusters, interconnected via an access control framework (which authenticates users) and a Transaction Messaging Service (TMS), which processes messages between clusters and application components;
- Within individual clusters, most communication is via HL7v2 with HL7v3 being required for TMS interconnectivity on the N3 Spine; and
- A team of around 30 people is responsible for interacting with business teams to define message structures; however, there are over 100 people from the NHS and various different suppliers involved in their implementation. Initial implementation experience has indicated that there are issues that need to be resolved through engagement with HL7, including:
 - How to achieve unambiguous content definition so that the same concept is not represented in many different ways in a message;
 - How to achieve common, consistent approaches to HL7v3 message design and implementation so that different developers will arrive at interoperable representations of any given information model; and
 - Dealing with rapidly increasing message volumes and diversity of sources as CfH applications and infrastructure are rolled out and integrated with Cluster systems.

Current initiatives being undertaken by CFH in collaboration with HL7 to address these issues include:

- message optimisation to ease volumetric problems;
- an improved HL7v3 implementation technology specification (ITS) for a more direct, canonical and understandable realisation of message structures;
- improved logical design techniques and constraint mechanisms (including templates) to ensure compatible messages and rigorous content definition; and
- a tooling collaborative to improve the automatic generation of messages.

Dennis Giokas, Chief Technology Officer, **Canada Health Infoway** gave an overview of Infoway and how it is working toward a patient-centric EHR that gives each individual in Canada a secure, private lifetime record of their key health history and their care within the health system. The following points were noted:

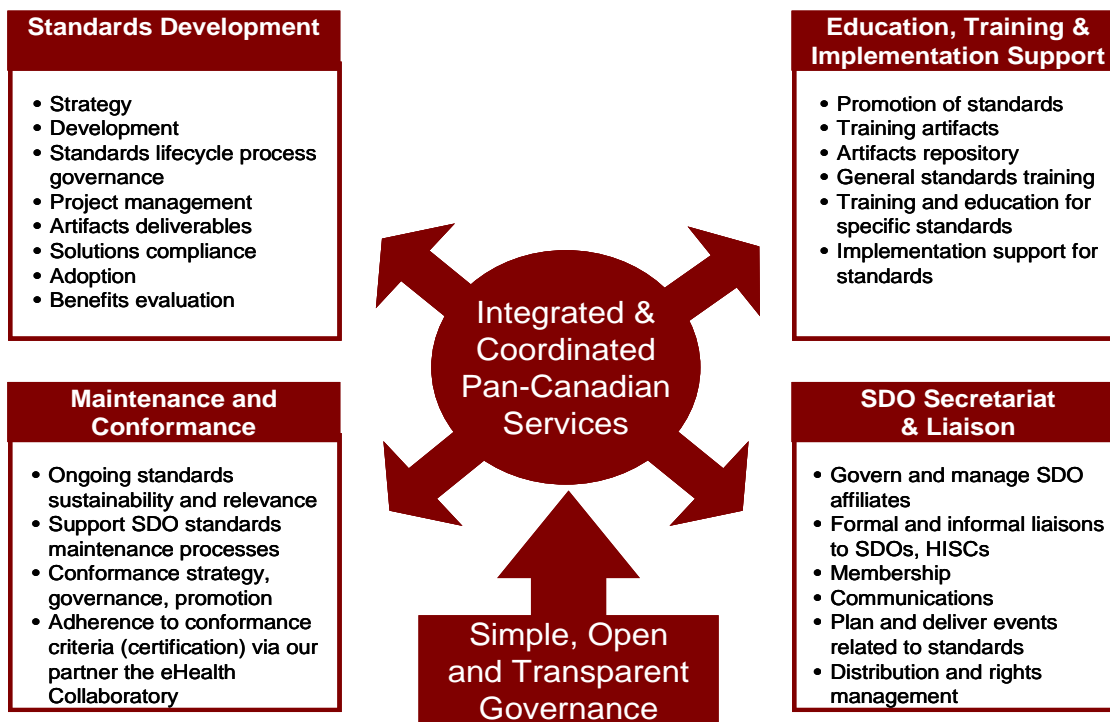
- The EHR is designed to facilitate sharing of data across the continuum of care, and be available electronically to individuals and their care providers, anywhere, any time. Respect for individual privacy is also fundamental to this vision;

- Current funding of Infoway programs is CAD\$1.2 billion; however, recent estimates indicate that a total investment around \$4 billion will be needed. Achievement of key business objectives: better access to care, improved quality of care and increased productivity is through nine strategic investment programs:
 - Registries – a \$134 million foundation addressing individual identification and demographics, providers and locations;
 - Interoperable EHR - \$175 million;
 - Drug systems - \$85 million;
 - Laboratory systems - \$150 million;
 - Diagnostic imaging - \$280 million;
 - Infostructure - \$25 million;
 - Public health surveillance - \$100 million (including immunization);
 - Telehealth - \$120 million; and
 - Innovation and adoption - \$60 million;
- The Infoway EHR strategy is founded on an architecture, blueprint and standards that enable local clinical systems to integrate with local and regional registries and repositories – with federation of comprehensive provincial hubs that enables Pan-Canadian access to an individual’s information;
- Standards are a key to the overall architecture, with common services in the Health Information Access Layer being v3-based *“because of what CHI is trying to do”* [assumedly from the interoperability viewpoint]. DICOM, IHE, SNOMED CT and LOINC are among other standards and specifications having important roles;
- Infoway invests \$0.75 in every dollar spent on approved provincial or local initiatives needed to implement EHR interoperability. These investments are subject to mandatory investment eligibility requirements that include compliance with Infoway guidelines and standards for infostructure and architecture;
- Following a series of stakeholder conventions, it was resolved that CHI Infoway is best current home for a new standards co-ordination function (the “Standards Collaborative”). However, the Collaborative will not be a standards developer but, rather, will work with HL7, ISO, DICOM, IHE to ensure that appropriate standards are available;
- The Standards Collaborative is subject to 11 guiding principles for Pan-Canadian EHRS standards selection, to ensure that standards selection:
 - is business driven;
 - focuses on adoption of existing standards wherever possible; and
 - is coordinated via open, transparent collaboration processes controlled by stakeholders. Details are available at <http://knowledge.infoway-inforoute.ca>;
- The following table identifies the standing of current areas of standardization supporting the EHRS initiative:

Architecture Standards	Data Messaging Standards
<ul style="list-style-type: none"> • EHRS Blueprint • EHR Use Cases • EHR Data Model • EHR Services Model • EHR Interoperability Profiles • Terminology Standards Strategy 	<ul style="list-style-type: none"> • Client Registry (ready for use) • Provider Registry (ready for use) • Pharmacy CeRx (ready for use) • Laboratory (in development) • Diagnostic Imaging/Teleradiology (ready for use) • iEHR Clinical Messaging (in development)

<ul style="list-style-type: none"> • Terminology implemented in data messaging standards 	<ul style="list-style-type: none"> • iEHR Technical Standards (in planning) • Public Health Surveillance Standards
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- The following diagram illustrates services of the Standards Collaborative:



François Macary, Chairman of HL7 France, Co-chair of the IHE Laboratory Committee and R&D Manager Laboratory Information Systems, Agfa Healthcare then addressed the Plenary on the **French DMP project**. The following points were noted:

- DMP stands for “Le Dossier Médical Personnel”, French for personal health record and the program’s goals are:
 - to improve patients’ health and the efficiency of care;
 - to facilitate sharing of information between patients and care providers giving due respect to the confidentiality of personal health information; and
 - to provide better treatment while spending less;
- The DMP initiative builds on other e-health infostructure and programs including:
 - national individual healthcare identifiers supported by PKI-based patient care cards – in place since 1990s;
 - smartcard based provider tokens with national PKI digital signature; and
 - use of electronic documents for storing clinical information in existing systems;
- Some other features of the DMP program include:
 - It is being trialled by 6 consortia in different locales with a view to comparing outcomes and selecting a preferred approach and technology. The

- experimentation phase commenced in June 2006 and runs to year-end with up to 30,000 real patient DMPs implemented;
- An enrolling patient declares his/her principal treating physician (*Médecin traitant*), nominates a healthcare data host on which their DMP will reside and plays a central role in managing access to their own DMP; however, patients may delegate control of the DMP to the principal treating physician;
 - The principal treating physician is the starting point for all care pathways except emergency treatment and feeds information into the DMP;
 - Other care providers including physicians, nurses, midwives, pathologists, pharmacists and physiotherapists are able to view and feed the DMP;
 - A healthcare data host will handle DMPs for a proportion of the French population and protect the confidentiality and security of patient information in DMPs against unauthorised access;
 - It builds on an existing orientation toward XML documents as the predominant means of recording patient health information electronically and sharing it with other care providers and the patient;
 - IHE XDS document sharing profiles have been adopted to specify submission sets and also metadata associated with DMP query; and
 - CDAR2 has been adopted as the standard for representing documents to contain coded and structured data, such as: a care record summary ("*Volet Médical*") and laboratory reports (defined by IHE "Sharing the lab report" profile). CDA also supports other formats (e.g. PDF, HDRIM) enabling the system to immediately capitalise on existing documents in hospital, regional or specialty networks;
- Implementation of content access policies is inherent in the design of the DMP architecture:
 - patients decide who gains DMP access, or they may delegate this function to their physician;
 - all access is subject to patient consent (except in an emergency);
 - patient may choose to selectively hide some documents from some professionals
 - optimal reimbursement for care is proposed where no clinical documents are hidden by patients or clinicians [economic incentives for sharing]; and
 - access is controlled through an access portal with a patient DMP directory and care provider directory. Access may be blocked at either the portal or by arrangement with individual providers.

Further information may be obtained from the project web site:

www.d-m-p.org.

Other Issues

In concluding the plenary, two topics were canvassed during questions:

- Experiences in translation between HL7v2 and HL7v3. This had proven an area of considerable challenge requiring a regular approach that recognises the wide variety of HL7v2 implementations. In addressing this issue speakers also noted that:
 - Representation, storage and conversion of non-HL7 data is even more difficult; and
 - The harder part of the above problem is translating back from v3 to v2.x in a way that reproduces a message compatible with the original and

- The growth in interest in Personal Health Records (PHRs), the extent to which this is becoming a driver and the means by which patients may be able to add to their own EHR/PHR information. It was noted that while individual access and integration of individual contributions remains part of most EHR visions, there are strong care provider sensitivities in some programs, where this is seen as secondary to the establishment of EHR infrastructure and the basic capability to share key EHR information between providers.

7 Standards Development

Australia's involvement in HL7 standards development reflects the objectives and priorities expressed in section 3 above.

7.1 V2.5.1

Based on requirements articulated by HITSP, HL7 will put out an enhanced version of the V2.5 standard to include three fields in the OBX segment. A streamlined 90-day process (30 day announcement, 30 day ballot, 30 day reconciliation period) will be followed to deliver what is required.

7.2 V2.6

Some concern was expressed at this meeting about the considerable length of time it is taking to deliver a final balloted version of V2.6. This is due to many factors including some formal requirements of the ballot process, considerable scope creep, and most attention being directed to V3.

7.3 V3

There appears to have been a substantial increase in real-world use of V3:

- The UK NHS has more than 3.5 million prescriptions sent using V3. Other V3 messages are being used;
- Several US vendors (including Northrop-Grumman and Accenture) are using V3 to amalgamate region-wide EHR data from diverse sources (RHIOs – Regional Health Information Organisations) into a consolidated patient record into the NHIN (National Health Information Network).

Laboratory Fulfiller is an example HL7 v3 implementation site currently implementing a subset of the laboratory domain messaging. This will soon be online with example SMTP, TCP/IP and HTTP/SOAP transport interfaces implementing a demonstration laboratory system.

7.4 V3 ITS

The UK National Health Service (NHS) provided interim feedback to HL7 on its review of business issues related to the useability of HL7 V3 and the ease with which V3 can be learnt and deployed efficiently. The NHS reported that it is pursuing several new approaches – noting that some of these have aspects that are potentially mutually contradictory. These approaches include:

- New ways of deriving implementation technology specifications (ITS) based on formation of compatible XML- UML models ("XUMs") to represent information that may be communicated in a domain;
- A single canonical set of logistical definitions and models for complex datatypes (e.g. time intervals) being used to convey health information. Once they are defined, NHS proposes to seek support for these data types in HL7, CEN and ISO standards and, also, in *openEHR*. This work should be of prime interest to Australia;
- Commercial, open-source tooling to support UML/XML representation and serialisation (including supporting a Request for Tender via a collaborative body);
- Clearer naming of elements based on domain concepts while maintaining formal relationships to abstract HL7 RIM constructs; and
- More specific (and less generic) serialisation of individual XUM packages.

At a more general level, the NHS appears to be considering how to make greater use of *openEHR* concepts and, particularly, clinical archetypes in conjunction with the EN 13606 reference model and HL7 V3 communications.

While some V3 focussed-members are somewhat uncomfortable with the directions being considered by the NHS, it seems likely that NHS will continue, in collaboration with their vendors and with HL7, to invest in a practical implementation of interconnectivity based on a revised form of V3. This seems likely to involve significant changes to V3 methods and content and, also, within the UK, some incorporation of CEN and ISO concepts and *openEHR* archetypes, to facilitate sharing of information and interoperation.

In reporting their interim findings to the HL7 Board, the NHS noted that the HL7v3 implementation problems being faced by the NHS go beyond what can be achieved by an improved ITS. Further results are expected to be reported back to the HL7 Board at the next WGM in January 2007.

Attachment 4 provides an expansion of this issue.

Robert Worden (from England) demonstrated an interesting transform from HL7 V3 instances to simplified and reduced messages which carry the same semantic content and which can be transformed back into the original V3 instance when received. This is a private initiative by Robert Worden - it has not been endorsed by the HL7 Board and it does not have wide distribution. This approach also appears worth monitoring.

7.5 EHR

The major item of business for this meeting was ballot reconciliation.

The EHR Systems Functional Model went to Membership Ballot as a normative standard in the last balloting cycle, and the EHR Interoperability Model went to Committee Ballot. The results of balloting were as follows:

	Functional Model	Interoperability Model
No. of people who registered for ballot pool	88	64
Number who voted	78	51
Affirmative	42	22
Negative	26	15
Abstain	9	14
% required to pass ballot	(i) 60% of the ballot pool return a vote and (ii) 90% of votes returned are affirmative.	(i) 60% of the ballot pool return a vote and (ii) 67% of votes returned are affirmative.
% of ballot pool who voted	89%	80%
% of those voting who voted affirmative	54%	43%
Number of comments to be reconciled	661	44

Interoperability Model

Like the Functional Model (FM), the EHR Interoperability Model is just that - a model rather than an implementable specification. It highlights the sections of a record and lists interoperability "assertions" or characteristics for each section, elaborates these and relates them to the HL7 RIM. Work is underway to develop a CDA profile for the Model. Future work will include aligning the document and record architectures.

A definition for EHR interoperability has been developed, contained within a research paper, "Coming to terms", which will hopefully be published in the near future. It is noteworthy that the White House has recently released a definition of interoperability and an expectation that interoperability will be achieved in healthcare. A copy is attached for information (Attachment 5).

Personal Health Records (PHR)

A Functional Model is being developed for PHRs, but it remains unclear to what extent this can be integrated with the EHRS Functional Model. At this stage the plan is to go to Committee ballot in January, but work in the near future will address whether PHR Functional Model descriptions can be fully accommodated by the EHRS Functional Model.

7.6 Patient Care

The Patient Care Technical Committee HL7 2.6 ballot was reconciled and clears a path for the pursuit of the new collaborative care message (CCM) for HL7 2.7 which extends the existing referral (REF) message published in HL7 2.6 standard. This future work is of great interest to Standards Australia's IT-14-06-06 Collaborative Care Messaging committee and is greatly influenced by previous work of this Australian committee.

Key issues included the following.

- It became apparent that the way V3 is organised & published is at least very disjointed. This means CMETS can become duplicated and/or contradictory, and it can be very difficult to find what a potential user is looking for. Max Walker proposed that a new Domain be established, called Query. This domain would not only oversee all Queries, but also have the responsibility of ensuring ordering and consistency of all models and CMETS. This concept was to be taken to the Modeling and Methodology Roundtable, but was considered not necessary by the TC's representative.
- Order Set is part of a Care Plan. This item concerns creating a document standard, but significant problems arose from balloting – some use cases did not get through. It has since become clear that there are 2 sets of Use Cases for Order Sets - one where the order (or Act) is present with the result; the other where only the result is present. The former is necessary for Care Plans, where in some cases the order is actually more informative than the result. A model needs to be devised to support both scenarios.
- Harmonisation of Assessment Scales. The key issue for this item is that systems already have conditions (& hence scales) embedded, so if the model changes there will be considerable impact to existing implementations. It is now proposed as an RMIM. The derivation is from the total score class (i.e. the sum of all the Act Relationships) and not the attribute. An example is the Apgar Score (for babies just after birth). This a score across 5 measures (pulse, respiration, activity, grimace & appearance) taken at 3 time intervals – 1 minute, 5 minutes and 10 minutes. Each has allowed values and the score is the sum of these allocated values. These are different from a battery as the battery is not component dependent (i.e. no values can be missing, whereas they can be in a battery) and there is a time dependency of multi measurements. The question is - should ownership of these live with Orders & Observations (OO) TC? This was followed up via a joint meeting with OO, who agreed that prime responsibility existed with OO, but recognized that these sorts of measurements had multiple areas of ownership.
- OO agreed they had been slow to respond to the requirements of Common Observations and as a result others groups have moved on. OO made a commitment that at the WG Meeting they would commence to rectify this by establishing a starting point that everyone is happy with and then begin to move forward. This will include Scales.
- These assessment scales seem to need to link to Template ID's. Clinical Statement topics need to also be included to ensure everybody develops the same way. This would seem to supply an important link that does not tend to appear elsewhere (e.g. LOINC merely states the value is derived – does not say how).
- Consensus seemed to be that there are probably 2 representations required for Scales.
- Pediatrics SIG is working on Immunisation in an EHR. In Jan 2006 it produced a storyboard. This was adopted by the Patient Care TC. Pediatrics is now beginning the V3 mapping steps. Public Health is also working on Immunisation.

The Patient Care V3 Ballot Reconciliation raised a number of issues that need to be pursued through this and other WG meetings. It is not obvious what is a Domain and what is merely a value set. X Domains were created before Value Sets were invented, hence all x Domains should be replaced by Vocabulary. This needs to be raised with Clinical Statements, which will then need to go to Harmonisation. CMETS should be reviewed and where appropriate deleted in favour of the RMIM. Substance Administration needs to be defined.

Patient Care needs a Steward to regularly attend Harmonisation Meetings, who will write up Harmonisation proposals and attend (either in person or by phone) to argue the case. Harmonisation Meetings are 2-3 days in length between WG meetings. Dan Russler will represent Patient Care at the November meeting but cannot commit beyond November. From a knowledge sharing perspective also, there is a need for another person's involvement.

7.7 Community Based Collaborative Care

Considerable time was spent with representatives from other organisations including HL7 France & IHE regarding privacy and the regulation of information access, in particular by consumers. With the disbanding of the Medical Records TC, privacy requires a "home" and the Behavioural Health people favour its move to CBCC. It would seem to others that this would be more suited in the Care Provision Domain. However a presentation was made to CBCC and subsequently a motion passed to recommend to the Architecture Review Board that Privacy be accommodated by CBCC.

Discussion ensued on the projects currently underway and the role of the SIGs & TCs. The Behavioural Health people want to develop an EHR profile. This needs to link with the EHR TC, but the work will need to be done within CBCC. The Role of the SIG (and its parent the Patient Care TC) is to support this development and transition of ownership.

Peter Kress gave an update on his Continuity of Care Project in the Aged Care setting. The project is to culminate in the participation in a IHE Connectathon. Emphasis is on health and wellness, not disability, so it is thought that new stakeholders will be identified. The project will also identify new data sets.

7.8 Medical Records/Information Management

A joint meeting was held with the Community Based Health Services SIG on international privacy architectures

Work is being undertaken to develop and clarify the messaging requirements for management and maintenance of access control policy implementation. A survey is being undertaken of privacy approaches and considerations in different national systems. This survey is to identify the least and most stringent policies and how these have been negotiated and how this can inform standards development in this area.

Policy, standards and technical support for patient consent to collect, use and disclose Patient health information were discussed. Management options presented included

- Opt out
 - Total
 - Conditional
- Opt in
 - Total
 - Conditional
 - Masking / or locking. This can be achieved by user, role, or context.
 - Ad/Hoc – specific requirement for a given element (special secrets).
 - Special 'break the glass' occasions.
- Within nodes (regional hubs, sub-networks)
 - Sharing is generally agreed upon privacy policies between nodes)
- Among nodes (national information network (e.g. UK spine, US NHIN))
- Role based access control
- Standards for electronic consents, shared secrets, and privacy policies are required.

Standards for electronic representation of node consent policies and patient consents is needed to support E.H.R. developments. Such a standard needs to identify computable processes to manage access at each node point and to manage the policies that control these rules. The issue of what element of accesses to be transmitted with the message was also discussed.

Restriction by service of specialty.

This concept holds that some access restrictions should be based upon specialty or service group information sets (e.g. mental health) suggesting that the assumption that this is not or must not be shared must be manageable. In some cases there is the need to fence this data – where there is a legal requirement not to share it.

However, some consumers want to share such information, to support safe healthcare. There is a problem with assuming that sexual health, mental health are the things we want to hide – many people find other health conditions as sensitive to them as these. Heather Grain requested that the group consider the model of a single approach to these issues, with the potential to switch from automatic opt in or opt out dependant upon specialisation, but with the patient able to modify the access to meet their requirements.

Role based access

Discussion occurred on the use in Europe, and considerations in Australia and Canada of the ISO standard on privilege management to support automation of access control management. This was a new concept to the USA contingent, who found the proposal useful. Early trials in Australia on consent showed that it was possible to develop a consumer understandable and non provider intensive implementation of this requirement.

Level of access control

It was suggested that access control be both at the record and data element level. However, this level of restriction presents management difficulty as well as making it

more difficult for consumers to understand. Canada and the UK supported the idea of restriction at the compositional level.

Consumer Access to Update

Consumer Access was discussed. It had been suggested that the consumer could add data, in a segregated part of the record, but nothing else.

However, consumers need to be able to add and to indicate errors in the data (in a way that maintains the previously available data) to support quality information collection and safe use.

Masking.

There was considerable discussion on whether a masked item will make its presence known (e.g. icon indicating that there is masked data).

Heather Grain presented the consumer perspective that the mask be invisible – the use of this device can distract the clinician and destroy consumer trust in the system, though paternal and professional desire to protect the patient makes this an issue of education, implementation and trial. It is important to educate providers to understand the danger of assuming that information is ever *all* there. It was also recognised that this approach requires clarification of clinical responsibility to explain risk to the consumer, and the legal protection of the provider who acts without the knowledge that is masked. Two levels of masking were identified - mask except in an emergency (when you may break the glass – by requesting additional information if it exists) or mask always.

Heather also introduced the concept of management where information can only be masked after the event by returning to the original provider, or other provider who has accessed this information to explain risk – recognising that copies already made will not be retracted. Where there is masking this can be removed at any location by the consumer at any time.

Requirement for audit trail of the person who has seen the information.

For the purpose of ease of management and the protection of the privacy of care providers it was suggested that:

- Individual consumers have access to the audit trail to the level of provider organisation, site and service and the role of the accessor;
- If a problem is perceived (after individual review) there is an ability to get details of the individuals who accessed; and
- Organisations may monitor audits at the individual level to support duty of care.

7.9 Conformance

Work for the early part of the week consisted of completion of v2.6 ballot reconciliation, which was completed - there are now no outstanding v2.6 items for reconciliation. Discussion then took place on outstanding v2.7 proposals, including

finalisation of the length of field issue raised at the San Antonio meeting in May 2006 (see San Antonio report).

Conformance SIG met with Infrastructure and Messaging regarding some conformance issues, including Chapter 2.B.5.1 & 2 uses value sets. This is a v3 concept, and needed clarification from Infrastructure and Messaging. It was agreed by Infrastructure and Messaging that value sets be changed to table values.

The V3 conformance implementation manual, specifically the vocabulary domains and constraints and data type constraints, was considered. There was clarification on mandatory and required terms in V3 messaging.

Messaging Work Bench

Version 6.6 is the latest and was released on the HL7 website at the end of the WG meeting. Fifty two errors have been fixed and there is now a feature to allow for the addition of repetitions of segments and the ability to define each segment separately. A new feature, not readily available, concerns value sets. Users can set a series of specific values to repeating elements. The messages, when parsed, will then be checked against these values.

Message Maker

There is now a framework to support testing of HL7 messages based on conformance profiles. There is also considerable work in progress on setting up configurable actors by using a set of services (java API). Work is also underway with DICOM for IHE testing. Message generation and validation services are being developed using a web service as an interface.

AHML

New hardware and software has been implemented since May 2006, resulting in faster service to customers. Two new profiles have been implemented and one new Australian Standard over the last 4 months. Work volumes from international countries have increased recently, specifically from Europe and the Indian subcontinent. New services are being planned to allow testing to be done via web services and to have a store of trusted messages for clients to use as example messages. Work is progressing well with implementation of all v2.x standards. This should be complete by the end of this year.

Version 3 ballot reconciliation went well, with all negative minor comments dealt with.

7.10 Structured Documents (and CDA: Clinical Document Architecture)

There appears to be steady growth in the selection of HL7 CDA as a technology for practical sharing of health information in the form of structured electronic documents. New implementations are using, or planning to use, CDAR2, typically at level 2 with structured content to section level. It was noted that:

- Several of the US-RHIO initiatives are claiming early success sharing information using CDAR2 – some based on IHE XDS specifications;
- Standardised translations of v2 material to CDAR2 and v3 (and back) are increasingly being sought to enable gradual transition to new information sharing networks in a world dominated by legacy systems;
- It has just been announced that the NATO forces have agreed to move to HL7v3 and CDAR2 for electronic communication and storage of clinical information;
- Some more advanced CDAR2 implementations expect to hold a proportion of their information at Level 3 to aid automated interpretation, CDS and more advanced applications – but most use of CDAR2 is expected to be limited to Level 2.

It is recognised that, even in areas covered by required standards (such as CCD for US referrals), there is still considerable latitude in the structure and representation of clinical information within CDAR2. Further guidance, standards and education are required

7.11 Modelling and Methodology/Templates

The Template Special Interest group work to formalise functional requirements of HL7 templates was continued. This will be balloted as informative content for the next cycle of publication. These functional requirements are based on analysis of templates use cases and CEN 13606 part 2, Annex A content with the aim of harmonising the core requirements of HL7 templates and CEN archetypes.

Furthermore templates content is to be updated in the HL7 v3 ballot with respect to issues relating to template creation, best-practice approaches to template definition, and details on the implementation of templates within the XML ITS (wire protocol). This includes the appropriate use of 'template id' within instances of HL7 v3. This material will include example template definitions and message instances. This material will be the basis of applying patterns to the RIM, Domain Information Models (DIM), and Constrained Information Models (CIM – or message models). This material will also include the relationship between templating and conformance profiles. This material will feed into the HL7 tooling collaborative to supply support for features defined.

The promise of HL7 Templates as a means of representing clinical information is still not generally appreciated and, if realised, is most likely to come about through the DCM initiative and/or the activities of the NHS. Informal discussions indicate that many in the HL7 community (including some HL7 specialists) have difficulty conceiving how Templates might work as object-oriented constraints.

There was some discussion (flowing from presentations of Grahame Grieve's work with the NHS) that HL7 should consider simplifying its entire modelling hierarchy. This included demonstrations of how lower-level models (RMIMs and CMETs) might be replaced by constraint models (defined in ADL).

There is growing acceptance within HL7 that ADL can be applied as a constraint language on HL7v3 models and that this is preferable to alternatives such as OWL, OCL or an alternative home-grown language.

There was discussion of theoretical grounds for asserting the models that instances might conform to, namely:

- Expressed model – The RMIM that the message conforms to;
- Implied model – DMIM and RIM which the RMIM conforms to;
- Applied model – Other models that apply – Template; and
- Potential model – other models that may apply now or in the future

In the openEHR world this equates to:

- Expressed model – Reference model classes;
- Implied model – Ancestors of reference model classes; and
- Applied model – Archetype

The problem is that there is no limitation on the V3 instance – in terms of unrolling – so it is not possible to limit the model. Further, if there is a choice box in the model and it is desirable to leave the choice open, the applied model becomes very difficult to express and implement.

Template ID is being used for annotation and description in CDA – this is problematic for any introduction of templates as a mechanism in CDA. There was substantial discussion on the use of templates and all uses of template IDs were proposed as inappropriate by different members of the committee. Vendors appeared bemused.

Grahame Grieve presented his views on the advantage of using ADL to constrain the RIM to RMIMs rather than other technologies. An option is taking ADL to the Object Management Group (OMG) or similar to become part of the UML specification, and then to tool developers to get off the shelf tooling in this space.

Grahame then summarized to say that HL7 and *openEHR* would then share the same data types (he will present this tomorrow) and constraint model. The result is possible alignment down the track.

7.12 Healthcare Services Specification Project (HSSP)

It was noted that key players in the HL7 Security TC are well informed and strongly supportive of industry-standard approaches to information security in healthcare.

There is close liaison between various HL7 groups and IHE – particularly in relation to profiling of upcoming work from the HSSP/SOA project and addressing interconnectivity needs driven by US ONCHIT/HITSP initiatives.

A project has commenced to determine and specify service requirements. This is really to become a Roadmap for the next wave of services for the HSSP activity. A list of possible projects will be described and distributed to the HSSP group, for consideration on the 26th September. Volunteers will describe requirements and

submit them by the 25th. Max Walker will be describing the Human Services Directory, PKI & Provider Authentication.

Services for consideration include:

- Ordering;
- Scheduling/Resource Management;
- Cohort Selection;
- Adverse (Drug) Event Reporting;
- Access Control (including role based);
- Privilege Management;
- Anonymisation;
- PKI;
- Demographics (Org / Provider / Person);
- Policy Management;
- Patient Consent;
- Workflow/BPM;
- E-Prescribing;
- Referral;
- Provider Authentication; and
- Template Registry.

7.13 Patient Administration

The committee (co-chairs G. Seppala & K. Veil) worked through its routine agenda with a focus on V3 enhancements and V2.x/V3 ballot reconciliation. There are a number of major issues under discussion, in particular new features for V2.x and V3 as well as organisational changes.

The Patient Administration V3 Release 2 September 2006 ballot passed with 72% and a quorum of 90%. The negative votes were processed in a V3 ballot resolution process, including post-ballot comments from HL7 The Netherlands.

For V3, a Pending Discharge Notification from Canada was put forward, as was a V3 Location Registry Proposal. Pending Discharge Notification messages are already in V2.x but not in V3. One option is to use the existing "Revised Inpatient Encounter" R-MIM with new trigger events. To be approved out-of-cycle. For the Location registry, a number of questions were raised with Lloyd will respond to and also post info to the PA web page. The discussion (with Ken Rubin from the SOA SIG) regarding possible conflicts between PA Registry messages and the Entity Identification Service specification was continued and will probably continue as a PA research project.

V2.5 ballot resolution was also worked through with all negative votes resolved.

The PA TC also discussed the possibility of PA looking after the content from the Medical Records TC after it ceases to operate. A similar issue has arisen with the Personnel Management TC, which is suffering lack of participation.

A Joint Meeting with Personnel Management and Patient Care TCs was held to discuss a harmonisation proposal to make the Patient Encounter act class a child of the Care Provision act class (They are currently siblings). This proposal found agreement.

Looking into the future the Person and Patient topics will be balloted as a DSTU in Jan 2007.

7.14 Pathology

The main work at this meeting was resolving comments from the last ballot and addressing some systematic issues identified.

Pathology TC will have ballotable material for the next ballot cycle. The group has been asked by the HL7 Board to restrict this ballot cycle to the Laboratory Results topic (and hence to not prepare ballot material for Laboratory Orders etc).

An out-of-cycle meeting will be held in Atlanta during the week commencing October 16. This will prepare ballot material for the January Ballot cycle.

A group in Canada had produced a new (local) model for the structure of a Microbiology report and brought it to this Working Group Meeting for comment. They have since produced a new model that uses the same structure as that published in the last cycle. They indicated that they considered this to be a substantial improvement over their initial model. This is been quite gratifying to those who have battled for a single model for a Microbiology report over the past six years.

7.15 Vocabulary and Terminfo

The Terminfo group is developing an approach to the management of terminology systems in an HL7 V3 environment, but this could be seen as consideration of the relationship between terminology and structural models. However there appears to be an increasing awareness of this potential for models to support terminology and relive some of the requirements for terminology to 'do it all'.

Specific issues considered included:

- The Modeling and Methodology decision that code and value are required to always be considered as a pair to ensure semantic consistency creates a need to modify some elements of the Terminfo document

There was considerable discussion arising out of the consideration of the representation of terminology in care plans. In this context you need to know the status of requests/processes. In care plans you need to know if your question has been given an answer. This discussion is raised to automate support for care planning where the system can identify that a specific observation result meets a specific request.

There was discussion as to whether a number of complex concepts can fit into a 2 box model (Act/Code/Act/Value); and the roles Templates, Archetypes etc. have, if any, in providing solutions to this problem?

The original model is that the "code" contains what was done and the "value" is what resulted. This caused an arbitrary split for these 2 items. David Markwell (HL7, UK) asked if whether or not the code fundamentally and consistently

informs what is in the value. David is concerned with the relationship Order & Value - they must be paired.

The current split is defined in the RIM. There now appears to be a need to 'clean up' quite a bit of the language in the RIM given the clearer understanding of code and value that has now been established for observation. The need for a harmonisation activity to complete this task was agreed. Going to a 1 box model with the semantics embedded in the code may violate the consistency of a Care Plan if Act & Act_relationship are separated. For Care Plans, ensure the activity was performed is as important as the result. There are potentially two different Acts - some cases represent procedure & result; others may simply involve an observation.

However, for more general statements, expressed using SNOMED CT, the split leads to a potential diversity of representations when carelessly applied. This is best resolved by fully specifying both the action in the ACT.Code (as LOINC does) and the result in Act.value "even if there is overlapping information". For example, if "assessment of nausea for severity" is coded in ACT.code, "severe nausea" should be coded in Act.value. In other words, "severe" should not be the value when 'nausea' is the code.

- Unacceptable patterns for observation code/value. There will need to be changes in this section also. There is a difficulty in how to express an observation that has negation, and later has a value as this mixes the value types. The mathematics could be *SNOMED* findings interpreting an observable and then interpretation is a finding. If the finding called blue eyes, it will have interpretation of blue - the finding can be equated to an observable and a qualifier.

The work of this group is highly relevant to Australia in the context of terminology development and management. It would seem appropriate to develop further knowledge of the work being done in this work group. Though it relates to V3, it is equally relevant to the content required with archetypes and message structures for semantic integrity.

7.16 Decision Support

The Decision Support Services ballot reconciliation was completed - most comments were regarding details of informative HL7 profile content referring to existing HL7 v3 standards, particularly in the Care Provision Domain. The HL7 profile for the decision support service will be worked on in more details to flesh out the RFP (request for proposal) document to be produced as a work product of the Health Services group at OMG. This equates to a detailed function requirements document. Significant areas to be addressed in this profile will include patient de-identification of HL7 v3 content; query use cases used by decision support; and the functional definition of wire protocol and constraint models that are referenced by 'Semantic Signifiers'. The work on 'Semantic Signifiers' is still outstanding and is required to enable services to refer to models used in query format, output format and update format profiles.

7.17 Clinical Guidelines

The clinical guidelines special interest group discussed projects towards convergence models. It was suggested that a conference be held with relevant stakeholders to identify greatest areas of need in creating, maintaining and evaluating guidelines. This will be most likely pursued outside the HL7 process as a non-committee related event. There were also discussions on the very different approaches used to construct guideline content knowledge – it was broadly agreed that there was no model that supported all kinds of knowledge. This led to a suggestion that very specific kinds of knowledge could be used as the basis of standardization, with an eye to harmonising where possible between models - for instance a suitable model to support drug-drug interactions. This work is ongoing and related to existing development of models to support decision points in care provision currently being developed in the areas of order sets modeling (specific protocol definition), and patient care plan modeling (care provision domain).

7.18 V3 Dynamic Model

Progress here is currently very slow. Discussion is occurring with much enthusiasm but at very abstract levels.

7.19 Tooling

Tooling has been upgraded to allow attribute-level descriptions to be entered for messages.

8 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 representation on the Board, Advisory Committee, Technical Steering Committee, numerous Technical Committees and SIGs, the Strategic Initiatives Task Force and SDO Coordination Groups, as well as via informal channels. Australia's participation in these groups (many by election or invitation) reflects both acknowledgement of our technical and managerial expertise and sustained efforts at relationship building and management on the parts of Standards Australia and HL7 Australia.

A clear signal was sent to the HL7 Board at this meeting that greater transparency is required to ensure the effective functioning as a standards development organisation.

The strategic positioning of HL7's key products (HL7 V2x, V3, CDA, EHR Models, etc.) is still evolving but the realisation is growing that significant enhancements to V3 are necessary to enhance its implementability and thus its viability. Australian organizations and personnel (Jiva Medical/Grahame Grieve; Ocean Informatics/Tom

Beale and Sam Heard; HL7 Board/Klaus Veil) are leading efforts within both HL7 and the NHS to resolve these concerns and harmonise international standards. Standards Australia and HL7 Australia will continue to monitor developments.

Work on healthcare services specifications appears to be progressing satisfactorily, with significant Australian involvement, and CDA appears to be picking up momentum internationally although it remains early days in its implementations.

Inclusion of Australia's requirements into HL7 standards such as patient administration, diagnostic and collaborative care messaging and the EHR Functional Model is now routine and progressing satisfactorily and although further work is required, there are no current concerns.

After a substantial and frustrating hiatus caused by lack of resourcing, harmonization of data types is on the move again triggered by work within the NHS and the need to harmonise CEN13606 and HL7 V3. This once again illustrates the point that standards development benefits from close association with implementation projects, and vice versa. The commitment of national programs such as Connecting for Health, Infoway, the Netherlands e-health program and NEHTA to active participation in standards development is fundamental to achievement of standards based interoperability.

Attachment 1 – HL7's Technical Committees and Special Interest Groups

HL7 working groups are characterized as being administrative, special interest or technical:

- Standing Administrative committees focus on organizational or promotional activities. Current administrative committees include the following areas: Education, Electronic Services, Implementation, Marketing, Outreach Committee for Clinical Research, Process Improvement, Publishing, and Tooling.
- Special interest groups encourage sharing of common experiences in particular interest areas. Active special interest groups are Arden Syntax, Attachments, Clinical Genomics, Clinical Guidelines, Clinical Trials, Community Based Health Services, Conformance, Government Projects, Imaging Integration, Java, Laboratory, Lab Automation Point of Care Testing, Patient Safety, Pediatric Data Standards, Pharmacy, Public Health and Emergency Response, Templates, XML.
- Technical committees are chartered by the HL7 Board of Directors upon member petition specifically to create, maintain, and extend the HL7 Protocol Specifications. Technical committees frame the actual language of the specifications, conduct formal balloting on that language, and then recommend approval to the whole HL7 organization via full membership ballot.

Currently active technical committees are: CCOW, Clinical Decision Support, Control/Query, Financial Management, Electronic Health Records, Medical Records, Modeling & Methodology, Orders/Observations, Personnel Management, Patient Administration, Patient Care, Regulated Clinical Research Information Management, Security, Scheduling & Logistics, Structured Documents and Vocabulary.

Currently active special interest groups and task forces are: Anatomical Pathology, Arden Syntax, (Claims) Attachments, Cardiology, Clinical Guidelines, Clinical Guidelines, Clinical Genomics, Community Based Collaborative Care, Conformance, Emergency Care, Generation of Anaesthesia Standards, Government Projects, Healthcare Devices, Imaging Integration, Java, Laboratory, Patient Safety, Paediatric Data Standards, Pharmacy, Public Health and Emergency Response, Service Oriented Architecture, Templates, XML, Ballot Task Force, Clinical Statements, Common Message Element Types, Dynamic Model, Harmonization, Terminfo, Tooling Collaborative.

Attachment 2 – HL7 International Affiliates

Current HL7 International Affiliates are:

Argentina
Australia
Brazil
Canada
China
Croatia
Czech Republic
Denmark
Finland
France
Germany
Greece
India
Ireland
Italy
Japan
Korea
Mexico
New Zealand
Spain
Sweden
Switzerland
Taiwan
The Netherlands
Turkey
United Kingdom
Uruguay

Attachment 3 – Detailed Clinical Models Project

A meeting to discuss an initiative to enable open collaborative sharing of clinical information models being developed by sizeable teams in several major healthcare establishments was convened by Dr Stan Huff, a former Chair of HL7 and world leading clinical informatician. It was recognised that such a move by those practically involved with implementations around the world had the potential to increase greatly the compatibility and comparability of clinical information and accelerate the interoperability of clinical information systems.

The meeting was held in Boca Raton on 8 and 9 September, just prior to the September 2006 HL7 Plenary and Working Group (WG) meetings and was attended by a hand-picked group of leading contributors, including:

Dr Stan Huff and Craig Parker (Intermountain Health Care – IMHC)
Mark Shafarman (HL7), Charles Parisot (IHE & GE Healthcare)
Laura Sato (UK-NHS CfH), Dr Dipak Kalra (CEN TC/251 WG1)
Galen Mulrone (US-VHA by phone), Russ Hamm (Mayo Clinic)
Dr Sam Heard (Ocean Informatics and *openEHR* Foundation)
Prof Alan Rector (University of Manchester)
Grahame Grieve (Jiva Medical, Eclipse, UK-NHS and HL7)
Bob McClure (Apellon), Dr Ed Hammond (Duke)

While the meeting was a prelude to the HL7 Plenary/WG meeting and was attended by some with strong HL7 affiliations, it was very much an independent activity, partly driven by concerns about problems representing clinical data in HL7v3.

The participants agreed to work collaboratively and are seeking to formally invite HL7 (initially through the templates SIG), CEN (through TC/251 WG1) and the *openEHR* Foundation to work with them to progress a Detailed Clinical Models DCM project having the following characteristics:

DCM repository

To create a repository of Detailed Clinical Models, in which:

- The contents of the repository will be available in a free-for-use form to anyone;
- The models will be built upon commonly agreed standard terminologies;
- The repository will hold models in a single formalism (initially *openEHR* archetypes are being considered for this);
- The models in the repository should be capable of representation in other formalisms (e.g. OWL, HL7 Templates) with reasonable ease; and
- To qualify for inclusion, models should have been developed "for use" with nominated applications – and there should be an associated set of application

tasks or functionality that can be used to test the models – they should not just be theoretical exercises in modelling.

In this context, a "Detailed Clinical Model" is a generic term for clinical information models such as *openEHR* Archetypes, HL7 Templates and Intermountain Healthcare's Clinical Element Models (CEMs).

Improving Collaborative Processes for Representing Clinical Information

The project is aiming to achieve sustainable processes and not just a series of products and needs to plan for migration and change as it develops and grows.

There is a strong agreement that the governance of repository content should be based on editorial and expert review processes rather than general consensus and that the findings as to preferred would be recommendations (similar to those of the IETF) rather than purporting to be normative standards. Key underlying elements needed to ensure cohesion of the overall process may be offered for endorsement or agreement of international standards bodies.

Common Representation for Clinical Information Models

It has been agreed that EHR archetypes meeting the following definition correspond well with what is needed to provide a common representation for Detailed Clinical Models:

"An EHR archetype is an agreed, formal and interoperable specification of the data and their interrelationships that must or may be logically persisted within an electronic health record for documenting a particular clinical observation, evaluation, instruction or action."

Such EHR archetypes need to:

- Facilitate definition of data structures, including: optionality and multiplicity, data value constraints, and relevant bindings to natural language and terminology systems
- Incorporate algorithms, formulae or rules to define or constrain relationships between data values within a data structure
- Be capable of including other archetypes or be specialisations of other archetypes
- Include metadata that defines its core concept, purpose and use, evidence, authorship and versioning.

It was noted that *openEHR* and EN 13606 archetypes conform to this specification as sets of constraints, expressed in a standardised form (viz ADL), for instantiating their respective EHR reference models.

Code binding and Terminology Interfaces

Before a model is considered "done", it must have all of its terminology bindings specified to one or more actual code systems.

Where possible, the initial binding will be to a terminology that is "free for use internationally", rather than to a terminology that requires license fees

Any number of additional bindings to other terminologies can be added as needed.

Organization

The DCM group is seeking to progress its activities by seeking to join an existing body rather than forming a new not-for-profit organisation but with the least amount of bureaucracy.

It had been agreed that the operational and ballot processes should NOT be the same consensus processes as those used by HL7, CEN and ISO – simpler, more "editorial" approaches are needed.

It had also been decided that, in the initial stage, the activity should be progressed:

- as a joint project of HL7, CEN and openEHR, with HL7 as the principal parent – subject to discussion and agreement on specific details;
- by keeping the core leadership group and membership small, liaising with other bodies and co-opting experts for specific activities, as required; and
- Through early alignment with HL7 (Templates SIG), *openEHR*, CEN, US-NIH/NCI, UK-NHS, UK-NHS, NEHTA (in Australia) and US-VHA.

At a later stage, in collaboration with professional societies, clinical experts, AMIA, IMIA, other standards bodies and potentially as a domain committee under IHE.

The initial governance committee is Craig Parker (Chair) from IMHC, Sam Heard of Ocean Informatics, Dipak Kalra of UCL/CHIME, Laura Sato from the UK NHS, Charles Parisot of GE Healthcare and IHE and Mark Shafarman (representing HL7).

Initial Activities

The initial project was determined to be consideration of how to represent, record, compare and manage DCMs for adverse reactions in the form of archetypes – progression of this activity is to be led by Bob McClure of Apelon.

Existing work to be taken into account includes - CCD, IHE medical summary, NDF-RT, RX-Norm, SNOMED CT, Existing HL7 messages, VHIM, IHC Clinical Elements, existing openEHR archetypes, NHS models.

The *openEHR* reference model and ADL-based tools are to be used, with a parallel group re-creating the artefacts using NCI tools to enable an initial evaluation of the formalism and tools, points of good design practice, and what constitutes a good archetype representation.

Potential Future Directions

Potential future directions include:

- Expanding clinical content and good design practice: lab, clinical measurements, problems and orders, possibly focussed on one condition to start with (e.g. diabetes) and aiming to get input from multiple professions;
- Exploring available options for the repository; and
- Fostering work on OWL representation to help ensure the models are consistent and map to appropriate terms as a possible pathway to indexing and cross-referencing iso-semantic models and model fragments.

Attachment 4 – V3 ITS

The UK National Health Service (NHS) is making major investments in health information technology through the Connecting for Health (CfH) program with information interchange and interoperability aspects being thoroughly re-examined under the aegis of Ken Lunn. As noted above, NHS provided interim feedback to the Board and Committee Sessions on progress with its review of business issues related to the useability of HL7v3 and the ease with which v3 can be learnt and deployed efficiently –specifically in relation to an improved Implementation Technology Specification (ITS) for HL7v3

In this regard, NHS has identified a number of approaches which it is pursuing and reported its findings to the HL7 Board substantially in the following terms:

“The NHS national programme for IT experience to date has identified a number of business issues related to HL7v3 usability, mostly concerned with learnability, efficiency and satisfaction.

NHS has considered a number of proposals for improvements to HL7v3 that may address some of these issues. Key proposals, some of which are mutually contradictory, may be summarised as:

- *Introducing an implementation model called an XUM (XML-UML-Model);*
- *Building XUMs automatically, based on new annotations to RIM-Based Models (RBMs) that support implementation usability;*
- *Defining a formalism for data type constraints;*
- *Making XUMs easy-to-use with commercial tools;*
- *Having the capability to automatically create XUMs from any RBM (including profiles), but declare only one XUM as normative within any given domain. This XUM will define the ‘global’ v3 wire format; and*
- *Encouraging the use of ‘business name’ annotation to RBMs to provide a graphical view that links RBMs with terms used in requirements analysis models.*

Issues related to the inclusion or exclusion of fixed and default values in the instance are still under debate.

Further investigation is still required to complete the analysis of the best set of detailed proposals to package. One of the reasons for this is that the benefits to implementers vary depending on the approach they take for message processing.

During the NHS investigation, two main ways to process v3 instances were identified (by active v3 implementers). These may be categorised as “specific message processing” and “reference model processing” and the implications of this continue to be investigated.

In addition, a number of developments within this project have raised the opportunity for further convergence between EN 13606 and HL7v3. This is an important outcome for the NHS and will be pursued further.

Further testing will include the use of a RIM-based serialisation with allowance for a very specific model serialisation where appropriate. NHS undertook preliminary discussions at Boca Raton to help prepare a suitable HL7 project proposal to foster wider collaboration with the HL7 community in this work."

At a more general level, NHS is considering how to make greater use of *openEHR* concepts and particularly its clinical archetypes in conjunction with the EN 13606 reference model and with HL7v3 communications.

In addition to presenting material to the HL7 Board, Grahame Grieve and others presented the more detailed proposals in relation to data types and changes to ITS modelling requirements to various committees including Templates SIG, InM and MnM.

Through a collaborative with HL7 in the UK, NHS is funding work to update HL7v3 tooling to meet the needs of the NHS and UK stakeholders. An RFT for an HL7 model designer, schema generator and infrastructure components was issued in August and an announcement on the successful provider is due next week,

In addition to the NHS initiatives, Wes Rishel, a Gartner Analyst, current HL7 Board member and former HL7 Chair, has penned a Gartner Industry Research publication calling for a critical mid course correction for HL7 V3 messages. This analysis suggests that V3 adoption has been slow in part because the style of using XML is verbose and intractable for business analysts and programmers who are not expert in the RIM. Its recommendations are essentially that HL7 must act to improve V3 immediately, and that V3 users and potential user should use their collective influence to ensure that this occurs. If this does not occur, Rishel predicts that HL7 V3 messages will fail to achieve critical mass, being replaced by ever-more-elaborate use of V2, a series of dialects of V3 chosen by individual countries and large enterprises, or alternate standards.

Attachment 5 – US Presidential Order re Interoperability

Executive Order: Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs

By the authority vested in me as President by the Constitution and the laws of the United States, and in order to promote federally led efforts to implement more transparent and high-quality health care, it is hereby ordered as follows:

Section 1. Purpose. It is the purpose of this order to ensure that health care programs administered or sponsored by the Federal Government promote quality and efficient delivery of health care through the use of health information technology, transparency regarding health care quality and price, and better incentives for program beneficiaries, enrollees, and providers. It is the further purpose of this order to make relevant information available to these beneficiaries, enrollees, and providers in a readily useable manner and in collaboration with similar initiatives in the private sector and non-Federal public sector. Consistent with the purpose of improving the quality and efficiency of health care, the actions and steps taken by Federal Government agencies should not incur additional costs for the Federal Government.

Sec. 2. Definitions. For purposes of this order:

(a) "Agency" means an agency of the Federal Government that administers or sponsors a Federal health care program.

(b) "Federal health care program" means the Federal Employees Health Benefit Program, the Medicare program, programs operated directly by the Indian Health Service, the TRICARE program for the Department of Defense and other uniformed services, and the health care program operated by the Department of Veterans Affairs. For purposes of this order, "Federal health care program" does not include State operated or funded federally subsidized programs such as Medicaid, the State Children's Health Insurance Program, or services provided to Department of Veterans' Affairs beneficiaries under 38 U.S.C. 1703.

(c) "Interoperability" means the ability to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks in various settings, and exchange data such that clinical or operational purpose and meaning of the data are preserved and unaltered.

(d) "Recognized interoperability standards" means interoperability standards recognized by the Secretary of Health and Human Services (the "Secretary"), in accordance with guidance developed by the Secretary, as existing on the date of the implementation, acquisition, or upgrade of health information technology systems under subsections (1) or (2) of section 3(a) of this order.

Sec. 3. Directives for Agencies. Agencies shall perform the following functions:

(a) Health Information Technology.

(1) For Federal Agencies. As each agency implements, acquires, or upgrades health information technology systems used for the direct exchange of health information between agencies and with non-Federal entities, it shall utilize, where available, health information technology systems and products that meet recognized interoperability standards.

(2) For Contracting Purposes. Each agency shall require in contracts or agreements with health care providers, health plans, or health insurance issuers that as each provider, plan, or issuer implements, acquires, or upgrades health information technology systems, it shall utilize, where available, health information technology systems and products that meet recognized interoperability standards.

(b) Transparency of Quality Measurements.

(1) In General. Each agency shall implement programs measuring the quality of services supplied by health care providers to the beneficiaries or enrollees of a Federal health care program. Such programs shall be based upon standards established by multi-stakeholder entities identified by the Secretary or by another agency subject to this order. Each agency shall develop its quality measurements in collaboration with similar initiatives in the private and non-Federal public sectors.

(2) Facilitation. An agency satisfies the requirements of this subsection if it participates in the aggregation of claims and other appropriate data for the purposes of quality measurement. Such aggregation shall be based upon standards established by multi-stakeholder entities identified by the Secretary or by another agency subject to this order.

(c) Transparency of Pricing Information. Each agency shall make available (or provide for the availability) to the beneficiaries or enrollees of a Federal health care program (and, at the option of the agency, to the public) the prices that it, its health insurance issuers, or its health insurance plans pay for procedures to providers in the health care program with which the agency, issuer, or plan contracts. Each agency shall also, in collaboration with multi-stakeholder groups such as those described in subsection (b)(1), participate in the development of information regarding the overall costs of services for common episodes of care and the treatment of common chronic diseases.

(d) Promoting Quality and Efficiency of Care. Each agency shall develop and identify, for beneficiaries, enrollees, and providers, approaches that encourage and facilitate the provision and receipt of high-quality and efficient health care. Such approaches may include pay-for-performance models of reimbursement consistent with current law. An agency will satisfy the requirements of this subsection if it makes available to beneficiaries or enrollees consumer-directed health care insurance products.

Sec. 4. Implementation Date. Agencies shall comply with the requirements of this order by January 1, 2007.

Sec. 5. Administration and Judicial Review.

(a) This order does not assume or rely upon additional Federal resources or spending to promote quality and efficient health care. Further, the actions directed by this

order shall be carried out subject to the availability of appropriations and to the maximum extent permitted by law.

(b) This order shall be implemented in new contracts or new contract cycles as they may be renewed from time to time. Renegotiation outside of the normal contract cycle processes should be avoided.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

GEORGE W. BUSH

THE WHITE HOUSE,
August 22, 2006.