



**ISO TC215 Working Group Meeting
Istanbul, October 2008**

Meeting Report

Report on ISO TC215 Working Group Meeting Istanbul, Turkey, October 2008

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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.

Contributions to this report from Australian delegates to the October 2008 ISO/TC 215 working group meeting in Istanbul, Turkey are therefore gratefully acknowledged, along with the financial support of the Australian Government Department of Health and Ageing, which made the attendance of many delegates possible.

1. Summary of Main Points

1.1 Introduction

The International Organization for Standardization (ISO) develops health informatics standards through technical committee *ISO/TC 215 Health Informatics*. The responsibilities of TC 215 are mirrored in Australia by Standards Australia's Health Informatics Technical Committee, IT-014.

The ISO/TC 215 Health Informatics Joint Working Group meeting (Istanbul Meeting) was held in Istanbul, Turkey from 12 to 15 October 2008. ISO/TC 215 has the following working groups, all of which met at the Istanbul Meeting:

WG 1 Data Structure

WG 2 Data Interchange

(which has two streams - *Architecture and Methodology*)

WG 3 Semantic Content

WG 4 Security, Safety and Privacy

WG 6 Pharmacy and Medication Business

WG 7 Devices

WG 8 Business Requirements for Electronic Health Records

In Istanbul, TC 215 resolved to discontinue *Working Group 5 Health Cards* and pick up its ongoing activities through a Health Cards Task Force reporting through WG 4.

Australia provides the convener of WG 3 (Heather Grain) and the secretariat for WG 8 through the health informatics team at Standards Australia.

The ISO/TC 215 Secretariat is serviced by HIMSS in the US for ANSI and also provides secretariat support for the *Joint Initiative on Health Informatics Standards Development Organisation Harmonisation (JI)*. The JI was formed with the objective of reducing overlap and inconsistency and of promoting economy of effort in the standards development activities of ISO/TC 215, CEN/TC 251, HL7 and other health informatics standards development organisations (SDOs).

The Joint Working Group (JWG) that reports to the Joint Initiative Council (JIC) is formally constituted as ISO/TC 215/WG 9. The JWG reviews SDO work programs in detail and makes recommendations for harmonisation to the JIC. Australia also provides the JWG secretariat and website through Standards Australia.

A total of 8 delegates represented Australia at the Istanbul Meeting. Travel and accommodation costs were largely funded by the Australian Government Department of Health and Ageing with the balance of the cost being met by Standards Australia, the participants and their employers.

Draft minutes of the mini-plenary containing formal motions relating to the progression and/or acceptance of items on the TC 215 Work Program from the Istanbul Meeting may be found in Attachment 3 below.

This report was compiled by Richard Dixon Hughes, drawing heavily on contributions from most of those that attended.

1.2 Standards development program – highlights

The full work program, listing all documents (past, present and future) that have been produced or are being developed by TC 215 (as at July 2008) is provided as Attachment 6 to this report.

Recently completed TC 215 work

The following summary highlights new standards that TC 215 has recently finalised and approved for publication, as well as items on which an Australian position may be required in the period up to the next ISO/TC 215 meeting in Edinburgh, Scotland from 26 to 30 April 2009.

At the Istanbul Meeting, TC215 approved the following documents for publication:

- *ISO 12967 Health informatics service architecture - Parts 1, 2 and 3*
- for publication as full ISO international standards
- *ISO 21547 Health informatics -- Secure archiving of electronic health records -- Parts 1 and 2* - for publication as a full ISO international standard
- *ISO/TS 22600-3 Health informatics - Privilege management and access control -- Part 3: Implementations* - for publication as an ISO technical specification and completing the series on privilege management and access control (PMAC).
- *ISO 25720 Genomic Sequence Variation Markup Language (GSVML)*
- for publication a full ISO international standard
- *ISO 27931 HL7 Version 2.5* - for publication as a full ISO international standard
- *ISO/TR 28380-2 IHE Global Standards Adoption – Part 2: Integration and Content Profiles* - for publication as an ISO technical report

Following review, the following ISO technical reports were re-confirmed for publication for a further 3-year period:

- *ISO TR 20514:2005 EHR Definition, scope and context*
(a project originally led by Dr Peter Schloeffel of Australia)
- *ISO TR 17119:2005 Health informatics profiling framework*
(specifies 3 levels of specificity and 6 perspectives to classify health information)

Upcoming ballots - draft standards documents for approval

Having passed the “Draft International Standard” (DIS) ballot stage, comments are being incorporated into the following documents for final FDIS ballot to approve their publication as full ISO international standards:

- *ISO 13606-5 Electronic health record communication Part 5: Interface specification*
- *ISO 21090 Health informatics – Harmonized data types for information interchange* [being led by Grahame Grieve of Australia].
- *ISO 27932 Clinical Document Architecture, Release 2* [i.e.HL7v3 CDA]

Australia will need to do a final review of each of these documents at FDIS ballot and submit any final comments through Standards Australia IT-014. Under ISO Directives,

there is little opportunity for change at the final FDIS stage; however, it is also time to consider and, if appropriate, plan for their local adoption in Australia.

Following the Istanbul meeting, each of the following documents are expected to be released for ballot as either a Draft International Standard (DIS) or Draft Technical Specification (DTS).

- *ISO DIS 21549-8 Health informatics — Patient healthcard data — Part 8: Links*
- *ISO DIS 22857 Health informatics -- Guidelines on data protection to facilitate trans-border flows of personal health information [revision of existing standard]*
- *ISO DIS 27953-1 Health informatics – Pharmacovigilance – Individual case safety report [ICSR] - Part 1: The framework for adverse event reporting*
- *ISO DIS 27953-2 Health informatics – Pharmacovigilance – Individual case safety report - Part 2: Human pharmaceutical reporting requirements for ICSR*
- *ISO DTS 27790 Document Registry Framework* (based on IHE Korea work in relation to an extension to the IHE XDS specification)

DIS/DTS is the “public enquiry” stage at which detailed acceptance review and specific comment by Australian interests is appropriate.

Upcoming ballots - new work items for approval

It is expected that **Australia** will need to consider whether to approve the following **New Work Item Proposals (NWIPs)** in the months following the Istanbul meeting. If approving an item, one or more experts need to be identified who are prepared to contribute to the work.

- *Quality requirements and methodology for detailed clinical models* – proposed as an ISO international standard (the draft of this document is due for release on April 15 2009 and will be discussed in Edinburgh)
- *Clinical Genomics – Family History/Pedigree*. To be progressed based on experience with an HL7 DSTU in the same field, this is proposed as a full ISOP international standard.
- *Clinical Document Registry Federation* – proposed as an ISO Technical Report (by Korean interests – high level overview of clinical document registry (CDR) federation , issues and requirements to be addressed – with IHE XDS focus).
- *Quality criteria for services and systems for telehealth* – proposed as an ISO Technical Specification
- *Communication and Metadata Model and XML-interface specification for OID registries in healthcare* – proposed as an ISO technical specification (TS)
- *Guidance for maintenance of object identifiers, OID* – proposed as an ISO technical report (TR)
- Revision of *ISO 18104:2003 – Health informatics – Integration of a reference terminology model for nursing* [proposed as joint with CEN with ISO lead]
- A series of WG 7 projects to adopt more of the ISO 11073 series of standards being jointly developed with IEEE in relation to *Personal health device communication* as full ISO international standards, in particular: - *ISO 11073-10408* (thermometers), *ISO 11073-10415* (weighing scales), *11073-10441*

(cardiovascular fitness and activity monitors), 11073-10442 (strength fitness equipment), 11073-10471 (independent living activity hubs) and 11073-20601 (application profile for an optimized exchange protocol).

- *Business requirements for public health standards* – proposed by WG8 as an ISO Technical Report – identifying needs for adoption, adaptation or development of [information] standards in public health, with a focus on developing countries, WHO and leveraging existing work on EHRs and PHRs.
- *Personal Health Records: Definition, Scope and Context* – proposed by WG8 as an ISO Technical Report – including classification of PHR approaches, use cases and leveraging the HL7 PHR-S FM.

It is tempting to ignore NWIP ballots and wait until the work is more advanced before submitting comments but this is not a sound strategy - it is very important that any inappropriate or ill-considered standards development activity be identified and discouraged at the initial NWIP stage, before it gains momentum, consumes resources and becomes entrenched.

Other upcoming work for consideration

IT-014, its subcommittees and any relevant affiliated interest groups will also need to address the following:

- *ISO CD 10159 Web Access Reference Manifest* – consider suitability of Committee Draft, submit ballot and comments.
- *ISO TR 11633 Health informatics — Information security management for remote maintenance of medical devices and medical information systems Parts 1 and 2* – one month final review for publication as Technical Reports
- *ISO DTR 11636 Health Informatics – Dynamic on-demand virtual private network for health information infrastructure* – Australian review and position on publishing this predominantly Japanese work as an ISO Technical Report - for ballot at Edinburgh meeting.
- A series of Committee Drafts from ISO/TC 215/WG6 (Pharmacy and Medication Business) in relation to information structures and controlled vocabularies for Pharmacovigilance and, also, identification of medicinal products (*prEN ISO 11595, 11238, 11239, 11615, 11616, 11240*) – many areas (e.g. product identification, units of measure) are controversial harmonisation candidates.

1.3 Other notable points

Australian participation in TC 215

The total Australian contingent of 8 was sufficient for Australia to meet its obligations to ISO/TC 215 in relationship to convening WG3, providing Secretariat services and informed input to WG8 and the JWG, and contribute generally and participate in the most relevant parts of the Istanbul Meeting. Nevertheless, there is a lot to cover in a short time and it would-be desirable to have specific experts from the relevant fields to ensure greater continuity in relation WG 4 (Security, Safety and Privacy), WG 6 (Pharmacy and Medication Business) and WG7 (Devices).

Further details on the work program and Australian and other participants and are presented in section 2 below and Attachments 1 and 6 to this report.

Health informatics SDO harmonisation

As reported in sections 5 and 6.1 below, the Joint Initiative (JI) on Health Informatics SDO Harmonisation continues increase the focus on harmonisation of SDO work programs and the adoption of improved processes and procedures for management of joint projects.

This initiative is formally guided by the **Joint Initiative Council** (of SDO leaders) (JIC), supported by an open **Joint Working Group** (JWG) that coordinates planning activities.

The original membership of ISO/TC 215, CEN/TC 251 and HL7 has been extended by the approval of CDISC and IHTSDO as additional members of the Joint Initiative.

The JWG is a forum in which joint activities are reviewed, proposals for new joint activities are reviewed and the detailed problems of managing the joint program (such as inconsistent balloting or publication processes) are worked through on a case-by-case basis. The quality and feasibility of SDO harmonisation depends on the JWG functioning effectively identifying and recommending potential joint work for approval by the JIC and in finding solutions to problems affecting the progression of joint work.

The staff of the Standards Australia health informatics team provides the Secretariat for the JWG (which is officially constituted as ISO/TC 215/WG 9).

Following recent changes in personnel at Standards Australia, it is important that all those involved in the Australian health informatics community work closely with the support team to ensure continuity in the quality of support provided to the JWG.

In addition to the costs of staff time, communications and travel that are borne by Standards Australia and some contributions from the Australian Government Department of Health and Ageing, effective performance of this role depends on advice and assistance from Australian experts.

Continued contribution from Government toward these costs is essential to maintaining this capability and enabling Australia to be both better informed and influential in the international health informatics standards field.

Health informatics glossary

An on-line glossary for health informatics has been agreed as a harmonized activity between CEN, ISO and HL7, with Heather Grain of Australia leading the design, editorial curation and management of the Glossary with Canada providing the online tools (SKMT) and web-site. As described further in section 6.2 below, the aim is to capture and resolve differences between the various defined terms used globally in health informatics standards. This will simplify and improve communication about all activities in this area and reduce duplication. A pilot set of defined terms have commenced being loaded into the tool.

The equivalent of three months full-time effort by a person knowledgeable in health informatics and terminology is estimated to be required to identify and process resolution of the duplicates and conflicts through a harmonization committee and this work is scheduled to commence in February 2009 (initially on a volunteer basis).

Financial support is now being sought to progress the coordinated resolution of terminological variations in a suitable timeframe (months instead of years). This support is being requested from national health programs and broader health

informatics community - with some contributions having been made by Canada Health Infoway.

Given that the central component of this work is being led from Australia, support from Australian sources would be welcome.

ISO 13606 EHR communication

As reported in section 6.3 below, the first three parts of ISO 13606 are now all but finished and published as ISO international standards. Apart from later amendment incorporate harmonised data types and for ongoing maintenance of some reference code tables to continue aligning with HL7, these Parts have reached stability. IT-014 can now consider their adoption for greater availability and potential use in the Australian environment.

It is also an appropriate time for IT-014 to progress the planned project to produce a miscellaneous publication on EN 13606 - an activity which was deferred from the 2007/08 year partly because of uncertainty as to the outcomes of the ISO ballots.

Progress on ISO/TS 13606-4 EHR communication - Part 4 Security is reported separately in section 6.4 below and attracted considerable comment - some of it echoing negative comments submitted by Australia at the NWIP/CD stage. It is questionable whether ISO/TS 13606-4 needs local adoption as an Australian standard; however, we should continue to press for its effective harmonisation with other work on security, information privacy and control of access to EHR information.

As reported in section 6.5 below, *ISO 13606-5 EHR Communication Part 5 Interface Specification* recent passed DIS ballot and now needs to be updated based on disposition of the many DIS ballot comments received (almost half from Australia). Australian interests review the updated draft when it is circulated to WG 1 for several weeks prior to the final FDIS ballot expected in March 2009.

Australian representatives continue to press for earlier commitments to produce an HLv3 implementation guide for ISO 13606 needs to be honoured to avoid any negative sentiment in the FDIS vote on the various parts of ISO 13606 – particularly Part 5.

Progression of work on harmonized data types

Australia contributed intensively for some three years to progressing *ISO 21090 Health informatics - Harmonized data types for information interchange to finalisation*. This project, being spearheaded by Grahame Grieve, is one of the first joint projects under the ISO/CEN/HL7 Joint Initiative - with the aim of producing a single co-branded standard.

In the recent 5-month ballot held in parallel across HL7, ISO and CEN, there was a 100% acceptance of the DIS draft of *ISO 21090* from ISO and CEN national member bodies. It also technically passed the HL7 DSTU ballot, despite some significant negative comments being received from HL7 members; however, these comments had significant force and relevance that some changes to the technical content are required - which means at least one more round of balloting in HL7 is required and the amended document should proceed to a final FDIS/FV ballot in ISO and CEN. More details on the ballot outcomes and key issues are reported in section 6.6 below.

Australia (Richard Dixon Hughes) has argued strongly that, in order to maintain harmonisation, HL7 needs to advance this standard to full ANSI/HL7 normative status at the same time as the ISO FDIS and CEN FV ballots and not to go through an interim

DSTU stage. It is understood that HL7 has accepted the need for all three SDOs to move to a fully normative version in parallel, which should now occur around Q3/2009.

From that point onward, HL7 should seek to be made the “ISO Maintenance Authority” for the ISO 21090 standard – allowing it to be updated more dynamically.

This key piece of work needs continuing strong support from the rest of the Australian health informatics community to maintain momentum by participation in relevant international forums until its completion.

Patient and provider identification

As noted in section 6.7 below, Australia is to lead a piece of work on identifying harmonization activities for Patient and Provider Identification and ensure compatibility between the various activities being carried out in CEN, ISO and HL7. This activity will support and inform the current Australian review of standards for Patient and Health Care Client identification. The review will support essential capacity to communicate identifying information in a consistent manner.

Section 6.10 below, also notes the need for broader consideration and review of previous, current and proposed work on information privacy, confidentiality, access control and identity management across ISO, CEN and HL7, other SDOs and national/international programs. Whilst a lot has been done over the last decade, new projects are being proposed which potentially cut across, rather than building on, existing work.

ISO/TS 27527 Provider Identification was accepted in a DTS ballot which closed in April 2008, with its publication being approved at the Göteborg TC 215 meeting in May. Publication is awaiting the disposition of comments and updates to the document to reflect latest data types and value sets. Consideration needs to be given as to how the completion of this important publication, which has an Australian lead, could be assisted through additional local input.

Safety of health software

After much debate at the previous TC 215 meeting in Göteborg, the following documents were in the process of being balloted at the time of the Istanbul Meeting:

- *ISO/DTS 29321 Health informatics – Application of clinical risk management to the manufacture of health software; and*
- *ISO/DTR 29322 Health informatics – Guidance on the management of risk to ensure the patient safety of health software systems in deployment and use.*

When first proposed, there was originally considerable support within TC 215 for a safety regime that might apply to health software which was not part of a recognised “medical device”; however, as reported at some length in section 6.8 below; the need and nature of any such regime has been increasingly questioned - particularly by the developers and suppliers of health software. The regime’s requirement for a Clinical Safety Case Report (CSCR), the attendant questions of liability, and potential clashes with the existing Medical Device safety and regulatory regimes, which are increasingly being adapted to apply to software, have all become major issues leading to significant opposition to the proposals.

At the Istanbul Meeting, there was a special discussion of this topic – with considerable lobbying by those who considered that they would be adversely affected by a decision

to adopt these documents as international standards. Based on inputs from the Istanbul Meeting and after further detailed discussion backed up by detailed comments from the MSIA, Australia voted against both the proposed standards – making positive suggestions seeking a less onerous and better scoped regime with more emphasis on the proposed guidance for users.

Harmonisation of work on information privacy, confidentiality, access control and identity management

As reported in section 6.10, there are many potentially different but overlapping standards activities being undertaken, commenced or proposed in the areas of information privacy, confidentiality, access control and identity management, within both the health informatics and the wider ICT standards world - and also through national, sectoral and global initiatives.

To avoid disharmony and confusion over a proliferation of “standards” there appears to be a need for those working in this area, or commencing work in it, to be more aware of other activity and collaborate much more actively.

IT-014 needs to monitor developments in the areas of confidentiality, privacy, access control and identity management and work with NEHTA, IT-012 (IT Security), HL7/IHE Australia and with other national and overseas interests to influence ISO, CEN, HL7 and key stakeholders to work toward a coordinated program harmonising their activities in these areas, promoting, building on and refining their recent work – rather than reinventing wheels.

A strong program of communication and socialisation of standards work and developments in these areas might also be appropriate at a national level – and once developed this could be more broadly pursued.

Detailed clinical modelling (DCM)

As reported further in section 6.12 below, the Detailed Clinical Modelling (DCM) initiative seeks to bridge the gap between clinicians and health IT, collecting and modelling clinical information requirements once and then re-using the models by expressing the same information in different technologies (e.g. HL7 and *openEHR*) and to define different outputs – messages, documents and decision support tools.

Dr William Goossen (Netherlands) is now leading the DCM initiative within HL7, CEN and ISO and has proposed a range of measures to progress the work including a proposition that ISO/TC 215 approve a New Work Item Proposal (NWIP) for development of an international standard on *Quality requirements and methodologies for detailed clinical models* addressing all four key subject areas needed for DCM:-

1. Clinical content specification.
2. Quality criteria
3. Information modelling (and transformation)
4. DCM repository services

As a general principle, those at the Istanbul Meeting support and encourage progression of work on DCM as a joint activity of the health informatics SDOs; however, some experts have concerns about the particular approaches Dr Goossen is advocating, considering that they are too restrictive, do not allow sufficient flexibility and may ultimately hinder the achievement of broader DCM goals. In particular, his

proposed modelling approach was criticised for not building sufficiently on the significant amounts of information already captured (such as the archetypes developed by the NHS in the UK).

The immediate action is finalising an ISO New Work Item Proposal detailing the scope and content of the proposed new ISO international standard on *Quality requirements and methodologies for detailed clinical models*.

Following discussion at the TC 215 mini-plenary in Istanbul, it was agreed that the NWIP documentation – accompanied by an initial outline draft of the standard would be prepared by the DCM Team by early April to be circulated for ballot among national member bodies in time to allow discussion at the ISO and CEN meetings in Edinburgh.

When details of the proposed DCM standard are released, relevant interests in Australia (including IT-014-09 and NEHTA personnel involved in clinical information specifications) should review them, prepare comments as contributions for discussion in Edinburgh and for the ballot response, and consider whether and how to contribute to the more detailed development of the standard – both within ISO and HL7.

Proposed new work on telehealth

Based on a proposal from The Netherlands, discussed at both the Göteborg and Istanbul Meetings, TC 215 resolved to ballot an NWIP on *Quality criteria for services and systems for telehealth* aiming to commence work on preparation of an ISO technical specification at the Edinburgh meeting in April 2009 (as reported further in section 6.15 below).

After much discussion, it has been agreed that the focus will be on telehealth applications where a clinician using ICT remotely delivers a recognised health care service, noting that this may involve a combination of real-time, store-forward and/or remote monitoring functions, and may address:

- Care Provision
- Information Provision, and
- Business Processes

The intention is to provide a framework of criteria which experts would then decide how to implement in their specific situation, rather than to produce a set of absolute criteria which must be universally adopted in every instance where telehealth services are being delivered.

As previously noted, Australia (through Prof Anthony Maeder) has agreed to work with experts from The Netherlands in progressing this work item.

The Telehealth Standards Framework produced by Standards Australia IT-014 could be contributed to this effort, and areas identified for standardisation effort by Australia (e.g. telehealth session records) could be proposed for international consideration and our local approaches informed and modified by international experience. It is also important that there be mutual alignment of this proposed new work with the previous TC 215 work on telehealth - leading to the two-part technical report: *ISO/TR 16056:2004 ... Interoperability of telehealth systems and networks*.

Standards Australia IT-14 should encourage an active role for Australia in this ISO Work Item, given the relevance of telehealth services in Australia and its position of comparative strength and experience in telehealth and telemedicine.

Health informatics standards - knowledge management and classification

The ability to maintain intelligent, searchable catalogues of health informatics standards and to classify standards work are important to support:

- the easy online identification of the existence of a health informatics standard, its developmental status, and the responsible SDO (e.g. for those developing eHealth policy or in the procurement of health information systems);
- the identification of gaps and overlaps in the overall portfolio of health informatics standards;

These matters are being progressed by two closely related initiatives:

1. A new work item proposal (NWIP) put forward by WG 8 (EHR business requirements) for development of an ISO technical report *ISO/TR 13054 Knowledge management of health information standards*. This NWIP was being balloted at the time of Istanbul Meeting (and subsequently passed when the ballot closed on 21 November 2008).

This TR will review the field and make recommendations as a step toward determining a methodology, metadata and required tools for classifying and maintaining catalogues of health informatics standards.

The work is being led by Dr Andrew Grant of Sherbrooke University in Canada with Heather Grain of Australia being part of the team, as well as having a closely associated role in leading work on the Health Informatics Glossary.

More detail on this initiative is provided in section 6.16 below.

2. Noting various different approaches recently used on other projects to classify health informatics standards, and the needs of the JWG to progress its analysis of its existing portfolio, a JWG/WG 8 Task Group was established to work on the classification issue, with the aim of producing a draft report for April 2009.

Provisional members of the Task Group include Mark Shafarman (US), Paul Whitaker, Bernd Blobel (Germany), Dipak Kalra (UK), Beatriz Leao (Brazil), Dr Mike Mair (NZ) and Standards Australia (as holder of the JWG/WG 8 secretariat).

In addition to the various methods for classifying standards, the Task Group will consider tools available to capture and classify information on current health informatics standards – including the overall role of a standard; its contextual importance, its relation to other standards, and its stage of development. Ultimately, the aim is to have a classification and cataloguing tool that meets the requirements set out in the proposed *ISO/TR 13054*.

For more information - see section 6.17 below.

Australia has been supportive of both these initiatives, which will have a direct bearing on WG 8 and the JWG – which are both supported by an Australian secretariat. The assistance of Australian experts to ensure that the outcomes are well considered and practical should be sought and be welcomed – also to provide political support in ensuring that the views of the Secretariat are taken into account. Australia will need to consider practical measures to assist relevant experts to contribute effectively

EHR system functional model (ISO/HL7 DIS 10781)

HL7 published its *EHR System Functional Model* (EHR-S FM), firstly as a DSTU in 2004 and then in February 2007 as a full ANSI/HL7 standard: *ANSI/HL7 Electronic Health Record-System Functional Model - Release 1*.

A range of supporting conformance profiles has since been developed, and the model and accompanying profiles have been widely applied by CCHIT in the United States as the basis for certification of EHR systems – resulting in requests for more specialised profiles and, also, extensions and changes to the underlying EHR-S Functional Model.

The current ISO/TC 215 work item: *ISO/HL7 DIS 10781 Electronic health record - System functional model, release 1* seeks to move ANSI/HL7 EHR-S FM Release 1 forward for full acceptance as an ISO International Standard.

At the same time, the HL7 EHR Work Group (EHR WG) is under pressure to deliver changes sought by CCHIT, HITSP and others within the US who have actively used the model and profiles – with the HL7 EHR WG seeking to finalise Release 2 of the EHR-S functional model standard.

As reported in more detail in section 6.18 below, the difficulties of maintaining alignment and release cycles and versions of this cornerstone standard have been discussed at some length at recent HL7, ISO/TC 215, JWG and JIC meetings.

Following recent closure of a successful DIS ballot to accept *ISO/HL7 DIS 10781*, but with significant negative comments, there was extensive discussion in WG 8. It was concluded that ISO/TC 215 national member bodies (NMBs) would prefer to proceed with an international standard based on a draft of Revision 2 rather than the outdated Revision 1. On motion of Richard Dixon Hughes (Australia), WG 8 resolved to:

“Accept the draft disposition and proposed further amendment of the DIS draft for consideration by Working Group 8 in Edinburgh, and further consideration at HL7 WGM in Kyoto with a view to release for FDIS ballot in September 2009.”

This approach was subsequently adopted by TC 215 resolution in the mini-plenary at the Istanbul Meeting.

Australian experts played a significant role in early development of this standard and did their best to ensure that it reflected a truly international perspective. Recent input has almost entirely addressed local US needs, where the standard is widely used, with a risk that Australian and other international interests need to re-engage if this standard that specifies the required functional capabilities of clinical information systems is to serve its purpose and facilitate a truly international market for health information systems.

Request for Australian input for update of ISO/TS 21667:2004 (Health indicators conceptual framework)

As noted in section 7.1 below, Australia submitted significant comments at the time of the recent review ballot for *ISO/TS 21667:2004 – Health indicators conceptual framework*. Given the level of comment, Australia has been asked to nominate a suitable expert to contribute to the project team that is updating the document under Canadian leadership.

IT-014 now needs to consider potential contributors (AIHW, the sources of previous comments and State health authorities were mentioned) and secure a nominee to participate in the review and update work.

Australian input on ISO/DIS 21091 Directory Services

The updated version of the current ISO/TS 21091:2005 *ISO/DIS 21091 Directory Services for security, communications and identification of professionals and patients* has now been distributed for DIS ballot closing 27 April 2009 (on the eve of the Edinburgh TC 215 meeting).

It is important that this document, which needs to be informed by mainstream identity management and directory services experience be closely scrutinised by Australian interests during the current DIS ballot. IT-014 should look to coordinate this activity.

Pharmacovigilance and Medications Identification

Seven projects on the WG 6 Pharmacy and Medication Business work plan are being undertaken under the Vienna Agreement between ISO and CEN, with ISO/TC 215 as the lead SDO. These projects relate to Pharmacovigilance (Individual Safety Case Report) and Identification of Medicinal Product (IDMP) standards. They are also on the Joint Initiative work program, with each having an ISO/CEN lead and an HL7 co-lead (supplied by HL7).

As reported in section 12 below, these projects originated from an eHealth contract between CEN and the European Commission, which led to joint standards development with ISO/TC 215/WG 6. Original sponsors of much of the work included the European Medicines Agency (EMeA) and the ICH¹.

The projects commenced in 2006 and some of the work was found to conflict with approaches recently introduced in the US under the FDA and their arrangements with HL7. After a difficult period, communication is now much better (but far from perfect).

The originally planned scope of the WG 6 activities has now been significantly scaled back; there is typically a large attendance at meetings because of potential impact on industry, regulators and health service providers but overall progress is slow, despite many out of session meetings. Much of the work is increasingly raising potential overlaps or conflicts related to:

- Information models representing clinical content (overlapping WG 1, CDISC and HL7 Pharmacy, Laboratory and data types interests)
- The localised development of specific code sets and terminologies for “pharmacovigilance” including the identification of medications and their attributes (deriving from ICH but potentially overlapping WG 3, IHTSDO, WHO and HL7 interests).

The WG 6 defence is that it is focussed on specific regulatory reporting requirements, with special terminology, which is not intended for inclusion in EHR or more general recording of adverse results; however, this line is becoming increasingly unacceptable to the broader stakeholder community.

¹ The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use - a selective multi-regional consortium of some, but not all, pharmaceutical companies and regulators.

- In particular, the proposed specifications: *ISO/CD 11240 IDMP Units of measure (UOM)* and *ISO 11595 Pharmacovigilance – Test names and units for reporting laboratory results* - which need to be integrated with established work of other WGs and SDOs (including the open source LOINC and UCUM materials from Regenstrief Institute).

Flowing from discussions at the Istanbul Meeting, there is strong pressure for closer collaboration with other WGs (potentially WG 3, WG 1 and WG 2) in ISO and, also, other health informatics SDOs currently involved in terminology and code sets.

The other major concern is how the resulting controlled vocabularies and code sets - particularly those for IDMP - will be maintained and where the resources will come from to perform this function.

Upcoming ICSR Ballot

The upcoming DIS ballot for acceptance of *ISO/DIS 27953 ICSR* as an international standard will soon require a response from Australia. This activity has involved significant input from a large number of global interests and requires a response that aligns with our needs and directions of the full cross-section of stakeholders in Australia including TGA and NEHTA.

The strength of an Australian position will also depend on input from TGA concerning potential Australian/ICH adoption of a uniform, international, standards-based ICSR regime.

ICSR is discussed in more detail in section 12.1 below.

Upcoming IDMP Ballots

Drafts of all five IDMP (*11615, 11616, 11238, 11239, 11240*) working drafts will be shortly circulated in a ballot for acceptance as Committee Drafts (CDs) along with the associated *ISO/WD 11595*.

Given the potential overlap and inconsistency with other work on clinical terminology, regulatory value sets and medication identification, Australia will need to take the time to develop an informed and considered position on these proposed CD ballots. This is the most appropriate time to propose any fundamental changes.

IT-014 will need to initiate an activity to present and discuss the proposed documents and arrange for review by those familiar with terminology, laboratory communication and contemporary trends in health informatics to confirm, that the proposed approaches align with existing practices and/or preferred future directions – or that there is a strong case for any deviations.

If these proposed standards do not align with other work, there needs to be some consideration as to the appropriate vote and the comments to be submitted with them.

General Australian involvement in WG 6 and HL7 Pharmacy

It has previously been recommended that Australia should increase its involvement in WG 6 projects beyond the current monitoring /watching brief – this continues to be the case and also for parallel activities in the HL7 Pharmacy WG (see report on HL7 September 2008 meeting in Vancouver).

Liaison for WG6 projects should include NEHTA, TGA and State representatives interested in identification of medicinal products and case safety reports. Whilst much of this work originated in Europe, it has now gained attention and involvement from other countries HL7, CDISC and IHTSDO and Australia needs to consider the implication of these draft ISO Standards on Australian medicinal initiatives.

Laboratory Units of Measure

At the Istanbul Meeting, it became clear that several different initiatives face significant issues related to the specification, referencing, use and maintenance of Units of Measure (UOM), in particular:

1. Issues identified by WG 6 during work on its proposed *ISO/CD 11240 IDMP UOM* standard including the following:
 - SNOMED and the other leading options for representing UOM need additional terms to meet business requirements needs – where, how and by what authority would WG 6 source these additional terms?
 - Standardisation of value sets – the Regenstrief UCUM² code is widely supported and based on ISO 2955 but is strictly open source and cannot be licensed for incorporation, publication and sale as part of another standard – but its codes could be referenced from such a standard and are mappable to other term sets.
 - Apparently some problem has been raised with the suitability of the harmonised PQ (Physical Quantity) data type - although this may only reflect the views of one particular scientist at Regenstrief who has long opposed many of the changes now proposed for HL7 in moving to harmonised datatypes .
2. WG 3 had requested that WG 6 work on the *ISO/CD 11240 IDMP UOM* be transferred to WG 3 – as WG 3 considered the content is heavily dependent upon WG 3 terminology and, also, WG 2 data type harmonisation.
3. WG 6 considered leaving *11240* as a draft for the present - but TC 215 resolved that this document should go through to CD ballot along with the rest of the IDMP suite of standards, which has the advantage of giving NMBs the opportunity to make their views known.
4. In WG 7, the ISO 11703.x (device communication interface) series of standards do not presently reference UCUM but IHE profiles using these standards do. HL7 and DICOM also both mandate use of UCUM.
 - WG 7 currently propose that ISO standards make references to UCUM rather than bringing it into ISO documents, so people are not paying for something that is otherwise available as an open source product.
 - Long-term maintenance and governance of UCUM are other issues. Maintenance presently depends on 2 people that perform this function at the Regenstrief Institute.
5. There is a growing desire to build on the open source UCUM code and conversions maintained by Regenstrief Institute as the global standard for UOM but there remain concerns about the governance and how to manage the respective intellectual property rights issues.

² UCUM – Unified Code for Units of Measure.

6. The JI/JWG is now tracking and discussing work on UOM arising from WG 6 (Pharmacy & Medication Business) and the emerging work on methodologies for infrastructure, registration and maintenance of UOM code sets in WG 3 with a view to aligning interests and activities, taking into account those of HL7, Regenstrief Institute (in relation to UCOM), CDISC and others.

Australia needs to develop a well informed, widely researched and accepted domestic position in relation to harmonised global standardization of Units of Measure and the processes to be used to maintain them. It also requires appropriately informed experts participating in the further discussion of these issues.

Presentation of clinical knowledge management tools

Dr Heather Leslie of gave a presentation of Ocean Informatics archetype repository and clinical knowledge management tools to a lunch time session at the Istanbul Meeting, which was attended by over 50 people - showcasing some of the results of Australian investments in eHealth technologies that are finding increasing acceptance as solutions addressing some of the needs of the international eHealth marketplace.

The positive response highlights the value of continuing to pursue effective harmonisation between the various standards approaches, as the whole field of EHR, PHR and semantic interoperability continues to develop, matures and hopefully stabilises over the next decade.

Next meeting

The next meeting of the ISO TC/215 Health Informatics Committee is scheduled to be held in Edinburgh, Scotland (UK) from 27-30 Apr 2009 with preliminary meetings of the JWG and other coordinating groups on Sunday, 26 April. The annual TC 215 plenary meeting for 2009 will be part of the Edinburgh meeting will be.

2. Introduction

ISO TC215 holds two full international meetings per year. The first is known as the “Plenary Meeting” because it includes plenary sessions in which formal resolutions are taken in addition to meetings of TC215’s eight domain-specific working groups.³

The second meeting, known as the “Joint Working Group Meeting”, usually comprises meetings of the working groups but, in recent years, has also included a smaller “mini-plenary” to progress urgent matters.

The Joint Working Group Meeting for 2008 was held in Istanbul, Turkey from Sunday, 12 to Wednesday, 15 October (inclusive), in accordance with the following timetable:

Sun 12 Oct	0800-1100: ISO TC215 /WG9 SDO Harmonization (JWG) meeting 1130-1430: Joint Initiative Council for SDO Harmonisation (Closed) meeting 1500-1800: TC215 Operations & harmonization meeting (Secretaries, Conveners and Vice-Conveners – Grain, Hanley) 1830-2030: Meeting to discuss proposed standards on Management of Health Software Safety Risks and directive on software in medical devices
Mon 13 Oct	0730-0815: Australian team meeting 0830-0845: Welcome to Turkey and formal opening by Turkish Ministry of Health 0845-1000 (Q1): Working Group meetings (8 separate sessions) 1015-1215 (Q2): Working Group meetings (1 joint + 4 separate sessions) 1230-1315 (Lunch): Discussion on Traditional Chinese Medicine (TCM) 1315-1500 (Q3): Working Group meetings (2 joint + 4 separate sessions) 1515-1700 (Q4): Working Group meetings (2 joint + 4 separate sessions) 1700-1730: Australian team updates prior to Executive Council Meeting 1730-1930: ISO/TC215 Executive Council Meeting (Grain, Dixon Hughes, Hanley) 2000-2400: Canada-Australia dinner function
Tue 14 Oct	0730-0815: Australian team meeting 0830-1015 (Q1): Working Group meetings (1 joint + 6 separate sessions) 1030-1215 (Q2): Working Group meetings (1 joint + 5 separate sessions) 1230-1315: (Lunch) Dr Heather Leslie (Australia) presents Archetype management tools 1315-1500 (Q3): Working Group meetings (2 joint + 4 separate sessions) 1515-1700 (Q4): Working Group meetings (1 joint + 5 separate sessions) 1730-2300: ISO/TC215 Official Reception – Turkish Standards (TSE)
Wed 15 Oct	0830-1015 (Q1): Working Group formal meetings & finalisation of resolutions (9 separate sessions) 1015-1215 (Q2): Working Group meetings cont'd (8 separate sessions) 1215-1315: Australian team meeting – preparing for plenary 1315-1700 (Q3+): Closing Mini-plenary

As is the normal custom when a TC 215 meeting is held in the European region, the relevant working groups from the European CEN/TC 251 committee met in parallel with

³ In 2008, the Plenary was held in Gothenburg, Sweden from 27 May to Monday 2 June. See: Standards Australia. *Report of Australian Delegation to the ISO TC215 Health Informatics Standards Meetings in Gothenburg, Sweden May-June 2008.* June 2008

their corresponding TC215 working group – a practical measure to assist in harmonising CEN and ISO standards in the health informatics domain.

Some 200 attendees from 22 countries were present at the Istanbul meeting (see Attachment 1 for list by country). Representatives of several liaison organisations including CEN, HL7, IHTSDO, WHO, CDISC, IHE, IEEE were also present.

Australian was represented by seven delegates, most of whom were supported by funding provided by the Australian Government Department of Health and Ageing (DoHA) through Standards Australia. They were:

- Richard Dixon Hughes, Head of Delegation
- Heather Grain, Chair IT-014, Convenor ISO/TC215/WG3 Semantic content
- Grahame Grieve (attendance supported by Jiva Medical and UK NHS)
- Elizabeth Hanley (attendance funded by Standards Australia)
- Dr Evelyn Hovenga
- Dr Heather Leslie
- Prof Anthony Maeder
- Dr Vince McCauley

Since ISO/TC 215 generally has up to eight concurrent streams at its meetings, the delegation necessarily covers some areas in greater depth than others, taking into account the expertise and interests of the delegates and the priorities set out in IT-014's current objectives for Australian engagement in international standards development as discussed with DoHA as a basis for providing their funding support (see Attachment 2).

Most Australian delegates also participated in the meeting of the Joint Working Group for Health Informatics Standards Development Organisation Harmonisation.

Heads of Delegation, Working Group Convenors and Secretariats (in this case, three out of the seven Australian delegates) also attended various TC 215 strategic management and organisational meetings.

This report addresses the main matters that arose at the meeting with resolutions taken by TC 215 at the mini-plenary meeting being included at Attachment 3 below.

3. ISO Health Informatics Standards Background

ISO is a network of the national standards institutes of 157 countries, on the basis of one member per country, with a Central Secretariat in Geneva, Switzerland.

ISO standards are technical agreements which provide the framework for compatible technology worldwide. They provide a reference framework, or a common technological language, between suppliers and their customers - which facilitates trade and the transfer of technology. This is achieved through consensus agreements between national delegations representing all the economic stakeholders concerned - suppliers, users, government regulators and other interest groups, such as consumers.

ISO standards are developed by technical committees comprising experts from the industrial, technical and business sectors which have asked for the standards, and which subsequently put them to use. These experts may be joined by others with

relevant knowledge, such as representatives of government agencies, testing laboratories, consumer associations, environmentalists, academic circles and so on. The experts participate as national delegations, chosen by the ISO national member institute for the country concerned. These delegations are required to represent not just the views of the organizations in which their participating experts work, but also of other stakeholders. According to ISO rules, the member institute is expected to take account of the views of the range of parties interested in the standard under development and to present a consolidated, national consensus position to the technical committee.

Standards Australia is Australia's member of ISO and is responsible for arranging representation at Technical Committees such as TC215.

Much of the development and negotiation of international standards takes place via email. At international meetings, however, national delegations of experts meet to discuss debate and argue until they reach consensus on a draft agreement. The resulting documents are then circulated as a Draft International Standard (DIS) to all of the ISO's membership as a whole for comment and balloting. The ISO members then take account of any feedback they receive in formulating their position on the draft standard. If the voting is in favour, the document, with eventual modifications, is circulated to the ISO members as a Final Draft International Standard (FDIS). If that vote is positive, the document is then published as an International Standard. A similar but less lengthy process is undertaken for "Technical Specifications", "Technical Reports" and other standards documents produced by ISO committees. A diagram illustrating the main types of standards deliverables and the processes by which they may be produced is provided at Attachment 4.

ISO's technical committees also have formal liaison relationships with other relevant international organisations. TC215 has a range of liaisons which are listed in Attachment 5, but notable ones include HL7, IHE, W3C and WHO. TC215's processes are also influenced by bilateral agreements between ISO and CEN (the European standards body) and ISO and HL7, both of which allow for fast tracking of candidate international standards prepared by those organisations.

4. ISO TC215 Health Informatics Committee

4.1 Scope and Function

The ISO TC215 Health Informatics Committee is responsible within ISO for standardization in the field of information for health, and health information and communications technology (ICT) to achieve compatibility and interoperability between independent systems and also, to ensure compatibility of data for comparative statistical purposes (e.g. classifications), and to reduce duplication of effort and redundancy. However, the scope of ISO/TC 215's activities does not extend to standardization of:- clinical practices, health care delivery, clinical knowledge (other than defining how to represent and communicate such knowledge in digital form) or detailed internal operation of clinical devices.

At present the committee membership comprises 24 participating countries (P-Members) and 21 observing countries (O-Members) with Dr Yun Sik Kwak MD PhD (Korea) as the Chair and the Secretariat being held by the United States (ANSI) and serviced by the Health Information Management Systems Society (HiMSS) through Audrey Dickerson RN.

TC215's standards development work is carried out through the following Working Groups (which conduct parallel sessions throughout most of the time allotted for each TC215 meeting).

Working Group (WG)

Summary of WG Scope and Comments

WG 1 Data Structure

<p>Convenor: Grant Gillis (Canada) Vice Convenor: Tetsun Kiyoi (Japan) Secretariat: Andrea Ciemny (Canada)</p>	<p>Scope: Developing standards that establish the structure of health information in order to facilitate the sharing of information and data among enterprises, organizations, and information systems.</p> <p>These standards establish the definitional, context, organization (framework and models), relationship, and template requirements for health information and associated data sets.</p>
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WG 2 Data Interchange

<p>Convenor: Mike Glickman (US) Vice Convenor: Michio Kimura (Japan) Secretariat: Adrian Stokes (UK)</p>	<p>Scope: Standardizing means of messaging and communication in health informatics such that electronic exchange of information between individual systems (clinical and administrative) and organizations (clinical and administrative) is facilitated.</p> <p>This WG usually meets as two separate streams: one focussed on "Methodology", the other on "Architecture". It is the WG that has carriage of ISO adopting HL7, IHE and DICOM standards.</p>
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WG 3 Semantic Content

<p>Convenor: Heather Grain (Australia) Vice Convenor: Kathryn Hannah (Canada) Secretariat: Pat Village (UK)</p>	<p>Scope: Developing standards for representation of health concepts and data. These standards include formal models of representation and description of health concepts; principles of their organization within terminologies and related systems (including controlled clinical terminologies and classifications); and issues concerning context of their use in EHRs. Efforts are focussed on selection and integration of terminological content within health informatics applications.</p>
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WG 4 Security, Safety and Privacy (both title & scope amended by TC215 in Istanbul)

<p>Convenor: Ross Fraser (Canada) Vice Convenor: Lori Fourquet (US) Secretariat: Alice Rideau (France)</p>	<p>Scope: Defining health informatics security and privacy protection standards to</p> <ol style="list-style-type: none"> 1) protect and enhance the confidentiality, availability, and integrity of health information 2) prevent health information systems from adversely affecting patient safety; 3) protect privacy in relation to personal information; and 3) ensure the accountability of users of health information systems.
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WG 5 Health Cards (At Istanbul, WG5 was retired in favour of a Task Force under WG4)

<p>Leader: Jürgen Sembritzki (Germany) Secretary: Heike Moser (Germany)</p>	<p>Current tasks (not formalised as a "scope")</p> <p>Finalisation of balloting/publication of <i>DIS 21549-8 Health Informatics – Patient healthcard data – Part 8: Links</i></p> <p>Commencing three-year review of following parts of <i>ISO 21549 Health Informatics – Patient healthcard data</i>:</p> <ul style="list-style-type: none"> - Part 1: General structure; Part 2: Common objects; Part 3: Limited clinical data ; Part 5: Identification data
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Working Group (WG)

Summary of WG Scope and Comments

WG 6 Pharmacy and Medication Business

<p>Convenor: Ian Shepherd (UK) Vice Convenor: LuAnn Whittenburg (US) Secretariat: Shirin Goldyardi (Netherlands)</p>	<p>Scope: Establishing standards in the domain of pharmacy and medication (including for research, development, regulation, supply, use and monitoring) to improve the efficiency and interoperability of medication information systems affecting patient safety.</p> <p>This WG provides appropriate domain expertise to ensure that the business requirements for international standards in this area are identified and met either by cooperation with other groups (through adoption of their standards into ISO) or by development of new standards and technical reports within the working group.</p> <p>The WG also has a watching brief to monitor the need for health informatics standards and advise other TC215 WGs on requirements in the area of e-pharmacy and applications relating to medicines.</p>
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WG 7 Devices

<p>Convenor: Todd Cooper (US) Vice Convenor: Thomas Norgall (Germany) Secretariat: open Formerly: Melvin Reynolds (UK)</p>	<p>Scope: Standardization in the application of information and communication technology (ICT) to medical devices for plug-and-play interoperability at the point of care, as well as facilitating the efficient exchange of device in all health care environments.</p>
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WG 8 Business Requirements for Electronic Health Records

<p>Convenor: Marion Lyver (Canada) Vice Convenor: Beatriz Leao (Brazil) Secretariat: Standards Australia Elizabeth Hanley (to Oct 2008) Renati Barel (from Nov 2008)</p>	<p>Scope: Standardization in the identification of business requirements for all health informatics aspects applicable to health records for all healthcare settings.</p>
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As main standards development activities of WG5 (Health Cards) have now been completed and only a small core group have attended for some meetings, TC215 accepted a recommendation that WG5 be retired as a Working Group and be replaced by a smaller task force coordinated through WG4.

At the Istanbul meeting, the TC215 Executive Council updated plans re-visit the overall Working Group structure as part of longer-term strategy.

ISO TC215 Secretariat (Audrey Dickerson at HIMSS) provides Secretariat services for the Joint Initiative Council (JIC) that manages collaboration between ISO TC215, CEN TC251 and HL7 under the *Joint Initiative on SDO Global Health Informatics Standardization*.

In addition, the Joint Working Group (JWG) that supports the JIC is constituted as ISO TC251 WG9, with Australia playing a major role by providing the Secretariat. The profile of this Working Group may be summarised as follows.

ISO/TC 215 WG 9 - JWG for SDO Harmonization (TC 215/HL7/TC 251)

<p>ISO Co-convenor: Don Newsham (Canada)</p> <p>CEN Co-convenor: Melvyn Reynolds (UK)</p> <p>HL7 Co-convenor: Charles Jaffe, CEO HL7 (US)</p> <p>Secretariat: Standards Australia Elizabeth Hanley (to Oct 2008) Renati Barel (from Nov 2008)</p>	<p>Scope: JWG is a planning, process determination and coordinating group that makes recommendations to the Joint Initiative Council (JIC) on resolving gaps, overlaps or issues of counterproductive standardization in health informatics by:</p> <ol style="list-style-type: none"> (a) Identifying and analysing, defining and documenting specific gaps, overlaps, issues and tasks to be addressed; (b) Using use cases addressing all parts of the standards life cycle (c) Developing, testing and using effective decision processes for international standardization needs; and (d) Developing common processes for harmonization in accordance with participating SDO processes <p>The JWG is tasked with developing an integrated work program amongst the participating SDOs for approval by the JIC, including:</p> <ul style="list-style-type: none"> • Collection and summarization of participating SDO work plans; <ul style="list-style-type: none"> • Building awareness of relevant standards activity; • Reviewing the work plans of participating SDOs gaps, overlaps and counterproductive standardization; • Monitoring and providing feedback on the outcomes of the Joint Initiative; and • Encouraging stakeholder engagement and communicating output of the work programme.
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The JI and JWG meet three, four or five times per year concurrently with meetings of each of the participating organisations and conduct business by teleconference in between these meetings.

Current SDO harmonisation activity and outcomes in relation to JWG/JI activities is reported further in sections 5 and 6.1 below.

4.2 TC215 Scope, Organisation, and Work Program

The updated ISO TC215 work program (current to August 2008) is appended as Attachment 6.

An internal closed meeting of TC215's Working Group office bearers was held on Sunday, 12 October (from 1500 to 1800) to coordinate activities at the Istanbul Meeting.

4.3 Forthcoming Meetings

The next meetings of the ISO TC/215 Health Informatics Committee are scheduled for:

26-30 Apr 2009	Edinburgh, Scotland (UK)	Plenary
18-21 Oct 2009	Durham, North Carolina, USA	Summit V + JWG Meetings
Apr 2010 (dates tbc)	Brazil	Plenary (w DICOM conf)
Sep 2010 (dates tbc)	Cape Town, South Africa	JWG with MedInfo 2010

5. Collaboration between Health Informatics SDOs

At the October 2006 TC 215 meeting in Geneva, Switzerland, the three main world-wide health informatics standards development organisations (SDOs) at that time – ISO/TC 215, CEN/TC 251 and HL7 agreed in principle to a Charter for a *Joint Initiative on SDO Global Health Informatics Standardization* by which they would collaborate with each other – with the overall aim of responding to the following requirements of the health informatics stakeholder community:

- Relevant, consistently implementable, timely international standards
- One problem, one standard, one test
- Providing all the standards required to implement entire solutions

The Charter was subsequently ratified by relevant processes within each of the three bodies. Essentially the Joint Initiative Charter affirms the need for the health informatics Standards Development Organisations (SDOs) to work collaboratively toward “one standard-one test”, through:

- an integrated work program across the signatories,
- common processes for selection of projects, and
- common, cooperative communications; and

This initiative is formally guided by the **Joint Initiative Council** (of SDO leaders) (JIC), supported by an open **Joint Working Group** (JWG) that coordinates planning activities (and which has been formally constituted as ISO/TC 215/WG 9).

Working arrangements for SDO Harmonization were significantly progressed at the August 2007 TC 215 meeting in Brisbane, including holding the first formally constituted meeting of the JWG – for which Standards Australia provides the standing secretariat function. Meetings were subsequently held in Dublin, Ireland (November 2007), at the HIMSS meeting in Orlando, Florida (February 2008), Gothenburg, Sweden (May 2008 ISO meeting) and Vancouver, Canada (September 2008 HL7 meeting). The seventh meeting of the JWG is scheduled for Sunday, 11 January 2009 in conjunction with the HL7 meeting in Orlando, Florida.

In 2008, two more organisations – CDISC Inc (Clinical Data Standards Interchange Consortium) and IHTSDO (International Health Terminology Standards Development Organisation) sought to become members of the JI Council.

While there is considerable goodwill, each of the SDOs in the JI primarily addresses the needs of different groups within the overall e-health stakeholder communities and there are many practical barriers to seamless collaboration. Achievement of the JI's end-goals remains fragile, with the following being among the key issues:

- Each of the SDOs is very dependent on the work of volunteers and sponsors making their ability to commit resources to joint programs problematic – particularly when engagement in a joint initiative distances enthusiastic contributors from decisions about the work and its direction.
- Although the three organisations' standards development and balloting processes are derived from the ISO principles of openness, transparency and consensus, they operate with quite different cultures, timescales and support processes. Running a joint ballot has proven to be a logistical challenge (which may become even more complicated as more organisations join the JI).

- Individual SDOs need to be able to respond quickly to major stakeholder needs within their sphere of influence and not all stakeholders are prepared to change their requirements to accommodate the broader harmonisation agenda.
- It is hard to organise work collaboratively with participants spread across the entire globe without some being disadvantaged by distance, time-zone and/or language.
- Miscommunication: the three SDOs have traditionally operated in a decentralised manner with individual technical committees and working groups within each organisation having considerable ability to set their own agendas. The JI has highlighted a need to establish better systems for controlling and managing workflow and both internal and external communication.

As a positive outcome, the following has been achieved:

- Support from the leadership of major international SDOs to work through the Joint Initiative for collaboration, co-ordination and co-operation in delivering global health informatics standards
- Closer relationships with other significant global SDOs operating in the same space – with more becoming involved in the future
- Development of Joint Initiative processes for common / harmonised standards development (for Normative Standards)
- Joint SDO work program inventory listing all current ISO/TC 215, CEN/TC 251 work items and major HL7 standards development activities
- Improved communications between and within the initial three SDOs with each nominating an appropriate contact point for formal communication and educating their members and stakeholders about the JI and its activities.
- Constitution of the JWG as ISO TC215 WG9 with Standards Australia as the Secretariat.
- Joint work program with several major harmonisation projects already underway for example, data types, which have helped identify models for harmonisation of work processes and joint task groups for future projects.
- Development of the website for the Joint Initiative on SDO Global Health Informatics Standardization , which is hosted through Standards Australia at: <http://www.global-e-health-standards.org/>.

6. Major Issues and common themes

Several of the more significant topics progressed at the Istanbul meeting and common themes running across several Working Groups included the following:

- Progressing health informatics SDO collaboration
- Glossary of terms for health informatics
- ISO 13606 – EHR Communication Parts 1 to 3
- ISO/TS 13606-4 EHR Communication – Part 4 Security
- ISO 13606-5 EHR Communication – Part 5 Interface specification
- ISO 21090 - Harmonized data types
- Harmonization of patient and provider identification
- Safety standards for health software
- Standardizing purposes for processing EHR data
- Collaboration on information privacy, confidentiality, access control and identity management
- Traditional Medicine special group
- Detailed Clinical Modelling (DCM) as a new work item
- CDISC BRIDG model for clinical trials and research data
- Issues impacting semantic interoperability
- Telehealth/telemedicine
- ISO/TR 13054 - Knowledge management of health informatics standards
- Classification of health informatics standards
- ISO/HL7 DIS 10781 EHR system functional model

In many cases these matters were dealt with at the level of TC 215 itself or in joint sessions across several of the working groups, so these topics have been reported ahead of the activities of each ISO TC 215 Working Group.

6.1 Progressing health informatics SDO collaboration

The 6th meeting of the Joint Working Group on SDO Harmonization (constituted as ISO/TC 215/WG 9) was held at the Istanbul Meeting on Sunday, 12 October 2008 from 0800 to 1100 hours and attracted over 90 attendees from 20 different countries.

This was followed by a face-to-face meeting of the JI Council, which was held in closed session.

Minutes of the JWG meeting are included as Attachment 6 to this report. This meeting followed fairly close on the heels of the September JWG meeting in Vancouver. The following are the more significant points reported from the JI and JWG in Istanbul:

1. The International Health Terminology Standards Development Organisation (IHTSDO) has expressed interest in becoming a member of the JI and their admission as a provisional member was agreed at the JIC meeting in Istanbul.
2. With CDISC (Clinical Data Interchange Standards Consortium) having been admitted as a provisional member of the JIC, there is a need to add some 40 CDISC projects to the Joint SDO work program inventory, (which already has over 200 work items active across ISO, CEN and HL7).

[Note: Maintenance of the inventory is carried out by the JWG Secretariat – hosted by Standards Australia]
3. A rigorous means of classifying standards work is needed to help identify overlaps and gaps – various models raised in Vancouver (including extension of the SKMT health informatics Glossary Tool) are being actively pursued – linking with proposed work on *Knowledge Management of Health Information Standards* and the *Health Informatics Glossary*.
4. The potential of building on HL7's vision of having a common repository from which standards projects could be booked out to individual work groups while remaining visible to others was explored – noting that repositories are counter-productive if they are not up to date. Fundamentally, this requires :
 - (a) up to date tooling; and
 - (b) accepted shared business process for registration, classification and management of projects

Additional contributors were added to the task force which was convened at the Vancouver meeting to look at a projects/products repository, the tools needed to maintain it and the related analysis of the joint work program.

5. A proposal to form a Joint Initiative Task Group to progress the HL7v3 Implementation Guide for ISO 13606 had been submitted to JIC for approval.

[Note: The significance of this item is its aim of identifying how archetyped clinical information should be handled in the HL7v3 environment].
6. Harmonized data types. Work is progressing toward finalisation in 2009 [see section 6.66.6 below.]
7. Pharmacovigilance (Individual Safety Case Report and controlled vocabularies). Joint work was initiated at the behest of ICH and is being progressed by ISO/TC215/WG6 (Pharmacy and Medication Business). This activity has been underway for almost two years with some 30 organisations actively involved. It was reported that many lessons had been learnt about difficulties of working with different regulatory regimes, interest groups and a changes in committee participation over time; however, the Chair, Ian Shepherd, remained upbeat about prospects for significant progress across a range of specifications addressing a more compact scope than originally envisaged.
8. Health Informatics Glossary [see section 6.2 below]. A proposal to form a Joint Initiative Task Group to progress this work has been put to JIC for approval.
9. Entity Names Harmonisation. A proposal to form a Joint Initiative Task Group to progress this work still needs to be prepared for JIC approval.

10. Units of Measure (UOM). JWG is tracking work on UOM in TC215/WG6 (Pharmacy & Medication Business) and emerging work on methodologies for infrastructure, registration and maintenance in TC215/WG3 with a view to aligning their interests and activities, taking into account those of HL7, Regenstrief Institute (UCOM), CDISC and others.
 11. Detailed Clinical Models. Noting interest in the representation and exchange of clinical data through archetypes, templates and bindings to terminology – including: TC215/WG1 agenda item on detailed clinical models (DCM) and HL7 Vocab, Templates and CIC interests – the JWG Convener (Don Newsham) to arrange update report on DCM work for JWG Meeting 7.
 12. Publication of Joint work items. Prior to submission to the JIC, JWG Secretariat [Standards Australia] to load the details of each project proposed for a Joint Initiative Task Group to website: <http://www.global-e-health-standards.org/>.

[NOTE: This has yet to occur – requires action by Standards Australia IT-014.]
 13. Harmonisation of balloting, publication and maintenance of harmonised standards.
 14. maintenance, versioning and co-ordination of balloting to avoid multiple different versions of the same standard in different SDOs
 - Conduct of ballots for joint publications and disposition of comments. The preferred approach is through good will, with a singular joint ballot being hosted and managed by one SDO with all SDOs and their members being able to contribute to that ballot.
 - The need for a stopping process – and agreement on processes for “parking” issues to be incorporated in the next major update.
 - Intellectual property issues. Implications of allowing harmonised standards work to access and quote material from other standards – particularly those owned by other SDOs.
 - Formatting issues. ISO and CEN formats are designed around the production (and sale) of a series of paper-oriented documents; whereas, HL7's are geared toward production of aggregated hyperlinked electronic documents. The two formats are not easily reconciled.
 - Conventions used for cross-referencing – in general, the host SDO's conventions should be followed, with the other SDOs relaxing their requirements to accommodate the common product.
- Bev Knight (Canada) agreed to provide an update report to JWG Meeting 7 on how harmonisation issues are being addressed the Vocabulary documents being developed as separate technical and procedural documents in HL7 and ISO respectively and balloted simultaneously.
15. The next two JWG and face-to-face JI meetings are scheduled for:
 - Orlando, Florida on 11 January 2009 (with HL7)
 - Edinburgh, Scotland on 26 April 2009 (with ISO/TC 215 & CEN/TC 251)

Implications for Australia

While it is an honour and advantage for Australia to provide the Secretariat for the JWG, support services must be delivered consistently to a high standard – necessitating advice and assistance from members of the Australian health informatics community, as well as the costs of staff time, communications and travel borne by Standards Australia. Continued stakeholder contribution from Government toward these costs enables Australia to be both better informed and influential in the field.

6.2 Glossary of terms for health informatics

An on-line glossary for health informatics has been agreed as a harmonized activity between CEN, ISO and HL7.

Australia (through Heather Grain) is leading the design and management of the Glossary with Canada providing the online tools and web-site.

The mechanism for management of this harmonized glossary is being defined and will be trialled at the next meeting - documents regarding structure and process were with WG 3 for comment prior to being released for ballot in December 2008.

The glossary does not simply intend to provide a list of the terms and definitions, but to determine THE standard definition to be used for each term, or where there are differences, to declare the specific context in which the different definition applies. WHO have also indicated a willingness to participate in this process.

The glossary work will be harmonized with the development of an online standards index facility which will simplify identification of appropriate standards and the relationship between glossary terms and the standards in which these terms are used.

The advantage is that this will clarify terms used in health informatics around the world, thereby simplifying and improving communication about all activities in this area.

The development of the web based tool for presentation and management of the glossary content has been undertaken by individuals from Canada (with local financial support) and Australia (with no direct support). Access to the web based tool will be open source – and is considered a reference tool for indexing the content of standards, rather than as a standard in itself.

Financial support of the effort required to complete development of the tool and to coordinate resolution of terminological variations is required to progress this activity in a suitable timeframe. This support is being requested [and, since the meeting, some support for tool development has been obtained from Canada Health Infoway].

The equivalent of three months full-time effort by a person knowledgeable in health informatics and terminology is estimated to be required to identify and process resolution of the duplicates and conflicts through a harmonization committee and this work is scheduled to commence in February 2009 (initially on a volunteer basis).

With support, initial resolution of duplicate terms in the glossary was planned for completion by April 2009.

Further information, and the current system specification document on this activity is available through Heather Grain (heather@lginformatics.com).

Implications for Australia

If the Australian work in leading the design and management of the Glossary has to be undertaken as a volunteer background activity, it may take some years to complete unless additional funded support can be provided.

6.3 ISO 13606 – EHR communication Parts 1 to 3

The main significance of the ISO/EN 13606 EHR Communication standard is its role as the definitive, stable, definition of reference models that support the use and interchange of archetyped data for EHRs. It is closely associated with, and can be implemented using, *openEHR* technology.

Dr Dipak Kalra of UCL, 13606 project lead, gave an update on progress with the balloting of each of the five parts of the 13606 standard as at October 2008, which is summarised in the following table:

13606 Standard- Part:	Status in CEN	Status in ISO
1: EHR Reference Model	EN published in February 2007	ISO 13606-1 published February 2008
2: Archetype Interchange Specification	EN published in July 2007	Passed DIS ballot, document revised following Göteborg meeting, May 2008. Out for FDIS (acceptance) ballot
3: Reference Archetypes and Term Lists	EN published in February 2008	Passed DIS ballot, document revised following Göteborg meeting, May 2008. Out for FDIS (acceptance) ballot
4: Security	EN published in March 2007	Passed DTS ballot – comments under review.
5: Interface Specification	Passed ENQ/DIS ballot, under Vienna Agreement (CEN lead). Comments being considered.	

Because of potential clashes with the use of HL7v3 artefacts (including CDA) as the basis for EHR, some interests lobbied hard to have 13606 rejected as both a European (EN) and ISO standard, but these objections have been overcome through a commitment to produce an HL7v3 Implementation Guide for EN13606 archetyped data – preferably aligning with the Clinical Statement pattern in HL7.

There are now significant national interests that want 13606 archetypes to be able to co-exist harmoniously with HL7v3. On 14 February 2008, the county councils across Sweden announced a decision to use EN 13606 Parts 1, 2 and 3 within their health systems and Parts 1, 2 and 5 for communication of EHR information. Other countries using archetypes as part of official e-Health strategy include the UK-NHS for clinical knowledge sharing in England, and some implementations in the Netherlands, Denmark, Scotland and Brazil.

The progress of parts 1 to 3 within ISO is as follows:

Part 1. EHR Reference Model

This part has now been published as both a European and International standard but will need amendment or profiling to call up ISO harmonized datatypes, when these have been accepted.

Part 2. Archetype Interchange Specification

ISO 13606-2 provides definitive specifications of 13606 Archetype Description Language (ADL) as used to define 13606 archetypes.

Part 2 previously passed DIS ballot with 15 members out of 16 in favour. It was updated to address the comments received, presented in revised form to ISO/ TC 215/ WG1 in Gothenburg in May 2008 and accepted by TC 215, proceeding to Final FDIS ballot which closed on 15 October 2008. [Shortly after the Istanbul Meeting, advice was received that ISO 13606-2 was approved for publication as a full ISO international standard with 18 P-Members in favour, 1 (Germany) opposed and 5 abstentions].

Part 3. Reference Archetypes and Term Lists

Part 2 also previously passed DIS ballot with 15 members out of 16 in favour and was updated to address the comments received, being presented in revised form to ISO/ TC 215/ WG1 in Gothenburg in May 2008.

Many of the comments related to improving harmonisation with current HL7 vocabulary and code sets, which are referenced in 13606-3.

TC 215 agreed that the updated final draft should proceed to Final FDIS ballot which closed on 30 December 2008. [It has subsequently been advised that ISO 13606-3 has been approved for publication as a full ISO international standard with 20 P-Members in favour, 1 (Germany) opposed and 5 abstentions. Final comments were submitted by Australia, Germany, Italy, Netherlands and Turkey].

Implications for Australia

These three parts are now all but finished. Apart from the need to incorporate harmonised data types and maintain some of the reference code tables to continue aligning with HL7, they have reached a point of stability. IT-014 should consider their adoption for greater availability and potential use in the Australian environment.

With the final form of ISO 13606 now emerging, it is becoming an appropriate time for IT-014 to progress the project to produce a miscellaneous publication on EN 13606 - an activity which was deferred from the 2007/08 year partly because of uncertainty as to the outcomes of the ISO ballots.

6.4 ISO/TS 13606-4 EHR communication – Part 4 Security

Part 4 went out for DTS ballot to become a Technical Specification with the ballot closing on 28 June 2008. 14 countries voted in favour, 2 (Germany, Norway) voted against and 7 abstained or did not vote. There were close to 30 comments received, which were the subject of a progress report to the Istanbul Meeting. Points noted as being potentially significant included:

Area of comment	Response
Further alignment needed with ISO 27799 (CA)	Project team needs to discuss with CA in order to elaborate the suggested changes

Area of comment	Response
Need to explain concept of “sensitivity” [in relation to being limited here to access of health information and not wider safeguards] (CA)	Relates to model attribute from 13606 Part 1 and a better explanation may be needed.
May be a problem mapping 13606-4 roles and sensitivity codes to national, PMAC etc names (CA, JP, NO)	In the light of comments from CA, JP, NO - suggest rewording “Normal Conformance” clause to avoid this kind of clash.
Wish for better alignment with ISO TS 22600 PMAC (DE)	Considered beyond scope for this TS, but agreed will be essential if/when progresses to a full IS
Wish for better alignment with HL7 (Germany) Turkey already committed to use of HL7 confidentiality codes	Greater harmonisation is desirable but the workload on both sides is beyond our present scope – could be referred to JIC via JWG
The granularity of requirements for consent might prove unworkable (CA)	The granularity is optional and may be determined by jurisdictions (this needs to be better explained in the document). In reality, jurisdictions are still undecided and so a more prescriptive specification is not possible, albeit desirable
UK suggested that the document elaborate on: 1. Proposition that revealing sensitive information may not be safe from a legal standpoint but might be clinically safer than denying access. 2. Relationship of audit log to acknowledgement of the EHR Extract communication. 3. Applicability to inferred/implied consent	Wording might be improved – particularly the introduction.

At an earlier stage (about 2 years ago), Australia had voted against Part 4 of 13606 as we considered ISO/TS 22600 PMAC to be the primary health informatics specifications relating to role-based access to patient clinical information and could not see that there was anything additional in the normative content of this Part 4 that justified its separate existence (informative examples based on archetypes were not considered sufficient). One of the arguments used to counter that Australian position was that ISO/TS 22600 had not then been approved and would take longer to produce. In fact, the reverse turned out to be true (22600 was approved first). One of the conditions on which Australia agreed to support this work was that the document was initially developed as a TS, rather than as a full ISO international standard and that it be reconsidered and/or integrated with PMAC and other efforts in the area before being taken further.

It is noted that Canada has commented *“13606 Part 4 seems to be somewhat anachronistic in the context of the other parts. This is the first (only) part of 13606 that seems to move beyond the subject of how to represent and communicate EHR information, to a subject that is usually treated as part of the context of implementing an information architecture. It was expected that this section of 13606 would have been primarily concerned with any unique aspects of 13606 that should be considered in the application of typical role-based authentication schemes to this information architecture.”*

It is understood that *ISO/TS 13606-4* will be submitted for publication as an ISO/TS as soon as changes are made by the project team to reflect the various comments that have been made - with the implication that the ISO version will vary in some respects from the CEN standard on which it is based..

Implications for Australia

It is questionable whether IT-014 needs to specifically adopt ISO/TS 13606-4 as an Australian standard; however, we should be continuing to press for its effective harmonisation with other work on security, information privacy and control of access to EHR information – particularly HL7 PASS.

As discussed further in section 6.10 below, it appears timely to push for a more cohesive and consolidated approach to standards in the areas of information privacy, confidentiality of EHR contents and access control, noting the diversity of use cases and regulatory regimes that these standards must address.

6.5 ISO 13606-5 EHR communication – Part 5 Interface specification

Preparation of ISO 13606 Part 5 (Interface Specification) is a joint activity being managed by CEN/TC 251 on behalf of CEN and ISO under the Vienna Agreement. Part 5 will become increasingly important as people seek to implement 13606 in a services-oriented environment. In this regard, active collaboration has been established with the SOA Work Group in HL7 to work on harmonisation between 13606 Part 5 and HL7 service specifications and profiles. While HL7 harmonisation is proceeding positively, progress has been slowed by competing workloads on both sides.

The ISO DIS and CEN ENQ ballot for Part 5 closed on 8 October 2008 with the following results across the two organisations:

	CEN/TC 251	ISO/TC 215
Ballot result:	Passed ENQ	Passed DIS
Members in favour:	19	17
Members against:	1 (Germany)	2 (Germany, Netherlands)
Abstained or did not vote:	6	5
Countries submitting comments:	n/av	6

There were close to 30 comments received (14 from Australia). Given that the ballot had only closed a few days earlier, these were the subject of a preliminary report to the Istanbul Meeting. Points noted as being potentially significant included:

Summary of comment	Response
Should support delegation (where an EHRcom_requester acts on behalf of another party) (AU)	This is not an EHR communication specific scenario, and its implementation depends on delegation models within other security standards such as PMAC. Two access policies, one each for the requester and receiver, may be required. This change was suggested to better support the delegation.
Need concrete use cases (AU)	A non-exhaustive list could be added
Question when the rc_id of the requested component would be known (AU)	Will explain that this is known if the recipient already has received previous EHR Extracts
Propose that the request optionally includes a request ID, to match up with the response (AU)	To be considered further.

Summary of comment	Response
Should the three interfaces be separated into different documents to enable selective voting on parts? (CA)	Strong vote in favour suggests further division into sub-parts not needed
Extend scope to cover exception handling and request acknowledgement – including scenarios not handled by common transport protocols	Comment needs to be clarified with CA.
Extend scope to include other RM-ODP concepts (CA)	Comment needs to be clarified with CA.
Update this part to use the new ISO data types (CA)	Tricky! Part 5 also needs to be consistent with Parts 1-4
Standard should require reasons for requests being declined (FR)	Discussed – along with Canadian issues re request acknowledgement and exception handling – candidate for further clarification.
Germany, Netherlands voted no based on their general objections to all of 13606, including: <ul style="list-style-type: none"> • functional architecture not continuously realised • inconsistency/harmonisation with HL7 • inconsistency with the other parts of ISO 13606 • logical EHR architecture considered to exceed the scope of an EHR communication specification 	Previously addressed and considered non-persuasive by virtue of being too abstract – and now not shared by other respondents.
Several other areas identified that need rewording/clarification (AU, CA)	Noted

Way forward

With substantial support in the DIS ballot, ISO 13606 EHR Communication Part 5 Interface Specification now needs to be updated based on disposition of the DIS ballot comments and provided to ISO/TC 215/WG 1 for review prior to its release for FDIS ballot to approve publication as an ISO international standard, according to the following schedule:

- 12 Jan 2009 - Target date for provision of formal comment disposition and updated final draft (Dipak Kalra)
- WG1 Secretariat to circulate formal comment disposition and updated final draft to experts in both ISO/TC 215/WG 1 and CEN/TC 251/WG I for 6-week comment.
- March 2009 (approx) - Subject to favourable response from both CEN and ISO experts, issue FDIS ballot to ISO NMBs (ballot expected to close May/June 2009 – after Edinburgh).

Implications for Australia

Australian interests reviewed and submitted significant comments in the DIS ballot. There will be a need to follow up when the revised draft is released and then at the final FDIS ballot.

The earlier commitment to produce an HLv3 implementation guide for ISO 13606 needs to be honoured to avoid any negative sentiment in the FDIS vote on the various parts of ISO 13606 – particularly Part 5. Australian representatives continue to be

active in seeking to hold both the CEN/ISO contributors and HL7 to achieving this end but need to be present at the appropriate international forums to maintain this pressure.

6.6 ISO 21090 - Harmonized data types

ISO 21090 *Health informatics - Harmonized data types for information interchange* is to be a joint publication of the three global health informatics SDOs:- ISO TC215, CEN TC251 and HL7 with the aim of having a single, structurally correct, internationally recognised, co-branded standard for the next generation of abstract data types to be used in healthcare information interchange.

ISO 21090 is designed to be compatible with the more generic ISO/IEC 11404 Language independent datatypes standard and also to build on and replace an earlier CEN health datatypes standard and to align with required changes in HL7 abstract datatypes, Revision 1 of which are already widely used in HL7v3 messages and CDA documents. The harmonisation effort also involves an attempt to achieve maximum reconciliation with the *openEHR* data types which are used where the *openEHR* and the ISO/EN 13606 EHR communication standard are being applied.

Although the project has been underway since 2003, it proved very difficult to get agreement and it was only since the NHS in the UK became involved, around 2 years ago, that significant progress has been made. The document is now quite large – around 500 pages.

It had originally been agreed (via JI/JWG) that this harmonised standard was to be progressed via a coordinated, parallel, 5-month ballot as an ISO DIS (Draft International Standard), CEN ENQ (Public Enquiry) and HL7 DSTU – with all three ballots closing in time for reconciliation of comments at the Vancouver HL7 Working Group Meeting commencing on 14 September 2008. While HL7 normally has much shorter (30day) ballot periods, the 5-month ballot period was chosen to meet the requirements of CEN and ISO, which allow time for translations.

Unfortunately, the ISO documentation was unable to be issued in time to meet the original schedule, so the ISO and CEN ballots closed on 24 September 2008 – a week after the Vancouver meeting; however, as anticipated, the most critical comments came from HL7 members affected by proposed changes to the HL7 datatypes. Informal arrangements were also made for ISO and CEN member bodies to advise their votes and comments ahead of the ISO/CEN closing date and in time for Vancouver, with the result that considerable work on reconciliation was able to be progressed in Vancouver (see Standards Australia report on the HL7 Vancouver Plenary and Working Group Meeting, September 2008).

The final results of all ballots were presented and considered at the Istanbul Meeting by Grahame Grieve, with the following being noted:

Results of ballot

- HL7 – passed level required for acceptance with but with some significant negatives to be addressed
- ISO – 100% voted in favour
- CEN – all voted in ISO ballot, rather than separately

Technical comments submitted with both negative and positive ballots resulted in a total of 343 line items to be considered and reconciled – almost all from the HL7 ballot.

Reconciliation of these commenced in Istanbul and has continued via teleconferences and by email.

Residual technical issues

- Clarification of EntityName uses and part codes used to identify the various components of an EntityName
- Remove AD named part types model
- Correct missing nullFlavor on address (AD) and name (EN) parts
- Remove TS.BIRTH flavor
- Resolve controversy over ISO 3166 country code set (2 vs 3 vs #)
- Correct OIDs as per HL7 / ISO agreement
- Change the type of valueSetVersion from TS to ST
- Leave GTSAbbreviation codes to jurisdictions (as agreed in Göteborg)
- Physical Quantity. PQV has been removed and PQR format has been changed
- Remove <xml> tag from structured text
- Change how precision is handled for reals
- Accommodate Schematron constraints
- Clarify how flavors are represented in XML

Finalisation process

A 100% favourable vote in an ISO DIS and CEN ENQ ballot normally allows a specification to proceed directly to publication as a full ISO or EN standard without a final ISO/FDIS or CEN/FV ballot. This was noted in JWG discussions at the Istanbul Meeting but, it was also noted that significant technical issues are being resolved as a result of the most recent ballot and that some of the comments accepted by the document authors were “substantive” which means that re-balloting of the resulting changes would be required – at least within HL7. As the intention is to arrive at a single standard with universal support, it was recognised that the required changes will need to be made and the revised document submitted to FDIS/FV vote in parallel with the HL7 ballot on the disposition of comments.

At the Istanbul Meeting, ISO/TC 215 approved this going to FDIS ballot, when a revised final draft is ready.

Under HL7 rules, new standards are required to be balloted for publication as Draft Standards for Trial Use (DSTU) before proceeding to full normative ANSI/HL7 status. It is not clear how much change is required before an existing normative standard, such as the HL7 datatypes standard which underpins the current work, must revert to pre-DSTU status but HL7 has traditionally been conservative on this question.

The problem with publishing the 21090 as an HL7 DSTU is that the HL7 version would not be fully normative and would need to be reviewed, updated and reballoted for publication as a normative ANSI/HL7 standard within two years – at which time it could be expected that some changes – major or minor – would be made. At that point, there would no longer be a single harmonised version of the standard. In Vancouver,

Richard Dixon Hughes was raised this point with Charlie McCay (Chair of the HL7 TSC) and John Quinn (HL7 CTO) and put forward arguments in favour of HL7 putting 21090 to full normative ballot at the same time as the ISO FDIS/FV ballot, in the hope of having a single fully normative data types standard across ISO, CEN and HL7. It is understood that HL7 TSC has agreed to allow the common final version to proceed to a normative ballot in HL7.

These ballots will be conducted as soon as the reconciliation has been completed and the final revised draft has been produced and agreed by the ISO harmonised data types project team, led by Grahame Grieve. This is expected to occur in the first half of 2009 – probably after discussion at the January 2009 HL7 Working Group Meeting in Orlando.

From that point onward, HL7 should seek to be made the “ISO Maintenance Authority” for the ISO 21090 standard – allowing it to be updated more dynamically.

Implications for Australia

Working primarily from within HL7 but collaborating with relevant ISO and CEN experts Grahame Grieve from Australia is spearheading the production of this new international standard for a common set of abstract data types for use in HL7, CEN and ISO. Previous Australian input has included raising the need for harmonisation with other international work on identity management and resolution of differences.

This key piece of work needs continuing strong support from the rest of the Australian health informatics community to maintain momentum by participation in relevant international forums until its completion.

Those with technical queries are encouraged to contact Grahame Grieve by email at: grahame@jivamedical.com.

6.7 Patient and provider identification

Specific harmonization activities for Patient and Provider Identification have been identified.

These activities will learn from and build on activities in CEN, ISO and HL7. CEN have considered the requirements for identification on health cards, HL7 the representation of identifying information in messages and data types while ISO activities centred upon the functional requirements for identification. Each of these pieces of work will be reviewed to take advantage of the approaches adopted in each of the other work items, and to ensure compatibility between them.

It is likely that these learnings and developments will be brought forward at HL7 and ISO over the next 18 months, particularly as the resolution of data type issues emerge. Leader: Australia

Implications for Australia

Australia is currently reviewing the Australian Standards for Patient and Health Care Client identification. This activity will support and inform that review. The review will support essential capacity to communicate identifying information in a consistent manner. This activity involves coordination with data type work (being undertaken by Graeme Grieve) and update of HL7 capacity, as well as revision and harmonization of

content in the ISO work items. This work item will require Australian contribution to HL7 and ISO activities, both at meetings and outside of meetings.

This activity will advance our capacity to implement identifier strategies in Australian healthcare. It would be appropriate to establish liaison with State and National identification and Provider Registry projects for this work, and in particular to inform implementation of identification projects throughout Australia.

Further details can be obtained directly from the designated expert from Australia: Heather Grain (heather@lginformatics.com).

6.8 Safety standards for health software

After much debate at the previous TC 215 meeting in Göteborg, the following documents were in the process of being balloted at the time of the Istanbul Meeting:

- *ISO/DTS 29321 Health informatics – Application of clinical risk management to the manufacture of health software* – being balloted for publication as a Technical Specification; and
- *ISO/DTR 29322 Health informatics – Guidance on the management of risk to ensure the patient safety of health software systems in deployment and use* – being balloted for publication as a Technical Report.

The development of these two documents is formally being led by CEN/TC 251/WG iii and jointly balloted in CEN and ISO under the Vienna agreement.

ISO/DTS29321 is intended to specify how clinical risk management should be applied to health software not explicitly covered by regimes for clinical risk management of medical devices, which are covered by another standard, *ISO 14971*, often called up by regulatory authorities.

The main distinction is that *ISO 14971* requires the construction of a Risk Management File, while *ISO/TS 29321* requires a Clinical Safety Case Report or CSCR, which requires suppliers to document an argument for how a reasonable level of patient safety has been achieved.

It was previously reported (from the Göteborg meeting) that the UK NHS has operated with the CSCR approach for software (in Connecting for Health) and is intending to adopt *ISO/TS 29321*. The customer has the option to waive compliance with *ISO/TS 29321* if there is no apparent clinical risk apparent in the type of software and compliance is not required by the surrounding regulatory environment.

Nevertheless, debate on the merits, costs, and appropriateness of having such a standard that might be imposed has become increasingly heated – with both large and small suppliers of health software and systems becoming strongly opposed to the proposed standards as their implications become clearer.

ISO TC215 has been concerned to ensure that it has not put forward these documents in isolation and has been communicating with, and enjoys a cross-membership with the relevant ISO, IEC and IEEE committees – many of whom have representatives attending its working groups.

At the Istanbul Meeting, there was a special discussion of this topic – with considerable lobbying by those who considered that they would be adversely affected by a decision

to adopt these documents as international standards – given that that they may then be imposed by customers or regulatory regimes. Their biggest complaints were that:

1. The centrepiece of this regime – the CSCR as documented proof of clinical safety - represents a crippling overhead and liability exposure, which has the potential of never being able to be properly addressed, if interpreted rigorously.
2. Where software performs safety-critical clinical support functions, it is already covered by medical device standards and many jurisdictions already regulate it as a “medical device”. In these situations, there is no need for this new standard (as the proposed standard excludes these situations). However, where software is not regulated in this way, the proposed standards create an alternative and, arguably, more demanding regime – which means that vendors need to bear the costs of complying with two different regimes which may be imposed.
3. Specific guidance on the application of *ISO 14792* standards on medical device risk management to software used in medical devices is in an advanced state of development.
4. On the definitions and scope within the proposed standards, it is arguable that there is no situation in which these standards would apply – as all potential applications can be interpreted as software falling under the medical devices standard and thereby excluded from the scope of this standard. It is considered that this argument has been contrived to secure rejection of the proposal as it has not been offered with any substantive discussion of appropriate scope.
5. On more detailed examination, there is no evidence that the specific situations identified as risks are, indeed, current risks that require the introduction of a costly compliance regime.

These documents were also the subject of a procedural challenge from CENELEC/TC 62, which petitioned the ISO Technical Management Board (TMB) to have the ballot stopped. The challenge was not upheld, but raised many questions about the conduct of parallel ballots under the Vienna agreement (and whether the letter should more correctly have been addressed to CEN, rather than ISO).

On the other hand, proponents of adopting the standards (who mainly hail from academic, consulting and regulatory ranks) argue that the standards represent a statement of good software and systems engineering practice.

Other aspects noted (by Dr Vince McCauley) during discussion of these matters at the Istanbul Meeting included the following:

- (a) There was to be a CEN/TC 251 meeting in The Hague on 19 November 2008, to review the questions "What is Medical Software?" and "What is a Medical Device?"
- (b) The EC has drafted a Medical Device Directive (MDD) to be adopted by 21 December 2008 for compliance by 21 March 2010 covering software applications used for diagnostic and/or therapeutic purposes. Under this MDD, it would appear that:
 - Their definition of Medical Device could result in considerable implementation difficulties.
 - Most standalone software used in health/clinical settings is likely to be regulated as an active Medical device - making it difficult to

- differentiate between medical software and other hospital software systems;
 - Devices for recording X-rays are a Medical Device according to the EC. The question has been raised as to whether software used to monitor the results of a medical device is part of the medical device and/or needs to be approved as a medical device.
 - There is likely to be widespread impact on many Health informatics standards.
 - Alleged risks to patient safety are being touted as the main driver but there is little evidence of this being a significant risk
 - Certain large multinationals are supposedly pushing for this – allegedly to reduce competition from smaller firms by saddling them with high compliance costs.
- (c) There is a JAMIA article (author Randy Miller) on the decision in the USA – which is, if a device is doing something to patient without intervention then it is a “Medical Device”.

Implications for Australia

The ballot for acceptance of *ISO/DTS 29321* and *ISO/DTR 29322* closed at Standards Australia on 8 December 2008. There was initially no consensus on the way forward among the Australian delegates attending the Istanbul for ballot and, if passed, potential adoption would have been relevant to many Australian interests including local suppliers and producers of relevant health software, systems safety and risk management experts, consumer interests, health service provider organisations, software and systems engineering professionals, the TGA and other regulators.

Two approaches were made to TGA, seeking their input; however, after giving the matter some detailed consideration, they considered that making comment on this particular matter would not be appropriate.

After further detailed discussion backed up by detailed comments from the MSIA, Australia voted against both the proposed standards – making positive suggestions seeking a less onerous and better scoped regime with more emphasis on the proposed guidance for users.

6.9 Standardizing purposes for processing EHR data

Dr Dipak Kalra (UCL, UK) presented an overview of a proposal to standardise a list of ***purposes for processing EHR data***, to a combined meeting of WG 1, WG 4 and WG 8. The aim is to have a standardised, encoded set of high-level categories of potential purposes for which EHR information may be processed (where “processing” might entail any or all of: collecting, storing, accessing, analysing or communicating EHR information).

The underlying framework would need to be sufficiently broad to enable all relevant purposes defined by individual realms and jurisdictions to be mapped back to it with a view to assisting the consistent management of privacy policies and the confidentiality of client information.

The proposed standard would enable the establishment of a conformance regime for cross-border delivery of health care services and the cross-border communication of

electronic health records, whereby: a jurisdiction or country would conform to the standard if formally agreed purposes for which use of EHR information is permitted within that jurisdiction are categorised according to the defined framework and published.

The work was put forward as a potential NWIP that would focus on providing a normative classification supported by appropriate definitions and informative examples, elaborating on the fit with *ISO/TS 22600*, *ISO/TS 13606-4* and other relevant standards.

Other points noted in the formal presentation and discussion of this topic included:

- One of the challenges in the development of *13606 Parts 4 Security and Part 5 Interface specification* had been the lack of an organised structure to identify why EHR information is being requested - proposed lists in other standards have been merely exploratory and informative.
- The majority of decisions regarding the processing of EHR data will in the future need to take place computationally and automatically so policies need to be defined in fully computable and interoperable ways, so that interactions between heterogeneous systems and services can all be evaluated consistently from a the perspective of privacy and confidentiality policies.
- The proposed framework bridges between policies regarding the processing of EHR data and their realisation in access control – providing the semantic bridge to complement *PMAC (ISO/TS 22600)* and *ISO/TS 13606-4*.
- The potential application of the framework ranges from situations involving the provision and support of care to secondary uses involving the study of populations.
- While aiding the expression of privacy and access control policies, the framework would not seek to dictate the policies which require explicit as opposed to implicit consent, or which require data to be pseudonymised.
- The OASIS standard *Cross-Enterprise Security and Privacy Authorization (XSPA) Profile of Security Assertion Markup Language (SAML) for Healthcare*, is in development - the proposed NWIP should not conflict with this work, or be unable to interoperate with it. Discussion suggested that:
 - Influencing this OASIS standard, rather than creating the NWIP, may be a more beneficial endeavour;
 - If this doesn't meet the needs, then an NWIP for developing a document that aligns with the OASIS work would be the alternative.
- The proposed work would be beneficial for audit trails and definitional purposes.
- Lori Reed-Fourquet (US) agreed that a normative document (IS or TS) is needed and agreed to coordinate this within WG 4 as a joint activity with OASIS.

It was agreed that the NWIP development would be discussed further within WG 4 once a more detailed plan of action, outline and draft NWIP documentation are available - taking into account comments raised during discussion.

Comment: This appears to be potentially valuable work - but not if it competes directly with other standards or if it is done over years in a back room without any major stakeholder buy-in. If it is to be undertaken, it ought to be progressed rapidly in a very open way with joint sponsorship by Canada, the EC, UK, Australia, Japan and possibly the US.

6.10 Collaboration on information privacy, confidentiality, access control and identity management

In the preparation of this report, it was noticed that there are many potentially different but overlapping standards activities being undertaken, commenced or proposed in the areas of information privacy, confidentiality, access control and identity management, within both the health informatics and the wider ICT standards world - and also through national, sectoral and global initiatives.

To avoid disharmony and confusion over a proliferation of “standards” there appears to be a need for those working in this area, or commencing work in it, to be more aware of other activity and collaborate much more actively – hopefully, being guided toward harmonisation by the JWG and the Joint Initiative for Health Informatics SDO Harmonisation (JI). In this regard, the existence of the following standards and standards development activities are particularly noted:

- The cornerstone *ISO/TS 22600 Privilege Management and Access Control (PMAC)* suite is now complete with *Part 3: Implementations* now in the process of being published. In addition to having substantial EU/EC input, particularly from Bernd Blobel, the *ISO 22600* series also reflects the needs of US facilities as reflected in ASTM and IHE, largely through the efforts of Lori Fourquet.

The *ISO 22600* series has been several years in development and needs to be refined through use and build into a more robust international standard by being promoted, adopted and built on internationally/globally – modifying it where necessary in light of experience. Work on competing specifications should be strongly discouraged.

- *ISO/TS 22220 Identification of subjects of healthcare* – just published by ISO/TC 215 and addressing requirements for client/patient identification processes and systems.
- *ISO/DTS 27527 Provider identification* – approved for publication by ISO/TC 215 with final publication draft currently being prepared by the project team.
- *ISO/TS 21298:2008 Health Informatics - Functional and structural roles (FSR)* has only recently been approved but also needs to be taken into account by those working in the information privacy, confidentiality, access control and identity management space.
- The existing *ISO 22857: 2004 Health informatics -- Guidelines on data protection to facilitate trans-border flows of personal health information*. – currently being updated by WG 4 for re-balloting and re-issue.
- *EN and ISO/TS 13606-4 EHR Communication - Part 4 Security*. Although this has been approved as a European Standard and as an ISO/TS, it introduced its own interpretations of roles/sensitivities and access control – pre-empting and loosely connected to PMAC and FSR but criticised by Canada, Japan, Germany and Norway for being isolated.

The comments from Canada (referencing NIST etc) and others in response to the *13606-4* ballot indicates that national requirements for information privacy, confidentiality, access control and identity management solutions are approaching a level of maturity but the standards activities to support these requirements effectively are still fragmented and largely lacking collaboration and harmonisation.

In the earlier CD ballot, Australia noted that *ISO/TS 13606 Part 4 Security* has very little normative content and, what it does have, overlaps *ISO/TS 22600 PMAC*. This document needs to be heavily repositioned in the next round to interpret *PMAC* in the ISO 13606 archetype environment, rather than introduce potentially conflicting normative *PMAC* content.

- *EC Mandate M/403* and the European eGov and eHealth interoperability initiatives have also focussed attention on information privacy, confidentiality, access control and identity management - and on potential solutions – some grown from local research – rather than global standards. Mandate M/403 should help ensure that the final approaches are based on global standards but there are still many in Europe who remain inwardly-focussed, risking the introduction of further uncoordinated approaches.
- *EN 14484:2003 Health informatics – International transfer of personal health data covered by the data protection directive – High level security policy*. This European Standard (EN) is currently undergoing periodic systematic review by CEN/TC 251.
- *EN 14485:2003 Health informatics – Guidance for handling personal health data in international applications in the context of the EU data protection directive*. This companion to the previous European Standard is currently undergoing periodic systematic review by CEN/TC 251.
- The new CEN Technical Report: *Patient identification and cross referencing of identities* currently in preparation. This document is being developed to support cross-border information flows in the EU - where the next steps for CEN were identified as the addition of a privacy component and the consideration for consent records in the draft. (See report in section 7.3 below for more detail).

Work on this documented has highlighted the need for work on privacy of linkages and indexes was noted. The right details need to be included in index searches or privacy issues will impact search results. The clarification of issues and risks would be welcomed.

- Relevant ISO/IEC JTC1 standards in the area of security and identity management – primarily those managed by *JTC1/SC27 IT Security Techniques* and other groups working on biometrics and access/storage technologies.

SC 27 is a highly credible group with international support from government and the security industry, whose early work focussed on management of PKI certificates, but more recent work on frameworks and techniques for identity management, access management, authentication and privacy management are all highly relevant background. Further to the presentation by Prof Bryan Manning (see section 7.4 below), the following are among the relevant ISO/IEC ICT standards relevant to these areas:

- ISO/IEC WD 24760 ... A framework for identity management
- ISO/IEC NP 29146 ... A framework for access management
- ISO/IEC 9798 (Parts 1 to 6) ... Entity authentication
- ISO/IEC WD 29115 ... Entity authentication assurance
- ISO/IEC FCD 24761 ... Authentication context for biometrics (and related biometrics standards)
- ISO/IEC CD 29100 ... A privacy framework

- ISO/IEC CD 29101 ... A privacy reference architecture

- *HL7 Privacy, Access and Security Service (PASS)* specifications currently being developed and driven by US sectoral interests within the HL7 Community Based Collaborative Care Work Group but having much broader application. As a potentially major component in the emerging suite of HL7 services specifications, PASS should be a centrepiece of an international solution supplied collaboratively by HL7 as part of its overall solution architecture - not an individual activity meeting a single set of needs (particularly given the local restrictions on identity management imposed in the US by the HIPAA regime).

Whilst it needs to progress at a reasonable pace, it would be unfortunate if HL7 work on PASS should run in isolation from everything else – it needs to be solidly anchored in the collaborative JI/JWG space – with active input from international interests and drawing from existing international work. To achieve this, it will be necessary for internationally-aware experts to contribute to the development of the PASS specifications, which will take place under HL7 standards development processes. One way of encouraging this sharing may be to have ISO and CEN seek to encourage HL7 to progress this as a joint development – so that working drafts are at least circulated within the wider community.

- HL7 work on its *Entity Identification Service (EIS)* specification and *HL7 version 3 Security Module* - and W3C/IETF protocols, generally accepted within the HL7 health informatics community and IHE profiles.
- The draft OASIS standard, *Cross-Enterprise Security and Privacy Authorization (XSPA) Profile of Security Assertion Markup Language (SAML) for Healthcare*, currently in development.
- The proposed ISO/TC 215 NWIP to standardize *Purposes for processing EHR data* as put forward by Dr Dipak Kalra (see section 6.9 above). Following discussion at the Istanbul Meeting, this proposed classification of EHR usage needs to either be incorporated into, build on or at least not conflict with the previously mentioned OASIS XSPA profile.
- *ISO/DIS 21091 Directory Services for security, communications and identification of professionals and patients*. An updated version of this ISO/TS first published in 2005 is now up for ballot on its way to being progressed to a full ISO international standard. In this process, it needs to be carefully considered and reviewed for compatibility with other documents in the field – as its origins are external to the mainstream identity management and directory services environment.
- Parts of *ISO 21549 Health informatics – Patient healthcard data*, in particular, *Part 5 Identification data* are approaching their first 3-yearly systematic review and contain elements related to information privacy, confidentiality, access control and identity management.

Concluding observations

It would appear that strong ISO, CEN, HL7 collaboration on information privacy, confidentiality, access control and identity management may be needed – taking into account existing work on identity management and systems interoperability.

It was noted that several cornerstone standards development projects in this area have recently been completed and are proceeding to publication, while others are in the

early stages and about to start. There may therefore be a window of opportunity to reduce duplication and inconsistency moving forward – noting that one of the main reasons advanced for procrastinating on collaboration has been the perceived impact on work-in-progress.

Ideally, emerging requirements should be addressed by application, modification and extension of cornerstone international standards such as PMAC, ISO/TS 2220, FSR, HL7/EIS and the ISO/IEC authentication and privacy frameworks – and not by inventing competing specifications.

It is considered timely to push for a more cohesive and consolidated approach to standard development in the areas of information privacy, confidentiality of EHR content, access control and identity management, noting the diversity of use cases and regulatory regimes that these standards must address.

Positive steps that might be taken include having the JWG and JI:

- Commission a review (drawing on other work such as recent Mandate/403 reports) of existing standards and activity in the area of information privacy, confidentiality of EHR content, access control and identity management across for health informatics applications,
- Share the findings – identifying overlaps and gaps and, potentially, developing a roadmap identifying preferred activities deserving priority support, and
- Make sure that the availability and relevance of existing standards (particularly those standards recently completed) is widely publicised and that any further work in the area builds on genuine needs as identified by the roadmap.

Implications for Australia

This preliminary reflection has identified that is potential competition and overlap among existing standards and new standards development activities relating to information privacy, confidentiality, access control and identity management in health informatics applications. Other organisations in the general ICT standards space, bodies such as IHE and CCHIT (in the US) and national health informatics programs also have requirements and needs in this space – many of which are addressed outside the accepted standards or by customised modification.

Australia has strong interests – including, but not limited to:

- the role of NEHTA in facilitating the national schemes for the Individual Health Identifier, Provider Health Identifiers and associated location information
- Jurisdictional work on identity management and directory services; and
- IT-014's well regarded contributions to the development of national and international standards for identity management and, previously, managment of PKI security and privacy of health information. Through Heather Grain, we continue to have a leadership role in some of the current ISO and HL7 work across the areas being discussed.

IT-014 (particularly WG4 and WG9) needs to monitor developments in the areas of confidentiality, privacy, access control and identity management and work with NEHTA, IT-012 (IT Security), HL7/IHE Australia and with other national and overseas interests to influence ISO, CEN, HL7 and key stakeholders to work toward a coordinated

program harmonising their activities in these areas, promoting, building on and refining their recent work – rather than reinventing wheels.

In particular, we could encourage JWG and the JI to pursue the positive steps outlined above and with a view to bringing their own activities in the area together under the one roof.

A strong program of communication and socialisation of standards work and developments in these areas might also be appropriate at a national level – and once developed this could be more broadly pursued.

6.11 Traditional Medicine (TM) Special Group

Needs in the area of Traditional Medicine (most specifically Traditional Chinese Medicine and Traditional Oriental Medicine) were addressed at a lunch-time session of the Traditional Medicine Special Group hosted by WG3, which has oversight of TM issues within TC 215.

A number of use cases and requirements for the incorporation of traditional medicine concepts into international semantic content standards were presented by China. Specific discussions on how to progress these issues were held with participants from China, Korea and Japan, though there are many other countries interested in this issue. Specific work item requirements and actions were determined to include:

- **Guideline for development and maintenance of TM thesauri.**

Development of a new work item proposal for the process of Thesauri development, including indexing and retrieval functionality. Guidelines are needed to standardise the development and maintenance of such thesauri and to indicate principles and rules for the choice of terms and structure. ISO 5964 has been used as the basis but this work relates specifically to clinical thesauri (using existing work in china as the basis). The Chinese delegation, with assistance from Korea, Japan, Canada, Sweden and Australia will prepare a NWIP for this work item for presentation at the next meeting.

- **Concept representation and model for TM representation.**

This work was initiated by Korea and has now been advanced further and a new work item proposal will be developed by Korea, China, Japan and others to advance this work. The intent is that this work harmonises with existing standards for Western medicine and identifies any gaps. This work will be led by Korea.

Implications for Australia

Australia has a very strong community of TM practitioners and has one of the few fully recognised schools for Traditional Chinese Medicine outside China. As such this work will be of significant importance to that community in Australia. Australia also has a history of mentoring China in ISO TC215 community and has been given the role of coordinating these developments by the TC.

For further information contact Heather Grain (heather@lginformatics.com).

6.12 Detailed clinical modelling (DCM) - new work item

WG 1 is the ISO/TC 215 contact point for the Detailed Clinical Modelling (DCM) initiative, which commenced with cross-SDO meetings in 2006 with the aim of bridging the gap between clinicians and health IT. The aim is to collect and model clinical information requirements once and then re-use the models by expressing the same information in different technologies (e.g. HL7 and *openEHR*) and to define different outputs – messages, documents and decision support tools. Since that time there has been a series of workshops (including one in Brisbane in 2007 – resulting in the DCM Report widely distributed within HL7, CEN and ISO).

Dr William Goossen (Netherlands) has recently been leading progression of the DCM initiative within HL7, CEN and ISO and gave a presentation on the status of the work and his current proposals for discussion. His overview addressed:

- The reasons for pursuing DCM: re-use of work, conservation of clinical and technical resources,
- The fundamental assumption that clinical requirements exist independently of the underlying technology used to represent clinical information and workflow – and that transformation between technical formats should be possible.
- As discussed in the earlier DCM Report, achieving the overall DCM goals involves a coordinated approach to the following four components:
 1. Clinical content specification. The tools and clinical modelling approaches must be suited to the nature of clinical requirements and handle the difference between lower-level, re-usable building blocks (Detailed Clinical Models) and the complete set of information and rules applicable to particular clinical settings (“templates”).
 2. Quality criteria. There are many quality criteria that must be addressed, if the resulting models are to be capable of use or re-use, including features such as formal vocabulary binding (allowing synonyms), contextual metadata defining applicability, language-independence to allow translation without loss of precision and evidence-based means of assuring clinical content.
 3. Information modelling (and transformation). A rich underlying modelling environment is needed capable of representing all aspects of the captured information. This needs to be supported by comprehensive tooling that can handle transformation, presentation and mapping of information in different technical formats.
 4. Repository - with powerful indexing and information search, retrieval and organisation capabilities.
- Outcomes of the DCM proposal that he took to the May 2008 HL7 Working Group meeting in Phoenix. After discussion and having gained the support of several HL7 WGs:
 1. The HL7 TSC (Technical Steering Committee) accepted advancement of the four elements of the DCM approach as a work item.
 2. The chairs of the SDO Harmonisation JWG requested that it also be raised as a New Joint Work Item for consideration at ISO level

- 3 ISO/TC 215/WG1 and CEN/TC 251/WG I would jointly consider the matter on behalf of ISO and CEN – with the status/level of the work to be determined following discussion at the Istanbul Meeting
 3. It was proposed that HL7 have primary responsibility for DCM content
 4. It was proposed that ISO have primary responsibility for defining quality criteria covering the four components of DCM – the nature of this work and **New Work Item Proposal (NWIP)** to achieve it was the main topic on the table at the Istanbul Meeting.
- The proposal (supported by HL7) to use UML as the basis for initial model development and from there transform to archetype, HL7 R-MIM and vice versa and to technical implementations (XML-ITS, Schematron, Java applets etc).

The following are some of the salient points noted during wide-ranging discussion on the means of progressing DCM work and the proposed NWIP to standardize DCM quality criteria.

- There was continued support for collaboration in clinical content gathering and sharing of detailed clinical models.
- The need for academic rigour in the quality of DCM models was generally supported – noting that the approach needs to focus on capture of clinical practice rather than perfect theory. Timely production of output, checking and feedback are essential.
- It must be easy and natural for clinicians to choose and use DCM models of data they want to share.
- The DCM team's apparent unilateral endorsement by of UML as the modelling paradigm was debated. Some feel that UML had been an ineffective means of communicating with clinicians when it was used by HL7 for modelling clinical processes to produce clinical DAMs. UML is considered to remove clinicians too far from their information content.
- Conversely, the rigour of UML as an underlying formalism and the potential availability of tooling (and HL7 support for it) also need to be recognised. If UML is selected as the formal representation – the challenge becomes one of combining UML models with effective processes and representations for interaction with clinicians – archetypes and/or mind maps were suggested.
- Those close to the DCM project indicated that, in gathering information from clinicians, there was no suggestion that clinicians need to learn UML – rather existing artefacts would be translated into UML for comparison.
- Clinical information modelling is not a one-off process, As clinicians' requirements evolve and change, DCM needs to be a continuous, cyclical process and clinicians need to be able to review model outputs as part of development, review and ongoing comment.
- There is a potential difference between technical quality criteria and fitness for purpose in clinical practice. Fitness for purpose will depend on other factors – such as appropriate terminology bindings. It is essential that the governance process for DCM activities confirms the models are fit for purpose.
- Dr Goossen, DCM Team Leader, holds the view that *openEHR/13606* archetype repositories are insufficiently well developed to underpin DCM.

- There is a growing body of opinion, recently supported by Sweden: that archetypes provide a valuable tool for collecting clinical content and need to be integrated into the DCM approach.
- The DCM project is seeking to build up a repository of data and examples providing a growing set of use cases [but this aspect is outside the scope of the current ISO work item].
- There is already a large body of work that has been done in various places (e.g. UK, Brazil, US-HMOs, Canada, Europe) using various representation paradigms (including HL7v3 and *openEHR*/Archetypes). The introduction of yet another modelling paradigm (UML) and a repository that would need to be maintained and governed was questioned.
- Charlie McCay, Chair of the HL7 Technical Steering Committee, believes that the key to an effective DCM program will be the ability to establish equivalence relationships between different representations, rather than a single definitive form of representation – the key to this will be the adequacy of tooling.
- The DCM process should also seek to build up clinical data from research activities, to inform development of new models.
- Granularity of DCM models – there is significant differences in the granularity required to express the same phenomena in different clinical contexts - but models at different levels of granularity need to be compatible.
- Reference models (RMs) underpinning *openEHR* and HL7 have been evolved and are now supported by rich sets of attributes. By focussing on content, DCM may fail to support the richness of these models and this may pose problems if RM-specific attributes must be captured in different ways. There is a need for more DCM work comparing the fundamental attributes of existing RMs.
- A suggestion that the NWIP scope be broadened to include tooling requirements and semantic interoperability (terminology binding to information models) was discussed, noting that this could be achieved with collaboration with WG 2, WG 3 and WG 8 and HL7.
- Technical problems of semantic interoperability persist – how do you do it in a consistent way? The entire health informatics community requires a common set of robust open-source tooling and sound strategies to address these problems – other activities are already proposed to address these issues.
- Different SDOs have developed a diversity of different tools. Major initiatives are already underway to look at tooling, considering: - the identification of tooling requirements; where future tooling would be developed; current and proposed tools (under HL7, the UK NHS, Open Health Tools (OHT) Consortium etc..). Tooling is not part of the DCM NWIP scope but criteria defined through the DCM NWIP should help by defining tooling requirements.
- In Turkey, the Schematron model is used to validate information transferred in clinical documents. The DCM team expects XML implementations of the resulting models to be capable of Schematron validation.
- Re-emphasising that the DCM project is proposed as a joint ISO-HL7 activity with the intention that
 - ISO/TC 215 will focus on specifying clinical content and quality criteria
 - HL7 will work on facilitating and creating DCM content.

- There are many different formats, and the intent of the ISO NWIP is not to develop another format. In principle, the DCM NWIP aims to outline a consensus-based analytical approach to DCM work.
- The seeking to move forward with the DCM project, it was particularly emphasised by all present that:
 - There is a need to define exactly what is to be done
 - DCM should not aim to reinvent but to provide common ground
 - The creation of a repository is also outside of the scope of the NWIP
 - Detailed specification of semantic interoperability is outside the scope of this NWIP but the DCM and semantic interoperability projects will need to contribute to each other's requirements
 - Tooling is outside the scope of this NWIP but is proceeding as a range of initiatives, which will need to address DCM requirements.
 - CEN/TC 251/WG I strongly supports the initiative and will engage in the ISO work under the Vienna Agreement (Dr Pier-Angelo Sottile)
 - ISO/TC 215/WG 8 strongly supports the initiative (Dr Marion Lyver)
 - Joint scheduling of work on this item by WG 1 at future ISO/TC 215 meetings will seek to allow maximum input from WG 1, WG 2, WG 3, WG 8, CEN/TC 251/WG I and WG ii and HL7.
 - The preferred result is a full ISO international standard.
 - Early involvement and participation by relevant experts

The immediate action is finalising an ISO New Work Item Proposal detailing the scope and content of the proposed new ISO international standard on *Quality requirements and methodologies for detailed clinical models*. Following discussion at the mini-plenary, it was agreed that the proposal – accompanied by an initial draft would be prepared by the DCM Team by early April to be circulated for ballot among national member bodies in time to allow discussion at the ISO and CEN meetings in Edinburgh.

Implications for Australia

As a general principle, it was considered by those at the Istanbul Meeting that Australia should strongly support and encourage progression of work on DCM as a joint activity of the health informatics SDOs, emphasising the need for a practical approach that is “clinician friendly”, is scalable to potentially large numbers of clinical setting and can build on the significant amounts of information already captured (such as the archetypes developed by the NHS in the UK).

When details of the proposed international standard on Detailed Clinical Modelling (DCM) are released, relevant interests in Australia (including IT-014-09 and NEHTA personnel involved in clinical information specifications) should review them, prepare comments as contributions for discussion in Edinburgh and the ballot response and consider whether and how to contribute to the more detailed development of the standard – both within ISO and HL7.

6.13 CDISC BRIDG model for clinical trials and research

In a joint session of WG 1, WG 2 and WG 8, Rebecca Kush (USA)(CEO and President of CDISC) provided an introduction to CDISC (Clinical Data Interchange Standards Consortium Inc), its mission and its relationships with other SDOs.

CDISC establishes platform-independent data standards to support the acquisition, exchange, submission and archive of clinical research data and metadata – with a focus on secondary use. CDISC standards are freely available via the CDISC website: <http://www.cdisc.org/about/index.html>.

CDISC works with other professional groups to encourage sharing of information and minimum duplication of effort and has an active liaison with HL7 to ensure that its standards are compatible with those being produced by HL7, and has recently been accepted into the Joint Initiative for Health Informatics SDO Harmonisation.

Dave Iberson-Hurst (CTO of CDISC) provided an overview of the Biomedical Research Integrated Domain Group (BRIDG) Model, including its scope, and highlighting that it bridges a gap between healthcare and clinical research.

CDISC uses the BRIDG Model in formulating its data exchange standards, and in application and message development. The BRIDG Model is currently at Release 2, with Release 3 (a two-level model) expected in March 2009 with the aim of incorporating all of CDISC's key standards by the end of 2009.

CDISC is now seeking to bring BRIDG to a global community, specifically through the JIC, to further improve its links to healthcare. During discussion, the following points were noted.

- Both WG 1 and WG 2 share interests in the implications of the BRIDG model and other CDISC standards and how relevant aspects might be collaboratively progressed within ISO as a JI/JWG initiative.
- The formation of a joint WG1/WG2 Project Group to work with CDISC to scope and draft a new work item, initially for consideration by the JIC, was recommended [and was subsequently approved by TC2 215 at the Mini-Plenary].
- There is interest in the inclusion of devices as information sources under the BRIDG model. This is expected to be feasible as the BRIDG Model is protocol driven and testing is underway to ensure that it will support all protocols, including those involving devices.
- BRIDG is an abstract model that enables clinical interoperability; using UML. CDISC considers that Release 3 of BRIDG model will be a sound entity for review by the international community, with a view to creating an ISO standard.
- The proposed scope of the joint work is unclear and needs clarification – the new work item proposal should make this clearer, including specifics of the use case, business needs, and problem to be solved in undertaking the work.
- Some consider that WG 1 and ISO/TC 215 need to be cautious not to create too many models and specifications without understanding how the various models and their specifications relate to one another, how they should be used and which model is best to use in various circumstances. A rationalisation of models was suggested and the need for overarching models that fit multiple

purposes was highlighted, recognising that there are efforts underway to classify models appropriately.

- The BRIDG model is an instance of a Domain Analysis Mode (DAM) derived from the HL7 RIM to provide clinical research links and that the process by which it was derived included considering similarities and differences to other RIM-derived domain models.
- Publication of the BRIDG model as an ISO technical specification might be considered.
- A joint session of WG 1 and WG 2 be allocated at the Edinburgh meeting to consider the scope and details of the NWI proposal.

Implications for Australia

As CDISC pushes forward with a range of international activities aimed to cement its place in the health informatics firmament as the authoritative standards body for information interchange related to clinical research (and potentially other secondary uses) it is important that the underlying models and approach be well conceived and coordinated with the activities of other SDOs. While CDISC has worked closely with HL7, there is a need to ensure that its foundation artefacts are compatible with other realms and other environments. At this early stage, and given other priorities, it is probably appropriate that IT-014 socialise the existence of this activity within the Australian health informatics community (including AIHW in particular), with a view to identifying and engaging specific experts at the time that the NWIP is circulated after the April 2009 ISO/TC 215 meeting in Edinburgh.

6.14 Issues impacting semantic interoperability

Dr Dipak Kalra (UK) introduced discussion of semantic interoperability with a presentation in which he firstly reviewed the fundamental business goals being sought through EHR semantic interoperability:

- To support patient safety, quality of care, chronic disease management, extended home-care, patient empowerment
- To enable the safe, meaningful sharing and combining of health record data between heterogeneous systems and actors / care providers
- To enable the integration and safe use of computerised protocols, alerts and care pathways by EHR systems
- To link EHR data to explanatory and educational materials to support patient and family engagement and professional development
- To ensure the necessary data quality and consistency to enable meaningful and reliable use of longitudinal and heterogeneous data for public health, research, health service management

To achieve these goals, it is essential that clinical meaning (data, information, and knowledge) be capable of being represented consistently; however, this is proving a major challenge which requires effective integration of information models, data structures, clinical terminology and clinical knowledge.

Standards bodies and other organisations that have substantial activities addressing parts of this problem include: IHTSDO, HL7, ISO, CEN, *openEHR*, SemanticHealth Q-REC, NHS CfH (EHR Technical Advisory Group) and several Joint SDO activities.

Recent consideration of these questions within the IHTSDO Concept Model (CM) SIG identified that there must be collaborative development of both the SNOMED CT Concept Model and an information model using SNOMED CT in order for effective implementation of SNOMED CT – leading to a recommendation that IHTSDO work with key SDOs to integrate SNOMED CT cooperatively into their key information models.

The challenges facing such an approach are many, including:

- World-wide shortages of skilled health informatics resources to perform the work, test, check and evaluate the outcomes and make sure that they are safe and engage with the industry and other stakeholders,
- Lack of a recognised global forum to co-ordinate and share the progress being made by the various activities across the globe; and
- No governance body to quality assure the outputs

The conclusion, opening discussion, was that ISO/TC 215 and the other SDOs working on health informatics issues do not yet appear to be ready to standardise interoperability artefacts in this area, other than those that are already in progress through the SDOs.

Discussion of the topic was wide ranging and noted the practical realities that each of the SDOs had broad programs and many stakeholders with diverse requirements and that together they were working through issues of overlapping functionality and incompatibilities as the work programs evolved. The ability of ISO to progress the issue effectively was questioned and it was recognised that, if it were to do so, a work item proposal would be needed for ISO and/or the JIC.

The final upshot is that the WG 1 Convener, Grant Gillis (Canada) and Dr Kalra (UK) will prepare a briefing note on semantic interoperability issues, considering various approaches to the problem, including those raised during discussion.

Implications for Australia

None at present – await further developments and contribute if and when appropriate, being prepared to support any actions that appear to be effective and have broad international support.

6.15 Telehealth/Telemedicine

Work on standardization in the areas of Telehealth is being progressed as an “Architecture” project within WG 2 (Data Interchange), with interest and potential involvement of experts from WG 7 (Devices) and WG 4 (Security, Safety and Privacy).

At the previous May 2008 TC 215 meeting in Göteborg, Johan Beun, a consultant from The Netherlands, gave a presentation on Dutch work that had defined and scoped “telemedicine” to facilitate discussion of further standardization efforts. This work resulted in a national technical agreement - NEN NTA 2028:2007 Telemedicine (Health Informatics), ratified by NEN, the national standards body, in November 2007.

As had been agreed at the Göteborg meeting, NEN had supplied a discussion draft of a New Work Item Proposal (NWIP) for a WG 2 work item under the title “*Quality requirements (or criteria) for services and systems for telemedicine and telecare*” and, also, the English-language version of *NTA 2028* as a starting point for WG 2 to use when identifying aspects which could be considered for standardisation. There is active support and interest in this area from Australia, Brazil, Canada, The Netherlands and the UK.

The proposed NWIP and supporting document were discussed at the Istanbul Meeting with the following points being noted.

- There is an increasing interest in the adoption of telehealth/telemedicine to address business drivers including: the ageing of the population; improving citizen access to clinical services (particularly for those in remote areas or with mobility problems); increasing the productivity, effectiveness, quality and availability of clinical service delivery in a time of increasing demand and shortages. The emergence and establishment of such services requires shared understanding to enable issues such as service quality, provider reimbursement, servicing, over-servicing, supporting infrastructure, staff training and health service planning to be addressed and , where necessary, to be regulated.
- The proposed initial focus is on general standardisation - defining scope, terminology and business processes as a basis for open and consistent practice internationally, and providing the framework for further, more detailed standards development.
- Without such a basis, proliferating proprietary solutions, ad hoc practices and a lack of clarity about what constitutes telemedicine may compromise processes such as regulation and reimbursement.
- The meaning and applicability of the terms “telehealth”, “telemedicine”, “telecare” were discussed – with the more inclusive term “telehealth” being preferred over “telemedicine” as better representing the title and the scope of the proposed work – recognising that the standard will need to define the subset of telehealth activities that it is addressing.

Use of the telehealth term maintains the alignment of this activity with previous TC 215 work on telehealth, namely:

- *ISO/TR 16056-1:2004 ... Interoperability of telehealth systems and networks -- Part 1: Introduction and definitions;* and
- *ISO/TR 16056-2:2004 ... Interoperability of telehealth systems and networks -- Part 2: Real-time systems*

and noting: *ISO/TS 16058:2004 ... Health informatics -- Interoperability of telelearning systems.*

- The focus will be on situations where telehealth involves health care service delivery by a “professional actor” using recognised health care delivery processes, noting that these may involve a combination of real-time, store-forward and/or remote monitoring functions, and addressing:
 - Care Provision
 - Information Provision, and
 - Business Processes
- Brazil noted the importance of the telehealth criteria covering services provided by the wider range of clinical service providers – and not being restricted to

those provided by medical practitioners – this is particularly important for where telehealth supports remote communities and indigenous health programs.

- The relationship to other work was considered, especially EHR, where the focus being on future development of criteria for quality and of interaction with EHR systems – rather than trying to define EHR content and structures in detail.
- The intention is to provide a framework of criteria which experts would then decide how to implement in their specific situation, rather than to produce a set of absolute criteria which must be universally adopted in every instance where telehealth services are being delivered.
- An ISO technical specification (ISO/TS) was seen as the most relevant type of deliverable – expressing “criteria” rather than “requirements” – a working party (that included Australian input) came up with a revised title and scope to reflect the changes that had been discussed.

On the recommendation of WG 2, TC 215 resolved in the mini-plenary to ballot an NWIP on *Quality criteria for services and systems for telehealth* so that, subject to its being passed by NMBs, work may commence on preparation of a Technical Specification at the Edinburgh meeting in April 2009.

The Netherlands is to be the project lead.

Implications for Australia

As previously noted, Australia (through Prof Anthony Maeder) has agreed to work with experts from The Netherlands in progressing this work item.

The Telehealth Standards Framework produced by Standards Australia IT-014 could be contributed to this effort, and areas identified for standardisation effort by Australia (e.g. telehealth session records) could be proposed for international consideration and our local approaches informed and modified by international experience.

Standards Australia IT-14 should encourage an active role for Australia in this ISO Work Item, given the relevant of telehealth services in Australia and its position of comparative strength and experience in telehealth and telemedicine.

For further information on this work item contact Prof Anthony Maeder, chair of the Australian *IT-014-12 Telehealth* subcommittee (email:A.Maeder@uws.edu.au).

6.16 ISO/TR 13054 - Knowledge management of health information standards

WG 8 has lead for the work on knowledge management of health information standards which is seeking to address the need for a methodology and tools for classifying health informatics standards and standardization activities and is formalising the outcomes in the form of a proposed ISO technical report: *ISO/TR 13054 Knowledge management of health information standards*.

The new work item proposal for the project was circulated for ballot on 21 August, closing on 21 November 2008. The ballot was therefore in progress at the time of the Istanbul Meeting.

The project lead is Dr Andrew Grant of Sherbrooke University in Canada, who gave a presentation of the proposed work item to WG 8 followed by discussion. The work was

also addressed in a joint session of WG 1 and WG 8 and at the JWG. The following points were noted from the presentation and various discussions.

- The aim of the technical report (TR) is to describe a knowledge management methodology and metadata which should:
 - support the easy identification of the existence of a health information standard, its developmental status, and responsible SDO;
 - describe a knowledge based navigation methodology to enable rapid appreciation of the contextual roles and purposes of a standard and its relationship to other standards in the same domain
 - inform the design of tools to support knowledge management of Health Information Standards.
- The work is closely associated with the Health Informatics Glossary project being led by Heather Grain of Australia – with the potential to build on the associated Standards Knowledge Management Tool (SKMT) developed by Dr Grant in Canada and to use common metadata for classification.
- In developing the TR, the principles of the *ISO/IEC 11179* metadata standards will be followed and previous similar work by TC 215 in *ISO/TR 17119 Health informatics profiling framework* as well as current ISO deliberations on '*Standards as Databases*' be taken into account.
- One of the main potential uses for the TR is to address the needs of the Joint Working Group for Health Informatics SDO Harmonisation (JWG) for an effective approach to classification of health informatics standards and projects. This was discussed in some length at the meeting of the JWG on the Sunday - see item 3(a)(i) of JWG minutes in Attachment 7 and section 6.17 which follows immediately below.
- It has been proposed that the TR will review different ways that the content of individual standards and also relationships between standards might be indexed. In this regard, Andrew Grant will be in discussion with Mark Shafarman (US/HL7), Bernd Blobel (Germany) and others regarding JWG/WG 8 approaches to classification of standards.
- Potential further steps may include the development of a web-based tool for standards cataloguing and classification and a user guide.
- Whether a Technical Report is the appropriate approach, or whether TC 215 should be developing a set of internal procedures and tooling that would be used. During discussion of the approach it was considered that:
 - There is greater value in having a report available for information through ISO for NMBs about how to classify standards and access information about these standards
 - The tool is an implementation of the TR and will enable web-based access and searching of a repository of metadata about international health informatics standards.

In all cases, discussion concluded with the WG 8 convener encouraging delegates to ensure that their NMB ballots were returned – preferably with comments and guidance for the project team.

Implications for Australia

Australia is supportive of this work and will need to consider how relevant experts may contribute effectively – noting that Heather Grain is part of the team working on development of the TR, as well as her other roles in relation to the Glossary.

6.17 Classification of health informatics standards

As discussed at length in both WG 8 and the Joint Working Group for Health Informatics SDO Harmonisation (JWG), the JWG needs an effective approach to classification of health informatics standards and projects.

The JWG has assembled a catalogue of several hundred projects across the participating SDOs – ISO/TC 215, CEN/TC 251, HL7 and more recently IHTSDO and CDISC and the classification scheme (supported by a suitable tool) is needed to help identify overlaps and gaps in the combined health informatics standards work program of JI members and to facilitate searching of the catalogue by end-users to find the most appropriate standard to address a particular need.

This activity is closely related to Andrew Grant's proposed project on the development of the ISO technical report: *ISO/TR 13054 Knowledge management of health information standards* [see section 6.16 above] and Heather Grain's Health Informatics Glossary project [see section 6.2 above]. During discussion at WG 8, WG 1 and JWG the following points were noted.

- As discussed at previous JWG meetings this year, potentially relevant approaches include:
 - Practical experience of the European Mandate M/403 task force, which had used keyword classification (Reynolds);
 - HL7 in trying to classify and code standards and their impact;
 - The earlier Canadian Standards Map project, which had combined a Zachman architecture with a profiling classification (Canadian ACHI - Advisory Committee on Health Infostructure framework);
 - Bernd Blobel's research into a multidimensional health information systems component architecture – leading to his *Generic Component Model* (GCM).
- A JWG/WG 8 Task Group is to be set up including Mark Shafarman, Paul Whitaker, Bernd Blobel, Dipak Kalra, Beatriz Leao, Mike Mair and JWG/WG 8 secretariat to work on the classification issue, with the aim of producing a draft report for April 2009.
- In addition to the various methods for classifying standards, consideration needs to include tools available to capture and classify information on current health informatics standards – including the overall role of a standard; its contextual importance, its relation to other standards, and its stage of development. Ultimately, the aim is to have a tool that addresses requirements set out in the proposed *ISO/TR 13054*.
- The JWG Convener, Don Newsham (Canada), suggested that the Task Group needs to look at the different approaches, identify what works and decide what should be used in any classification of standards - based on the business use and customer focus for the proposed tool; key areas of business use include supporting the procurement of health informatics systems (which would require

the information to be available and accessible online) and the area of internal harmonisation of standards development work – particularly the identification of gaps and overlaps.

- The SKMT is currently set up for managing terms in a glossary, not the classification of Standards, for which it would need to be modified; however, SKMT and the Glossary contain relevant meta-data and information for standards classification.
- In response to a comment from Brazil on translation of terms, it was noted that SKMT was developed to be a multi-lingual tool.
- WHO / ICD-11 work on classifying health literature should be considered, noting that there is a new ontology for public health and indicators.

Implications for Australia

Australia is supportive of this work, which will have a direct bearing on WG 8 and the JWG – which are both supported by an Australian secretariat. The assistance of Australian experts to ensure that the outcomes are well considered and practical should be sought and be welcomed – also to provide political support in ensuring that the views of the Secretariat are taken into account. There is significant potential for this project to become disconnected from work on *ISO/TR 13054* and the *Health Informatics Glossary*, which Australia would want to guard against.

6.18 EHR system functional model (ISO/HL7 DIS 10781)

HL7 published its *EHR System Functional Model* (EHR-S FM), firstly as a DSTU in 2004 and then in February 2007 as a full ANSI/HL7 standard: *ANSI/HL7 Electronic Health Record-System Functional Model - Release 1*.

A range of supporting conformance profiles has since been developed, and the model and accompanying profiles have been widely applied by CCHIT in the United States as the basis for certification of EHR systems⁴ – resulting in requests for more specialised profiles and, also, extensions and changes to the underlying EHR-S Functional Model.

Current ISO/TC 215 work on *ISO/HL7 DIS 10781 Electronic Health Record-System Functional Model, release 1* is seeking to move ANSI/HL7 EHR-S FM Release 1 forward for acceptance as a full ISO International Standard - with Gary Dickenson of HL7 (representing the US ANSI TAG) being the ISO project lead.

At the same time, the HL7 EHR Work Group (EHR WG) is under pressure to deliver the changes sought by CCHIT, HITSP and others within the US who have actively used the model and profiles – with the EHR WG seeking to finalise Release 2.

There were many changes to the original 2005 DSTU drafts of the EHR-S FM to accommodate international input – mainly from Australia (*HealthConnect*, Dr Sam Heard and HL7 Australia), the UK and Canada. However, uptake in the US has outstripped usage in other realms, with little international input to balance a new wave

⁴ Note. In Australian parlance, the US notion of an “EHR System” would be more closely reflected by terms like “Clinical Information System” or “EMR System” – in the US an “EHR” is a system holding clinical information within a health facility relating to the treatment its subjects of care. It does not normally relate to the notion of a “health record” contributed to and accessible by multiple different providers. The common US usage is exemplified in the title of their EHR Vendors Association (EHRVA). After considerable international pressure, US standards bodies are prepared to accept there is an alternative view that an EHR is actually a record, rather than an application system.

of US-centric functions and requirements proposed for Release 2 (an example of “use it or lose it”).

The EHR-S FM standard is seen as a most important contribution to international health informatics standardization and its broader adoption is now on the radar at JWG/JI for health informatics SDO harmonisation meetings; however, there is controversy over the extent to which the ISO and HL7 versions of the standard should align with each other – and whether this is realistically possible. Questions include: should ISO go directly to Release 2? How would comments from an ISO ballot be handled by HL7? Can the processes be aligned and not lose US stakeholder support? Should ISO adopt Release 1, as is, or a modified Release 1.1?

The situation is not helped by the fact that, although the members and leaders of the HL7 EHR WG show great goodwill toward international participation, they have very little involvement or exposure to ISO/TC 215 and its processes and there is little active involvement of international delegates in their work – which is a major commitment if it is to be effective. At the recent HL7 Meeting in Vancouver, Richard Dixon Hughes and Elizabeth Hanley (Australia) addressed the HL7 EHR WG, along with Audrey Dickerson, head of the TC 215 Secretariat at HIMSS on ISO/TC215 and its activities, which has helped alert those present about some of the residual issues.

Work on *ISO/HL7 DIS 10781 EHR-S FM* in ISO/TC 215 is being managed by WG 8 (EHR Business Requirements). At the Istanbul Meeting, Gary Dickinson, the Project Lead and Dr Marion Lyver, Convener WG 8, presented and led discussion of the current status of *ISO/HL7 DIS 10781* in a joint session of WG 1, WG 8 and CEN/TC 251/ WG I, noting:⁵

- The ISO DIS ballot closed on 24 September 2008 with 17 NMBs in favour; 2 (Canada, Norway) against with 6 abstentions. A total of 50 comments were received from 5 countries, 40 of them from Canada.
- While the ballot achieved sufficient agreement for acceptance and proceeding on to an FDIS within ISO, Canada had a significant number of persuasive comments which require resolution via another ballot in accordance with ISO/HL7 Pilot Project agreement.
- Canada is very supportive of the EHR-S FM but, given the extent of important changes now being made to the underlying HL7 specifications, Canada is no longer able to support ISO publishing Release 1 as an international standard and requires changes to be incorporated into a revised document to meet their EHR implementation timelines in 2009.
- Given the need to harmonize ISO and HL7 processes and documents, Canada proposed that comments be incorporated into a new “Release 2” version of the DIS that will also be the HL7 Release 2 - incorporating feedback from multiple other sources.
- Under this scheme, Release 2 would be available to all ISO NMBs for input after HL7 release in March 2009 for an April ballot cycle.
- ISO will discuss/review at the end of April in Edinburgh; HL7 ballot will close in early May.

⁵ Dot points substantially taken from draft minutes of WG 8 meeting as provided by Elizabeth Hanley of WG 8 Secretariat.

- It is proposed that an FDIS be prepared based on changes agreed in Edinburgh discussion; Canada could make this version locally available as a Draft for Trial Use (DSTU).
- A second round HL7 ballot is planned for August 2009, followed by resolution of comments, with publication of HL7 Release 2 scheduled for September-October 2009.
- The ISO FDIS ballot would be planned for September-October 2009.
- Brazil are using the EHR-S FM and 18308 in their certification scheme.
- The Netherlands would want to comment and vote on Release 2.
- The EHR-S FM was specifically designed to have national profiles, i.e. it cannot be adopted and used without an accompanying national profile.

Further points raised included:

- Questions about the proposed schedule and impact of slippage by:
 - HL7 (particularly in relation to having Release 2 available by March and possibility of further substantive changes coming from the second round ballot in mid-2009) and
 - ISO (progressing its position sufficiently in April and timing for release of FDIS ballot).
- Whether HL7 can ensure access to all ISO/TC 215 WG 1 and WG8 members to review Release 2 in April 2009
- An invitation from HL7 to participate in the HL7 EHR-S FM Release 2 ballot would be appreciated by NMBs and may help address the issues.

In summary, WG 8 concluded that NMBs would prefer to proceed with an international standard based on a draft of Revision 2 rather than the outdated Revision 1. On motion of Richard Dixon Hughes (Australia), WG 8 resolved to:

“Accept the draft disposition and proposed further amendment of the DIS draft for consideration by Working Group 8 in Edinburgh, and further consideration at HL7 WGM in Kyoto with a view to release for FDIS ballot in September 2009.”

The WG 8 Convenor and Secretariat need to confirm acceptability of this resolution for progressing ISO/HL7 DIS 10781 with ISO Central Secretariat.

By resolution at the mini-plenary, TC 215 resolved to approve the draft disposition of comments and proposed amendment of ISO/HL7 DIS 10781 based on comments received with a view to issue of an FDIS ballot in September 2009.

Working Group Reports

7. WG 1 – Data Structure

Meetings of WG 1 were held over 2½ days, with a total aggregate attendance of over 70 delegates representing at least 18 countries.

WG 1 addressed the following substantive matters at the Istanbul meeting, some of which have been reported in more detail as either major issues or topics being led by other working groups:

1. *ISO/TS 21667 – Health Indicators Conceptual Framework* [see section 0 below].
2. Detailed Clinical Modelling. This was discussed in a joint session of WG 1, WG 2, WG 8 and CEN/TC 251/WGi and is covered in section 6.12 above.
3. CDISC proposal and the BRIDG model.
This was discussed in a joint session of WG 1, WG 2, WG 8 and CEN/TC 251/WG i and is reported in section 6.13 above.
4. *ISO 12967 - Health Informatics Service Architecture (HISA)* [see section 7.2 below]
5. *ISO/TR 20514 EHR definition, scope and context*

Under ISO Directives, a TC must review the relevance of a Technical Reports at least every three years. The continuing relevance of *ISO/TR 20514* as a reference point on which discussion of EHR is anchored and the role of Australia and Japan in its original development were noted. TC215 accepted the recommendation of WG1 to continue publishing this technical report.

6. *ISO/TR 17119 Health informatics profiling framework*

Noting current work on the harmonised health informatics vocabulary and standards classification, the continuing relevance of *ISO/TR 17119* as one of the existing reference points for classification of health informatics activities and artefacts was noted. TC 215 accepted the recommendation of WG1 to continue publishing this technical report.

7. Glossary of terms for health informatics.

WG 1 received an update on the work being carried out by Heather Grain (Australia) and Andrew Grant (Canada) through WG 3 on development and management of the harmonised glossary of terms and the associated, web-based repository - including noting timelines and resource implications. For details see section 6.2 above.

8. WG 6 activities of in relation to the Identification of Medicinal Products (IDMP).

Discussion of this item noted the potential for different models to emerge for representing the same information – in relation to pharmacovigilance this may include overlapping models for CDISC, EHR or laboratory result data. The WG 6 view is that it is focussed on specific regulatory reporting requirements, with special terminology, which is not intended for inclusion in EHR or more general recording of adverse results. The work also does not appear to be

connected to existing e-prescribing standards or CDISC clinical data interchange standards. WG 1 is to follow up with WG 6.

9. Activities of WG 8 (Business requirements for EHRs), specifically the status of the following work items, reported further under WG 8 in section 14 below.
 - *ISO/TR 12773 Requirements and specifications of common essential information for health summary records*
 - Update of *ISO/TS 18308 Requirements for an EHR architecture* to an ISO international standard [also see section 14.1 below]
 - Disposition of comments on *ISO/DIS 10781 EHR system functional model* [also see section 6.18 above]
 - *ISO/TR 13054 Knowledge management of health information standards* [also see section **Error! Reference source not found.**]
 - Preliminary work on *Personal health records: Definition, scope and context* – including presentations by Dr Dipak Kalra and Gora Datta [also see sections 14.2 and 14.3 below].
10. Activities of WG 9 (JWG on SDO Harmonization) and the JWG meeting that had been held the previous day [as reported at section 6.1 above].

WG 1 discussion of WG 9 activity focussed on: the status of procedures for joint work and practical issues surrounding the proposed use of the Standards Knowledge Management Tool (SKMT).
11. European work on a new CEN Technical Report on *Patient identification and cross referencing of identities*. [See section 7.3 below]
12. Identity Management Frameworks. An update on identity management framework activity in JTC1/SC 27 and the EU was presented by Prof Bryan Manning from CEN/TC 251/WG iii. [See section 7.4 below]
13. WG 1 involvement in TC 215 work on health cards.

Proposals for WG 4 and CEN WG iii to subsume work on health cards following the retirement of ISO/TC 215 Working Group 5 were noted.

While the use of health cards as identity management access tokens aligns with WG 4 scope, modelling and architecture elements relating to prescriptions and emergency records require WG 1 expertise. It was proposed that WG 4 set up a series of joint task groups to address specific health card work items with appropriate representation and technical input from WG 1 and other relevant expert groups.
14. Progression of *ISO/PDTS 29585 Deployment of a clinical data warehouse*. [See section 7.5 below].
15. Approval and publication of *ISO 13606 – EHR Communication – Parts 1 to 3*. This was presented to a joint session of WG 1 and WG 8 and CEN/TC251/WG I as reported in section 6.3 above.

16. Progression of *ISO/TS 13606-4 – EHR Communication – Part 4: Security*. This activity was discussed in joint session with ISO/TC 215/WG 4, which is leading it. [See section 6.4 above and further comments on proliferation of work on information privacy, confidentiality and access control in section 6.106.10 above].
17. Proposal to standardise a list of *purposes for processing EHR data*. [See section 6.9 above].
18. Progression of *ISO 13606-5 – EHR Communication – Part 5: Interface Specification*. This was presented to a joint session of WG 1 and WG 8 and CEN/TC251/WG I as reported in section 6.5 above.
19. Discussion on issues impacting semantic interoperability. The presentation and discussion of this topic at a joint session of WG 1, WG 3 and WG 8 is reported in section 6.14 above.
20. *ISO/TS 27527 Provider Identification*

This document passed DTS ballot, which closed on 15 April 2008, shortly before the Göteborg Meeting, at which Heather Grain reported on progress (see previous Standards Australia report on Göteborg Meeting). At that time, it was noted that:

- Comments from the DTS ballot and subsequent discussions had been resolved
- The document received approval to be submitted for publication as an ISO Technical Specification
- A final edited version was awaited by the TC215 Secretariat.

At the Istanbul Meeting, it was noted that the disposition of comments and updates to the document are still to be provided to reflect latest data types and value sets.

Working documents relating to WG 1 activities are posted on the TC 215/WG 1 secure portal, which is managed by Standards Council of Canada, which is responsible for the WG1 secretariat. Where required for approved standards development work, draft documents and reports produced by this Working Group may be obtained by contacting Renati Barel at Standards Australia (renati.barel@standards.org.au).

For other queries about WG 1 and more information about its activities, contact Richard Dixon Hughes (richard@dh4.com.au).

7.1 ISO/TS 21667 – Health indicators conceptual framework

At the May 2008 Göteborg meeting, it had been resolved following review that the existing technical specification *ISO/TS 21667:2004 Health indicators conceptual framework* should be revised and elevated to a full ISO international standard. Australia submitted significant comments at the time of the recent review ballot. Points noted by WG 1 during discussion included:

- Canada will lead the work and Indra Pulcins of the Canadian Institute for Health Information (CIHI), one of the original authors of the document, has agreed to be the project lead.

- Volunteer experts for the project included: Bob Owens (U.S.A.) Patrick Whitacker (World Health Organization -WHO), Gunnar Klein (Sweden), Jeremy Thorp (UK), and Mark Fuller (Canada).
- Brazil, France, Japan and Australia also indicated interest in participating and would be requested to confirm nominated experts at a later date.
- Given Australian comments, it would be helpful for Australia to contribute further details and nominate a participant to the project team.
- While indicators are nominated performance benchmarks are outside the scope of this standard.
- Scope, level of granularity, the evolution of indicators and indicator usage since the TS was first developed and the need for national member bodies to consult on any increased specificity were noted as issues for the project team to address and report back to WG 1.
- CIHI (Canada) will develop an activity schedule for the project.

Implications for Australia

IT-014 needs to consider potential Australian expert contributors (AIHW, the sources of previous comments and State health authorities were mentioned) and secure a nominee to participate in the review and update work.

7.2 ISO 12967 - Health Informatics Service Architecture (HISA) and its potential application

The three-part EN12967 Health Information Services Architecture standard was completed and published by CEN in 2007 and is based on the open distributed processing (RM-ODP) approach specified in ISO 10746. The HISA standard comprises three parallel parts:

- *ISO 12967-1 Health informatics - Service architecture – Part 1: Enterprise viewpoint*
- *ISO 12967 Health informatics - Service architecture – Part 2: Information viewpoint*
- *ISO 12967 Health informatics - Service architecture – Part 3: Computational viewpoint*

Development and adoption of ISO 12967 within ISO/TC 215 has followed a fast-track approach with all three parts being issued on 3 March 2008 for DIS ballot which closed on 28 August 2008. As 100% of national member bodies voting had voted in favour of adoption, all three parts of *ISO 12967* can proceed directly to publication as a full ISO international standard, without the requirement for an FDIS approval ballot.

The proposed resolution of comments (including several significant comments from Australia) was reviewed and agreed by WG 1 at the Istanbul Meeting, with TC 215 formally approving publication of ISO 12967 by resolution in the mini-plenary session.

Hide Hasegawa (Japan) rounded out the discussion of architectural issues with a brief presentation of a study into the potential adoption and role of *ISO/EN 13606 EHR Communication*, *ISO/EN 12967 HISA* and *EN 13940 System of concepts to support*

continuity of care (ContSys) as a framework for interoperability of clinical information and EHR systems within Japan, with it being noted that:

- ContSys provides rich set of concepts on which to construct the HISA Enterprise Viewpoint for clinical domains,
- Logical models defined by the ISO 13606 reference models and archetypes provide information models which can be adopted to construct the HISA Information Viewpoint
- Detailed processes for modelling business process and information need to be defined to bind the various aspects together in a cohesive fashion – particularly in relation to practical implementation using HL7, DICOM etc.
- In Japan, work on defining clinical pathways with associated DPC (Japanese DRG-equivalent) has been actively pursued since 2007 by the Japan Clinical Pathway Association (1600members), Japan Healthcare Management Association (5,000members) and others.
- The potential adoption and place of ContSys within the ISO standards framework is now being actively progressed by ISO/TC 215/WG 3.

Implications for Australia

It would be of benefit to Australian interests including NEHTA and the jurisdictions to consider the suitability and whether they can leverage benefits for the HISA standard (and potentially ContSys). IT-014 therefore needs to consider whether there is a need for increased awareness and education concerning HISA and other architecture framework standards and their potential inter-relationship.

7.3 CEN/TR on Patient identification and cross referencing of identities

CEN work toward a technical report on *Patient identification and cross referencing of identities* was presented to a joint session of WG 1, WG 4 and WG 8 by Karima Bourquard (France).

This work is being carried out by a joint Task Force of CEN/TC 251 WG i (Data content) and WG iii (security) with the aim of providing a defined framework which EU states, health authorities and healthcare organisations may reference when establishing policy, procedures and regulation on patient identification practices and systems.

Discussion focussed on the similarities, differences and potential overlap between this work and recent ISO/TC 215 work on identity management, ISO/TS 22220 *Identification of subjects of healthcare* and ISO/DTS 27527 *Provider identification*. Heather Grain (Australia), project lead for the ISO work, indicated that she would view these as complementary work items, as the ISO work relates to components of identification which the CEN work may extend; however, close collaboration is required to ensure consistency among the documents.

Next steps for CEN were identified as the addition of a privacy component and the consideration of consent records for inclusion in the draft, noting the need to recognise privacy of linkage and to include the right details in index searches to avoid privacy issues adversely impacting search results.

The suggestion is that this CEN work might be brought into ISO as a Technical Report or as an expanded Technical Specification – however, in either case, it would be important that the CEN draft be compared with the ISO identity management documents to determine the final work item proposal.

Implications for Australia

Australians involved in health informatics standards need to maintain a watching brief on the CEN work and be supported in encouraging harmonisation toward a single set of compatible (ISO) standards for patient (and provider) identification and associated aspects of identity management, privacy and access control. The number of competing and overlapping activities in these areas has been raised as a concern in section 6.10 above.

7.4 Identity management architectures and frameworks

Prof Bryan Manning (UK) gave a two-part presentation on activities in standardizing architectures and frameworks for identity management (IdM), which was followed by discussion.

The first presentation entitled *Formal Human Identities* provided an introduction to core concepts of IdM (e.g. Formal identity, physical identifiers, persona, roles, authentication) and the related work of JTC1/SC 27 (IT Security Techniques) and its various working groups in developing and updating the standards needed to provide an identity management framework, which include:

- *ISO/IEC WD 24760 IT - Security techniques - A framework for identity management*
- *ISO/IEC NP 29146 IT - Security techniques - A framework for access management*
- *ISO/IEC 9798 (Parts 1 to 6) IT - Security techniques - Entity authentication*
- *ISO/IEC WD 29115 IT - Security techniques - Entity authentication assurance*
- *ISO/IEC FCD 24761 IT - Security techniques - Authentication context for biometrics (and related biometrics standards)*
- *ISO/IEC CD 29100 IT - Security techniques - A privacy framework*
- *ISO/IEC CD 29101 IT - Security techniques - A privacy reference architecture*

The second presentation was entitled *eGov-Share, Interoperability Overview* and introduced work on eGovernment interoperability components that have been proposed for Pan-European eGovernment Services (PEGS) under the IDABC programme, where IDABC stands for **I**nteroperable **D**elivery of European eGovernment Services to public **A**dministrations, **B**usiness and **C**itizens. IDABC seeks to take advantage of the opportunities offered by information and communication technologies:

- to encourage and support the delivery of cross-border public sector services to citizens and enterprises in Europe,
- to improve efficiency and collaboration between European public administrations and,
- to contribute to making Europe an attractive place to live, work and invest.

Challenges to IADBC include the development of effective strategies and architectures to provide uniform trans-border interconnectivity of information services across different languages, regulatory environments and technology platforms. Work has included establishing standardized concepts, terminology and models needed for more detailed communication and achievement of semantic interoperability – much of it driven through CEN/ISSS activity.

During discussion on the two presentations, it was agreed that:

- A consolidated update on current work in relation to IdM and privacy (in relation to interoperability) be provided at the Edinburgh meeting in April 2009.
- The aim is to document a consolidated approach to identity management, interoperability and privacy of data, engaging with JTC1/SC27/WG5 experts for feedback on these issues.
- National Member Bodies would provide input on the use of identity management controls – for consideration in the IdM Framework report.

Implications for Australia

NEHTA, IT-014, HL7 Australia, HISA and the broader health informatics community in Australia need to be kept advised of these activities and IT-014 needs to collaborate with relevant experts in NEHTA and, possibly, HISA privacy group to provide input to any proposed report by TC215. As noted in section 6.10 above, there is a need for communication and consolidation of activities in areas associated with information privacy, confidentiality, access control and identity management.

7.5 ISO/PDTS 29585 - Deployment of a clinical data warehouse (CDW)

Dr Andrew Grant (Canada) introduced the session with a brief presentation on the development of *ISO/TS 29585 Deployment of a Clinical Data Warehouse (CDW)*, with the following being noted:

- This ISO technical specification aims to support the existing *ISO TR*

22221:2006- Good principles and practices for a clinical data warehouse (CDW)

by providing implementation guidance and describing: general considerations of development and deployment, issues and applications of data aggregation and data modelling, and architecture and analytical approaches.

- The role of a CDW is to enable data analyses in support of effective policies and decision making, to improve quality of care, to improve health services organisations, as well as to influence learning and research, among others. A CDW may be implemented as either a physical or virtual repository.
- *ISO TR 22221* had a primary goal of underpinning a coherent approach to the diverse and multi-stakeholder perspectives of secondary use of data from various health system sources. This Technical Specification is intended to have pragmatic relevance by indicating best practice in setting up a clinical data warehouse and in using it from data abstraction and architectural perspectives.

- Development of the document was discussed at the Montreal ISO/TC 215 meeting and subsequently approved by a ballot of NMBs closing in April 2007. The document is being developed in three sections:
 - Section 1. General considerations of deployment of a clinical data warehouse – being led by Dr Jeremy Thorp (UK NHS)
 - Section 2. Clinical data warehouse: Data aggregation and data modelling – being led by Dr Andrew Grant (University of Sherbrooke, Canada)
 - Section 3. Clinical data warehouse: Architecture and analysis – being led by Dr Mark Fuller (CIHI, Canada).
- A substantial draft was discussed in Göteborg in May 2008 resulting in revisions based on the comments received. An updated 67-page draft was circulated in the papers and was discussed in overview at the Istanbul Meeting.
- Next steps for the draft include WG 1 and WG 4 providing further input on the draft by 15 December 2008, with a view to the final revised draft being circulated to national member bodies for DTS ballot in January 2009.

The following are among the points noted during discussion:

- From the data modelling viewpoint, when data is extracted for records, context is important and needs to be included with any extracts for secondary use.
- Overall trust in CDW is crucial. The defined processes need to strengthen the emphasis on data quality.
- The content on data quality needs to address more thoroughly: cross organization data quality issues and the harmonization of classification of terms, noting that data quality is established during the data extraction phase.
- From a security perspective, data can be used for other purposes, which may not be controllable at the time of extraction. Therefore, data security and purpose of use are important – it was noted that anonymisation and pseudonymisation approaches are included in the existing draft.
- In relation to Section 3, which focuses on CDW architecture, it was recognized that direct experience in using CDWs was limited and there is a need for more coverage of:
 - RIM mapping (to be provided by Mark Shafarman)
 - How to use clinical terminology and classifications effectively - SNOMED CT as it relates to Data collection system for secondary use is often too granular
 - The importance of establishing continuity of reporting and trustworthiness of statistical trend measures – which can be impacted when a change is made from, say, native ICD-10 encoding to codes derived by mapping from clinical terminology
- Further advice, specifically on when and how to use terminology mapping, is needed and welcomed.

Implications for Australia

There are many organisations in Australia with an interest in CDW and a potential interest in this standard - including AIHW, State and Commonwealth health authorities (NHIPC), and peak advisory/health industry bodies.

Proposed actions. When the revised document is received for ballot, IT-014 approach relevant interest groups with a view to securing comment and input for the DTS ballot and advice as to whether there is merit in considering local adoption of ISO/TR 22221 and ISO/TS 29585 as Australian Standards through IT-014.

8. WG2 – Data Interchange

Meetings of WG 2 were held over 2½ days, with a total aggregate attendance of over 30 delegates representing 12 countries.

WG 2 carries out much of its work through two parallel break-out groups – the Architecture Breakout Group (WG 2/SWG 2) and the Methodology Breakout Group (WG 2/SWG 3) – with key topics also being addressed by WG 2 in plenary session.

Overall, WG 2 addressed the following substantive matters at the Istanbul meeting, some of which have been reported in more detail as either major issues or topics being led by other working groups:

Architecture Breakout Group (WG 2/SWG 2)

1. *ISO/TS 25720 - Genomic Sequence Variation Markup Language (GSVML)*. [see section 8.1 below].
2. HL7 Clinical Genomics – Family History/Pedigree

Draft documentation to establish this as a new work item was agreed at the Göteborg meeting in May 2008 but, for some reason, had not been sent out for ballot. It was agreed that the ballot should start as soon as possible with Australia, Korea, Japan, USA and the UK all provisionally agreeing to participate in developing the document.

More details on this project are reported in section 8.2 below.

3. *ISO/TR 28380-2 IHE global standards adoption - Part 2 Integration and content profiles*. The DTR ballot closed in September 2008 with 13 NMBs in favour, none against and 11 abstaining or not voting. A total of 18 editorial/general comments were submitted by Canada and Germany.

The ballot comments were resolved with corresponding changes to be incorporated into a revised document. By resolution in the mini-plenary, TC 215 approved the revised *ISO/TR 28380-2* proceeding to publication on receipt of the updated version by the TC 215 central secretariat.

The NWIP documentation for *ISO/TR 28380 IHE global standards adoption - Part 3 Use Cases and Integration Profiles* is expected in time for it to be considered at the Edinburgh meeting in April 2009.

4. Telehealth/Telemedicine. (See section 6.15 above).
5. CDISC proposal and the BRIDG model.

This was discussed in a joint session of WG 2, WG 1, WG 8 and CEN/TC 251/WG i and is reported in section 6.13 above.

Methodology Breakout Group (WG 2/SWG 3)

6. *ISO 21090 Harmonised data types for information interchange.* As reported more fully in section 6.6 above, notwithstanding a 100% favourable ISO/DIS ballot, substantive comments on this joint specification were received in the parallel HL7 ballot and it is to be further refined based on comments received, with the final version to be submitted to for final ISO/FDIS ballot in 2009.
7. *ISO/HL7 27931 HL7 Messaging Standard Version 2.5.* The DIS ballot for adoption of this mature, normative ANSI/HL7 standard closed on 10 June 2008 with 18 NMBs in favour, no negatives and 7 abstaining or not voting. A total of 7 editorial/general comments were submitted by Germany, Italy and Japan.

As 100% of national member bodies voting were in favour of adoption, *ISO/HL7 27931* can proceed directly to publication as a full ISO international standard, without the requirement for an FDIS approval ballot – and this was approved by resolution of the mini-plenary at the Istanbul Meeting.

As a result of reviewing the ballot comments, two technical corrections will be made to the ISO/HL7 specification before publication that will be reflected in corrigenda to the existing ANSI/HL7 HL7v2.5 standard and HL7 will make 5 corrections to the current draft HL7v2.6 standards.

8. *ISO/HL7 27932 Clinical Document Architecture – Version 2.* The DIS ballot for adoption of this mature, normative ANSI/HL7 standard closed on 10 June 2008 with 18 NMBs in favour, 1 negative (Norway) and 6 abstaining or not voting. Of the three comments submitted, only one was substantive - pointing out that many of the hyperlinks to external sites were invalid. The situation was reviewed by WG 2, which also considered whether it would be better for ISO to publish the standard in hyperlinked HTML form (as used by HL7) or to maintain it as a traditional hard-copy publication.

As one NMB had voted negatively, once the errors have been corrected, *ISO/HL7 27932* must be submitted to an FDIS approval ballot – this was approved by resolution of the mini-plenary at the Istanbul Meeting.

Germany has proposed sending this document to CEN for consideration as an EN ISO standard. This would be referred to the JIC.

9. *ISO/WD 10159 Web Access Resource Manifest (WARM).* Working draft of the proposed standard was presented and discussed at the Istanbul Meeting. It was resolved in mini-plenary that an updated draft would be circulated for CD (Committee Draft) ballot.

The project lead, Nicholas Brown (UK) apparently reported that (critical) comments from Australia had been received after the ballot deadline and were considered – it would appear that he was referring to comments submitted for the NWIP ballot in early 2007. It does not appear that this item is progressing with any reasonable pace.

10. *ISO/DTS 27790 Document Registry Framework.* A further draft of this work, which is being progressed by Korea, was presented, having addressed previous comments and discussions with IHE (the work is closely related to the IHE XDS specification). A proposal that the current draft be released for DTS ballot was approved by resolution of the mini-plenary at the Istanbul Meeting.

Sponsors of the work item still need resolve issues of maintaining the document between IHE, IHE-Korea and other interested parties.

11. *ISO/NPR 13128 Clinical Document Registry Federation*. A draft proposal for this new work item was presented by Byoung-Kee Yi (Korea). There is some scepticism as to whether this technical report is really needed but also some reluctance to pre-emptively refuse to support an item that is strongly sought by Korea, with some support. On recommendation of WG 2, the mini-plenary at the Istanbul Meeting approved that *ISO/NPR 13128* be released for NWIP ballot targeting a Technical Report. The ballot closes at ISO on 14 Feb 2009.
12. *ISO/NP 12974 Web access to DICOM persistent objects by means of web services (WADO-WS)*. As further reported in section 8.3 below, the NWIP for this item passed unanimously, targeting an ISO international standard within 12 months.

Other

13. Future Meetings

The next meetings of the ISO/TC 215/WG 2 are scheduled for:

16-17 Jan 2009	Orlando, Florida (USA)	With DICOM, HL7 and TC 215/WG 7 at HL7 WGM
27-30 Apr 2009	Edinburgh, Scotland (UK)	TC 215 Plenary (with CEN/TC 251)

Detailed notes on several of the following topics were contributed by Prof Anthony Maeder. In addition, the use of material from draft minutes for the ISO/TC 215/WG 2 meeting in Istanbul circulated by Dr Adrian Stokes (UK) is gratefully acknowledged.

Working documents relating to WG 2 activities are posted on the TC 215 Sharepoint portal, which is managed by HIMMS as the TC 215 secretariat. Where required for approved standards development work, draft documents and reports produced by this Working Group may be obtained by contacting Renati Barel at Standards Australia (renati.barel@standards.org.au).

For queries about WG 2 and more information about its activities contact Richard Dixon Hughes (richard@dh4.com.au).

8.1 ISO 25720 Genomic sequence variation markup language (GSVML)

The DIS ballot for *ISO 25720 GSVML* closed on 7 July 2008 with 12 NMBs in favour, no negatives and 14 abstaining or not voting. A total of 14 comments were received from Canada, Germany, Italy and the Netherlands. A late affirmative vote was also received from ANSI (US) with comments.

As 100% of national member bodies voting have been in favour of adoption, *ISO 25720* can proceed directly to publication as a full ISO international standard, without the requirement for an FDIS approval ballot – provided that there are no substantive technical changes.

The DIS ballot comments were reviewed and, since the changes were not considered substantive, it was agreed to recommend that *ISO 25720 GSVML* proceed directly to

publication and this was approved by resolution in the mini-plenary at the Istanbul Meeting, subject to a suitable updated version being provided to the TC 215 secretariat.

Points noted in discussion included:

- The need for this standard to bridge between bioinformatics and health informatics unambiguously – requiring its language to be precise. WG 2 will arrange for a thorough editorial review of the English expression, grammar and spelling used in the document.
- Use case descriptions should be improved and extended (e.g. include integrated biomedical database project from Japan)
- Interface with HL7 needs to be clearer due to the number of complex concepts (eg epidemiology, phenotype)
- Descriptions in other bioinformatics and genetic markup languages can be included by use of dbref elements
- There are several genomic description languages in existence, and still evolving, so GSVML maps these.
- A “best practice” tutorial is needed by ISO to help member countries give “actionable” comments when reviewing and balloting standards documents.
- The 3 year review process is a means of ensuring that standards are regularly reviewed for adequacy in light of changing/emerging technologies or and/or management approaches. It is not required to not “wait” for an area to become mature/stable before developing standards, if a sufficient need has been identified to undertake standardization.

8.2 Clinical genomics – Family history/pedigree

The HL7 Clinical Genomics WG (chaired by Amnon Shabo) produced an HL7 DSTU (Draft Standard for Trial Use) on Family History/Pedigree, which has been in place for several years and was successfully balloted as a fully normative ANSI/HL7 standard in May 2008.

Draft documentation to establish a new work item targeting an ISO international standard for Family History/Pedigree was agreed at the previous TC 215 plenary meeting in Göteborg but, for some reason, had not been sent out to NMBs for ballot.

At the Istanbul Meeting, it was agreed that the ballot should start as soon as possible with Australia, Korea, Japan, USA and the UK all provisionally agreeing to participate in developing the document.

Points noted in discussion included:

- Family tree representation is needed in order to be able to compute and record clinical risk assessment parameters.
- The proposed standard specifies how to construct and represent a family tree with all genetic information included, which can then be maintained in an EHR, PHR and/or genetic information database
- Applications have been constructed to assist people to map family history to analyse their genetic information and risks. “My Family Health Portrait” provided by the Surgeon General of the US /CDC Office of Genomics site in US

allows individuals to do this online (see: <http://www.hhs.gov/familyhistory/>). The National Society of Genetic Counsellors also has an interest.

- Partners Healthcare (Massachusetts General Hospital) has an internal HL7 based process to support family history construction for at- risk patients. This has been applied to breast cancer patients by Dr Kevin Hughes.
- CaGene program computes risk aspects (and so proves useability) but is not unique or dependent on one data source. Working with other family tree groups (My Generation, James etc.) implies a need for the standard to support transform between multiple representations.
- Informed consent needs to be built in to the family history process (activity diagram) – noting that information on family members may be held by or provided to many others.
- The HL7/ANSI Clinical Care Document (CCD) format is increasingly used for electronic medical records. It needs to be able to address family history/pedigree information in any record format proposed under this standard.
- The standard will support family history analysis being achieved by allowing applications to hook into an XDS-based registry and extract relevant family history data in a standardized format.
- Potential impacts and standardization needs will become critical if national health agencies take on the role of constructing standardised family history

Implications for Australia

While previous contact was made with Australian experts in molecular genetics, attempts to form an IT-014 Working Group in clinical genetics to consider the GSVML standard were not successful as the required critical mass of experts and continuity of leadership could not be sustained.

Australia has indicated a provisional interest in supplying an expert to work on this document, given the growing use of family history data for cancer screening and prevention. IT-014 will need to identify a suitable volunteer from within the community of interest, having the capacity to relate to the existing information models.

8.3 ISO 12974 Web Services access to DICOM persistent objects (WADO-WS)

WG 2 developed the earlier ISO 17432:2004: Health informatics — Messages and communication — Web access to DICOM persistent objects (WADO) standard to provide requesters of medical imaging studies and care providers with rapid and reliable access to reports and images via web-based technologies, without duplication of large data objects.

ISO 17432 supports clinicians (or their clinical applications) accessing the original image data in native DICOM format that allows extensive manipulation using specialized software using DICOM meta-data or, alternatively, rendering the data into generic format s(e.g. JPEG, PDF) that can be presented with off-the-shelf applications.

Following on from regular review of ISO 17432:2004 a need was identified for an extension of DICOM into Web Services, including a Notification Service for the availability of DICOM objects and a Query Service based on ID(s) for DICOM objects.

Following discussion at the May 2008 TC 215 meeting in Göteborg, it was decided to reconfirm the existing ISO 17432:2004 WADO standard without change and to ballot a new work item to address the additional requirements of accessing persistent DICOM objects via web services.

The NWIP ballot for *ISO/NP 12974 Web access to DICOM persistent objects by means of Web Services (WADO-WS)* closed on 11 October 2008 with 15 NMBs in favour, no negatives and 9 abstaining or not voting. 2 comments were received, one from Turkey, emphasising the importance of this standard in support of their SOA approach to health systems interconnectivity. Experts from six countries were named to participate in the work.

A number of issues concerning the work arose at the meeting – a working draft is to be produced by the Project Lead, Nicholas Brown (UK) for further review at the joint meeting of WG 2 and DICOM on in Orlando on 16 January 2009. The targeted completion date on the NWIP ballot was 12 months but early 2010 would seem more likely.

Implications for Australia

Subject to this standard having global traction and support, like Turkey, Australia would be keen it progressed to facilitate the strategy of moving toward SOA-enabled interoperability. Australia probably has an insufficient stake in the technical outcomes to justify the time and cost of contributing a relevant expert to participate in the work.

NEHTA needs to be aware that the standard is being prepared and their assistance should be sought to review the first Committee Draft, when available – to ensure that it is compatible with the interoperability framework.

IHE Australia may wish to consider whether there is a need to consider profiling this standard for a future Australian Connectathon. The international IHE position on uptake of this standard and the previous WADO work should also confirmed – to ensure that the work actually has global traction.

9. WG 3 Semantic Content

WG3 had a very large attendance (over 30 people from 16 countries) including representatives from Australia, Brazil, Germany, France, Sweden, Denmark, Norway, Russia, Netherlands, UK, USA, Canada, Japan, Korea, Turkey, China and liaison representatives from IHTSDO and WHO. This is indicative of the new open approach to management of the working group and the collegiate international desire to standardize concept representational elements once.

The European CEN /TC 251 /WG II Terminology working group again met jointly with ISO TC215 WG3 at the Istanbul meeting (for all but the last day) – continuing the close relationship and joint work items commenced in Gothenburg. As a result, several new work items will be brought forward from CEN to ISO to become full international standards. These are indicative of a much closer relationship between the European standards community and the ISO working group.

Of the matters addressed by WG3 at the Istanbul meeting, the following have been reported separately as major issues and are not further considered in this section of the report:

- Glossary of terms for health informatics
- Harmonization of Patient and Provider Identification
- Traditional Medicine

Heather Grain, the current Chair of the Standards Australia IT-014 Health Informatics committee is the Convenor of ISO TC215 WG3 and provided most of the commentary on WG3's activities.

Further details on the items reported in this section can be obtained by contacting Heather by email heather@lginformatics.com.

9.1 Standard on categorial structure for terminologies of surgical procedures

Revision of the European Standard *EN 1828:2002 – Health informatics – Categorial structure for classifications and coding systems of surgical procedures* was to be undertaken by CEN/TC 251/WG ii as a joint activity with ISO/TC 215/WG3 (after which it was to be adopted by TC 215 as a full ISO standard under the Vienna Agreement); however, the joint work item was moved from CEN to ISO with voting to accept the work item in ISO to conclude in November 2008.

Categorial structures offer a set of categories that standardise the structure for specific types of clinical information. These structures support development of archetypes as well as hierarchies and implementation strategies for clinical terminologies, refsets and subsets. Europe has developed a number of structures of this type.

A New Work Item Proposal has been developed that will review and extend the existing CEN standard to incorporate the broader categorial structures required to represent health care actions or interventions in general. The categorial structure standard is a model to which the terminology can be related containing the semantic links. It does not mean that the terminology does not have to contain these elements. It is a means of checking the quality of terminological representation. To encompass this broader scope, the title has been changed – new title is *Categorial structures for terminologies of procedures*.

This work will incorporate review of the ISO nursing terminology standard to include interventions. This work supports WHO developments (particularly its classifications of procedures in medicine) and is likely to inform these developments. WHO member states are looking for developments in this area, particularly they are seeking a tool for recording of interventions. WHO supported this work item proposal and are intending to be involved on the thinking around this standard and to inform member states about developments. This work is being led by The Netherlands.

Implications for Australia

Potentially informing and building on relationships between ICD-10-AM, SNOMED-CT and the proposed ICD-11 classification, this work item will have practical impact on work in Australia. It is recommended that representation from NCCH and NEHTA (as

IHTSDO representatives) be established to liaise with activities in this area over the development period.

9.2 Adoption of EN 13940 – System of concepts to support continuity of care (ContSys)

European standard EN 13940 comprises two parts:

- EN 13940-1:2007 *Health informatics – System of Concepts to Support Continuity of Care – Part 1: Basic Concepts* – a published European standard.
- prEN 13940-2 *Health informatics – System of concepts to support continuity of care – Part 2: Core process and work flow in health care*, which was in the early stages of development as a European Standard by CEN TC251 WG2.

At the May 2008 TC215 Meeting in Göteborg, consideration was given to whether and how the two parts of European standard EN 13940 should be adopted within ISO.

EN 13940 Part 1 – Basic Concepts

As agreed at the previous meeting this published European Standard is to be presented for fast tracked into the ISO work area and has gone out to ballot as a Committee Draft (result due in November). Although the document could go straight out to DIS ballot – the meeting decided that it would go to committee ballot first to provide an opportunity for internationalisation, rather than adoption of the whole document as is (through the Vienna Agreement for adoption of CEN standards at ISO).

This standard identifies a set of concepts that are both useful and used in support of continuity of health care. It does not, at the moment, include social care which could be an extension. There are 58 different concepts that are interrelated and their relationships are described. The concepts are spread between 6 different categories, actors, issues with management, times (episodes periods etc), concepts related to activities and management of knowledge, concepts related to responsibility such as the use of mandates in the management of patient data and care, and information management in relation to coordination.

Since being published as a full European standard, it has been adopted as the basis of the requirements in northern European countries, including Belgium and France.

The Chinese, Korean and Japanese delegations were keen to ensure that the work produced reflects the needs for traditional medicine.

This work is being led by France.

EN 13940 Part 2 – Core process and work flow in health care

This is now a preliminary work item for ISO and is no longer being considered as a CEN specific piece of work. It will identify the relationships between the partners and presents a process model for continuity of care information. There is a need to analyse the process of care and the variety of views necessary to support business processes such as clinical process, the management process, the information and documentation process. Currently they are identifying those new concepts that have not been considered in part 1 (gap identification). Gaps currently identified include tele-medicine concepts (both clinical and administrative, and patient empowerment concepts). This work introduces the concept of the subject of care as one of the actors in the process

model, thereby enabling the patient to have an active participant role. Further discussion and development of this item will occur at the next meeting.

Implications for Australia

Further to previous comments IT-014 is seeking notification of contacts to be informed of these developments but this has not progressed. It is anticipated that there will need to be input both from national and State initiatives. Given State-based development of data collection in this area it seems a logical work area of interest to Australia. Further consideration should be given to how to progress these activities and involve relevant stakeholders (including NEHTA).

When documents are available they should then be provided to identified liaisons in Australia for comment.

9.3 CEN/TS 15699 Clinical knowledge resources – Metadata

For many years CEN worked on development of *CEN/TS 15699: Clinical knowledge resources – Metadata*, which has now been approved as a technical specification – it extends metadata already available from library science (eg: ISO 11179) to describe what is in a document or database and, now we have computerised documents, web resources etc – the need to identify the source of knowledge. This metadata standard will extend the existing library domain to add medical information for source references. The work does not include security issues.

This work was presented to ISO as a NWIP for publication as an International Standard (via the Vienna Agreement with CEN lead) including a Request for Comments (RFC), which will be issued in the coming months. Significant additions/comments are expected to improve the document.

Implications for Australia

When received, the document will be forwarded to NEHTA and AIHW for comment, and additional liaisons could be required and can be included if identified.

9.4 ISO/DTS 17117 - Criteria for the categorisation and evaluation of terminological systems

A major revision of the previously prepared document is being undertaken and will result in a significantly changed scope and content. This will be a major work item at the next meeting.

This specification uses criteria for categorisation and evaluation and other characteristics of terminologies, content and organisation and support the measurement of viability for maintenance. The intention is that the characteristics of the terminology that support maintenance over time be incorporated into this document, while another new work item accepted for work at this meeting will deal with the actual processes of terminology maintenance and management.

This work is now being led by Germany and it is considered that Australia currently only needs to maintain a watching brief.

9.5 ISO/NP TR 12309 – Health informatics – Guidelines for international healthcare terminology standardisation

This technical report looks at the organisational behaviour and management systems requirements for development and maintenance of standardised terminology systems.

Production of the technical report received support in the voting process, with disposition of comments now being undertaken. The work is being led by the UK.

Implications for Australia

Australia should consider our capacity to meet these standards. A specific NEHTA liaison from the Terminology project team would be appropriate for this work item.

9.6 Mapping of terminologies to classifications (ISO/NP TR 12300)

This proposed new work item passed ballot with enormous support, including the provision of 9 national experts supporting the work. As a basis for this activity IHTSO are contributing their work on SNOMED/ICD10 mapping and the UK will provide nursing guidelines. The document will include information on:

- the value and purpose of mapping. What is a map and how are they used
- the process of mapping, where to begin, and the steps in a quality mapping process and the essential criteria required to undertake a mapping exercise.
- definitions of the terms used to describe maps and the process of mapping.
- quality control processes for mapping, including the use of backward mapping to improve understanding of classification content and to assist in assessing the quality of the forward map.
- dangers and difficulties in the use of maps
- identify the issues relevant to mapping for purpose
- the relationship of the mapping process as an informant of the next generation of classifications in healthcare.
- infrastructure requirements for the development and ongoing maintenance of quality maps.

This document should inform those developing mapping approaches and those who manage and plan these processes to assist in defining the tasks to be performed and the options available when undertaking these tasks. The document will develop a shared understanding of these issues and processes.

This work is being led by Australia. A draft of this document will be prepared for teleconference discussion in the New Year.

Implications for Australia

Australia is increasingly looking to use terminologies to represent health concepts. A sound understanding of the processes and capacity of mapping to meet business needs should be well understood. Liaison for this activity should include NEHTA, NCCH, AIHW and State representatives interested in data collection and representation.

This work item will be actively run through IT14/2 Health Concept Representation Committee to whom additional representatives and resources would be welcomed.

9.7 ISO/NP TR 12310 - Principles and guidelines for measuring conformance in the implementation of terminological systems

This new work item was accepted just prior to the May 2008 meeting in Gothenburg.

An outline of the proposed content of this document was discussed at the Istanbul meeting. The meeting was highly supportive of inclusion of issues to resolve identified technical issues such as version control from a procedural perspective and the HL7 work on technical mechanisms to maintain and communicate versioning information in relation to messages and terminology services. This is the first time a coordinated approach to such work has been attempted and will require ongoing liaison with HL7 and IHTSDO. The work is being led by Canada.

Implications for Australia

The standard implementation of terminologies into Australian health software is an emerging issue. This work item offers considerable opportunity both to learn and to contribute to developments. Liaison with NEHTA, NCCH, AIHW and State agencies would be appropriate.

9.8 Integration of a reference terminology model for nursing (ISO 18104:2003)

It was agreed that this document will be reviewed, but that the reference to nursing will be more clearly used as an example rather than as a single domain only standard.

9.9 OID Registration Problem – referred from HL7

OIDs are required within CDA and within messaging and for other eHealth applications. This item was presented by Germany and HL7. Every terminology, value set and code set gets a unique number. ICD10 for example has a number (OID) that identifies it uniquely as a code system. There is an international system for the registration of OID numbers (OID registries).

The proposal harmonised through HL7 is to develop a standard for the management and establishment of OID registers, including specification of metadata requirements.

The first document being proposed will address a UML model and exchange format for OID metadata to communicate the content of an OID registry between repositories.

Use cases are being identified including sharing of an OID list, retrieval of an OID list. The data model and exchange format are being done as a joint exercise with HL7.

A technical specification will address maintenance of an OID repository to identify best practice in OID management. Further work will relate to defining use cases, good practice, recommendations for implementers, content of applications, recommendation for top level Arcs (tree position) and business requirements.

An initial proposal has been discussed and will be put forward for voting as a new work item proposal.

This work is being led by Germany and is for noting by Australian interests.

9.10 Potential future activity

WG3 have a full work program at the moment, but in their longer term plan there is still significant international interest in incorporation of Australian-originated user interface and clinical decision support standards to improve patient safety, at this point we do not have the resources to advance this objective. Standards in this area that will form the basis for international activities come from Australia and the UK. These activities are likely to come forward as New Work Item Proposals in 2010.

10. WG 4 Security, Safety and Privacy

Meetings of WG 4 were held over 2½ days, with most work being conducted in joint session with WG 4's European mirror committee, CEN/TC 251/WG iii. Unfortunately, there were insufficient Australian experts able to provide full coverage of WG 4 activity.

WG 4 addressed the following substantive matters at the Istanbul Meeting, some of which have been reported in more detail either as major issues or as topics being led by other working groups:

1. Welcome. Ross Fraser (Canada), the convener of ISO/TC 215/WG 4 (WG 4), and Luuc Posthumus (Netherlands) representing Colin Nolder (UK), the convener of CEN/TC 251/WG iii (WG iii), welcomed members of both working groups to the Istanbul Meeting and reviewed the combined agenda – noting that the activities of both working groups would all take place in joint session except for two different quarters - one allocated to a formal meeting of WG4 and the other to WG iii. To avoid potential conflicts for members of both WG 4 and WG iii, each working group scheduled time off, when the other was holding its formal meeting.
2. *ISO 27779:2008 Health informatics –Security management in health using ISO/IEC 2700* was published following the Göteborg meeting in May 2008 and was also the subject of an ISO press release.
3. *ISO/TS 25237 Pseudonymisation*. Following TC 215 approval for publication, there was an objection from ISO CS to a reference to ISO 9000. Following discussion with WG4 the matter has been resolved and publication of the final draft is now expected imminently. [Note: the stipulation of a conformance regime in a technical standard is contrary to widely accepted standardization practices].

4. *ISO/TS 21298 Functional and structural roles.* This technical specification, approved for publication by TC 215 is still being reviewed by ISO editors prior to publication, which is now expected imminently.
5. Title and scope of WG 4. An extension of the WG 4 title and scope to more clearly indicate its responsibilities in the area of safety/risk and privacy had been proposed at the Göteborg meeting in May 2008 but was deferred to the Istanbul Meeting to allow NMBs and the TC 215 Executive Council time to consider the proposal. On taking up the motion at the mini-plenary, TC 215 approved changing the title and scope of WG 4 to:

WG4 Security, Safety and Privacy

Defining health informatics security and privacy protection standards to

- 1) *protect and enhance the confidentiality, availability, and integrity of health information;*
 - 2) *prevent health information systems from adversely affecting patient safety;*
 - 3) *protect privacy in relation to personal information; and*
 - 4) *ensure the accountability of users of health information systems.*
6. *ISO/DTS 22600-3 Privilege management and access control (PMAC) Part 3 Implementations.* The DTS ballot for adoption of this, the third part of the 22600 PMAC standard, closed in early October 2008 with 12 NMBs in favour, none against and 12 abstaining or not voting. Canada submitted 15 comments, which were mainly editorial or suggestions/requests for greater clarity. Australia had abstained.

Guided by project leader, Bernd Blobel (Germany), remaining comments were reconciled and it was recommended that *ISO/TS 22600-3 PMAC Part 3* be submitted for publication as an ISO technical specification – this was approved by resolution of the mini-plenary at the Istanbul Meeting.

7. Health professional cards. There was a discussion of activity in this area, noting:
 - Dr Christoph Goetz is Project Lead for work on. prCEN/TR Health informatics - Overview of national health professional cards in the CEN member countries – but was unable to be present to provide an update.
 - Work on the EU project HPRO card (www.hprocard.eu)
8. Risk Management. WG 4 hosted a joint session of ISO/TC 215 WG 4, WG 7 and CEN/TC 251 WG iii and WG Iv on the subject of health software risk management and, more generally, managing all health information risks. The originally scheduled topics included:
 - *ISO/DTS 29321 Health informatics: Application of risk management to the manufacture of health software* (Ray Rogers)
 - *ISO/DTR 29322 Health informatics: Guidance on risk evaluation and management in the deployment and use of health software* (Ray Rogers)
 - A new work item on “Totality of risk” had been previously raised by Steve Daniels, who is developing the NWIP ballot documentation. Steve was not available at the Istanbul Meeting, so detailed discussion of this topic was deferred to the Edinburgh meeting.

ISO/DTS 29321 and *ISO/DTR 29322* were out to ballot at the time of the Istanbul meeting so discussion of technical content during the formal WG 4 sessions was limited; however, there a separate informal session was held to debate some of the deep concerns of the health information systems community over these two documents.

These events are reported in more detail in section 6.8 above.

9. *ISO/TR 11633 Health informatics -- Information security management guidelines for remote maintenance services for medical devices and health information systems.*

Work on this two-part technical report (led by Hideyuki Miyohara and based on translation of a Japanese national guideline) commenced in 2007 and has been the subject of internal review and update within WG 4, which recommended that TC 215 approve publication of:

- *ISO/TR 11633-1 Health informatics — Information security management for remote maintenance of medical devices and medical information systems Part 1: Requirements and Risk assessment,*
- *ISO/TR 11633-2 Health informatics — Information security management for remote maintenance of medical devices and medical information systems Part 2: Implementation of ISMS,*

following a one month informal review by NMBs. This recommendation was approved in the TC 215 mini-plenary at the Istanbul meeting. The documents do not yet appear to have been circulated to NMBs.

10. *ISO/TS 21547-1 Part 1 and ISO/TR 21547-2 Part 2: Health informatics – Secure archiving of electronic health records – finalisation of this standard is reported in more detail in section 10.1 below.*
11. Identity Management. Members of WG 4 and WG iii attended a joint session of ISO/TC 215 WG 1, WG 4, WG 8 and CEN/TC 251 WG i and WG iii hosted by WG 1/WG I on of identity management, with the following being noted:
 - Previous WG 1 work led by Heather Grain (Australia) resulting in the delivery of *ISO/TS 22220 Identification of subjects of healthcare* (awaiting final publication) and preparation of *ISO/DTS 27527 Provider identification.*
 - Presentation by Karima Bourquard (France) of work toward a CEN technical report on *Patient identification and cross referencing of identities*, reported more fully in section 7.3 above.
 - A presentation by Prof Bryan Manning (UK) from CEN/TC 251/WG iii on identity management framework activity in JTC1/SC 27 and the EU [reported more fully in section 7.4 above].
12. *ISO/PDTS 29585 Deployment of a clinical data warehouse.* Progressed in joint session of WG 1, WG 4 and CEN/TC 251/WG i and WG iii as reported in section 7.5 above.
13. *ISO/TS 13606-4 – EHR Communication – Part 4: Security.* Progression of this activity was discussed in joint session of WG 1, WG 4 and CEN/TC 251 WG i and WG iii and is reported further in section 6.4 above. [Also note comments on proliferation of work on information privacy, confidentiality, access control and identity management in section 6.10 above6.10 above].

14. *ISO/CD 27789 Audit trails for electronic health records.* Progressed in joint session of WG 4 and CEN/TC 251/ WG iii as reported in section 10.2 below.
15. *ISO/DIS 21091 Directory Services for security, communications and identification of professionals and patients.* The updated version of the current ISO/TS 21091:2005 was progressed in joint session of WG 4 and CEN/TC 251/ WG iii and has now been distributed for DIS ballot closing 27 April 2009 (on the eve of the Edinburgh TC 215 meeting).

Required action. It is important that this document, which may no longer reflect mainstream identity management and directory services environments be closely scrutinised by Australian interests during the current DIS ballot.

16. *ISO/DTR 11636 Dynamic on-demand virtual private network for health information infrastructure.* Work continued on this project, which was initially put forward by Japan in April 2006, was confirmed as a new work item in January 2008 and was progressed through WG 4 consideration of comments in Göteborg. The project leads are Hiroshi Shimada and Kouichi Kita of Japan.

The proposed technical report provides an overview of modalities for security threats to health information and outlines a two-layer PKI-encrypted hardware-supported approach for remote authenticated access to patient health information held in repositories at individual health care provider institutions.

At the Istanbul Meeting, there was further discussion on finalising the draft with WG 4 proposing to TC 215 that an updated draft of ISO DTR 11636 be circulated to NMBs in January 2009 for ballot seeking approval to publish following the April 2009 TC 215 meeting in Edinburgh. An updated draft was posted to the WG 4 website in November 2008 for one month informal review by members of WG4 before being circulated to NMBs.

Required Action. Through IT-014, Australia will need to consider and respond to the DTR ballot.

17. Security requirements for EHR software and related software certification. Luis Kiatake (Brazil) raised the potential need for a new work item in this area in a joint session of WG 4 and CEN/TC 251/ WG iii. A documented proposal for such an item is to be discussed in Edinburgh.

Suggested Action. Following on from the experience with ISO/TS 29321 and ISO/TR 29322, it would seem appropriate that the Australian delegation to Edinburgh be prepared to speak to this item – with background information on the rules for standards that specify certification regimes and a scan of competing efforts. This should not proceed if there is no clear net public benefit. Getting feedback from ISO/CASCO, the health software industry and regulators should be considered once the details are clearer.

18. Migration of EHRs. Pekka Ruotsaleinen (Finland) raised the potential need for a new work item in this area in a joint session of WG 4 and CEN/TC 251/ WG iii. A documented proposal for such an item is to be discussed in Edinburgh.

Proposed Australian position. It would be appropriate that the Australian delegation to Edinburgh be prepared to speak to this item – with a scan of competing efforts [noting the comments in section 6.10 above about overlaps of SDO activities in the area of information privacy, confidentiality, access control and identity management]. This item should not proceed if it represents significant duplication or if there is no clear net public benefit – getting feedback

from other SDOs through the JIC/JWG on health informatics SDO harmonisation should be considered once the details are clearer.

19. Proposal to standardise a list of *purposes for processing EHR data*. As reported in section 6.9 above, Dr Dipak Kalra's proposal to develop a standard addressing this topic was discussed in joint session of ISO/TC 215 WG 1, WG 4, WG 8 and CEN/TC 251 WG I and WG Ii.

20. WG 4 involvement in TC 215 work on health cards.

It was agreed that WG 4 and CEN WG iii would subsume work on health cards following the retirement of ISO/TC 215 Working Group 5.

While the use of health cards as identity management access tokens aligns with WG 4 scope, modelling and architecture elements relating to prescriptions and emergency records require WG 1 expertise. To address this, WG 4 has been asked to set up a series of joint task groups to address specific health card work items with appropriate representation and technical input from WG 1 and other relevant expert groups.

21. *ISO 22857:2004 Health informatics – Guidelines on data protection to facilitate trans-border flows of personal health information*. Review commenced in Göteborg was continued in Istanbul with the next step being the balloting of proposed revisions (no timeline set).

Working documents relating to WG 4 activities are posted on the TC 215 secure portal, which is managed by HIMSS. Where required for approved standards development work, draft documents and reports produced by this Working Group may be obtained by contacting Renati Barel at Standards Australia (renati.barel@standards.org.au).

For other queries about WG 4 and more information about its activities, contact Richard Dixon Hughes (richard@dh4.com.au).

10.1 Secure archiving of EHR data (ISO 21547)

This long-standing work item led by Pekka Ruotsalainen (Finland) was progressed significantly at the Gothenburg meeting with TC 215 having approved that:

- *ISO/DTS 21547-1 Health Informatics — Security requirements for archiving of electronic health records — Part:1 Principles and requirements* be balloted as a Technical Specification, and
- *ISO/DTR 21547-2 Health Informatics — Security requirements for archiving of electronic health records — Part 2: Guidelines* be balloted as a Technical Report.

The ballot for adoption of the first part, *ISO/DTS 21547-1*, closed in early October 2008 with 13 NMBs in favour, none against and 11 abstaining or not voting. A total of 78 comments were submitted (66 from Canada, 10 from Japan).

The ballot for adoption of the second part, *ISO/DTS 21547-2*, also closed in early October 2008 with 12 NMBs in favour, none against and 12 abstaining or not voting. A total of 23 comments were submitted on this part.

At the Istanbul Meeting, WG 4 worked on reconciliation of the many comments and recommended that the two parts be sent for publishing on delivery of the corrected

versions (targeted for 1 December 2008) – which TC 215 approved by resolution in mini-plenary.

Prof Maeder reported that issues considered in discussion of comments included:

- Scope of definitions of key concepts were clarified, specifically - archiving, EHRs, regulatory aspects and purpose of use.
- Whether digital data may only be archived in original raw format or whether it can be transformed (eg compressed).
- Differences between countries on what is collected and owned by health system as against the individual: may permit some extra data to be contributed, or secondary uses.
- Disclosure of data to third parties may need to be regulated within archiving guidelines: for whom is it archived?
- Responsibilities for keeping and providing data when it resides across multiple distributed sites: EHR can be logical [or virtual] rather than physical.

10.2 Audit trails for EHRs (ISO/CD 27789)

Luuc Posthumus (Netherlands) reported in joint session of WG 4 and CEN/TC 251 WG iii on progress with *ISO/CD 27789 Audit trails for electronic health records*, being developed for adoption as a full ISO international standard and parallel adoption in CEN under the Vienna agreement (with ISO lead). Two sessions of WG 4 at the May 2008 TC 215 meeting in Göteborg had been devoted to review, update and comment reconciliation in preparing a working draft of this document for ballot as a Committee Draft (CD)

The ballot for *ISO/CD 27789* closed on 10 October 2008 with 13 NMBs in favour, 1 (Japan) against and 10 abstaining or not voting. In total there were some 100 comments – many from Canada, which had clearly reviewed the document thoroughly from both a technical and editorial perspective. Significant contributions also flowed from the US, UK, Finland, Canada and Australia.

Japan's negative vote is based on the concern (shared by others at many points over the life of this document) that there are general ICT standards addressing the management of audit trails across many domains and that *ISO 27789* should not replicate measures contained in those standards but, rather, concentrate on any specific considerations relating to audit trails for use with EHRs. In responding negatively to the CD, Japan's comments included noting that the CD still has too broad a scope, contains many issues simply copied from *IETF RFC3881 Security Audit and Access Accountability Message XML* and needs to ensure that its provisions in relation to data integrity and long-term archiving take into account:

- *RFC 4810 Long-Term Archive Service Requirements, and*
- *RFC 4998 Evidence Record Syntax (ERS)*

Resolution of comments from the CD ballot commenced at the Istanbul Meeting and was planned to continue out-of-session with a view to a revised, marked-up version and reconciliation of comments being available by end-December 2008 to a dedicated task force, which would meet in Delft in the Netherlands on 20 February 2009 (in conjunction with CEN/TC 251 strategic planning meeting) with a view to progressing

the work sufficiently to have a Pre-DIS draft ready for discussion at the April 2009 TC 215 meeting in Edinburgh and release to DIS ballot immediately thereafter.

It is noted that this project is running behind schedule and risks being suspended by the ISO/TMB if the DIS stage is not activated in the first half of 2009 (current deadline for DIS registration is actually 26 January 2009 – so the proposed schedule is already into over-run).

11. WG 5 Health Cards

Following broad consideration and discussion of a recommendation from WG 5, TC 215 passed resolutions at the mini-plenary to the effect of:

- Retiring WG 5 Health Cards so that it would no longer continue operating as a separate Working Group within the TC 215 structure;
- Subsuming its remaining on-going functions into a Task Force to be led by former WG 5 convener, Jürgen Sembritzki (Germany), reporting through WG 4 with involvement of experts from WG 1, WG 8 and other WGs as required;
- Foreshadowing a further amendment to the WG 4 scope to reflect these changes;
- Noting that ongoing work is no longer limited to magnetic stripe health cards and that smartcard, thumb drive and other media technologies need to be accommodated - a connection with ISO/IEC JTC1/SC27 is to be retained for the specific purposes of identifying and working appropriately with relevant security-enabled devices and techniques;
- Circulating *ISO/DIS 21549-8 Health informatics — Patient healthcard data — Part 8: Links to NMBs* for DIS ballot;
- Noting the need for systematic review of published standards every 3 years, initiating review of the following parts of *ISO 21549 “Health informatics – Patient healthcard data”* in Edinburgh:
 - *Part 1: General structure*
 - *Part 2: Common objects*
 - *Part 3: Limited clinical data*
 - *Part 5 Identification data*
- Progressing work on developments in health professional cards.

12. WG 6 Pharmacy and Medication Business

A full program of WG 6 Pharmacy and Medication Business meetings were convened over the available 2½ days, with a total of around 40 experts from 10 different countries and 4 liaisons participating.

Prof Evelyn Hovenga attended many of the WG 6 sessions on behalf of Australia and is thanked for her notes which have contributed to this section of the report.

Seven projects on the WG 6 Pharmacy and Medication Business work plan are being undertaken under the Vienna Agreement between ISO and CEN, with ISO/TC 215 as

the lead SDO. These projects are also on the Joint Initiative work program, with each project having an ISO/CEN lead and an HL7 co-lead (approved by HL7).

1. *ISO 27953 Health informatics – Pharmacovigilance – Structure and Data Elements for Individual Case Safety Reports*
2. *ISO 11595 Health informatics – Pharmacovigilance – Test names and units for reporting laboratory results*
3. *ISO 11615 Health Informatics – Identification of medicinal products – Data Elements and Structure for the Exchange of Product Information for Drug Dictionaries*
4. *ISO 11616 Health informatics – Identification of Medicinal Products – Pharmaceutical Product Identifiers*
5. *ISO 11238 Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for Ingredients*
6. *ISO 11240 Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for Units of Measurement*
7. *ISO 11239 Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for Pharmaceutical Dose Form, Units of Presentation and Routes of Administration*

This series of projects commenced in 2006 under a six part contract between the EC and CEN with support of a CEN project team (the WG 6 secretariat is with NEN in the Netherlands). The EC subsequently discontinued three of six parts which had consequences for the CEN project team.

Experience with these projects has highlighted many challenges in realising the apparently simple goal of health informatics SDO harmonisation. In this case, harmonisation has not been assisted by most of the projects initially arising out of EC contracts and involving many activities and interests of ICH (the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use), regulatory authorities, notably the European Medicines Agency (EMeA) and the FDA and NHI in the US, and the activities of other SDOs including CDISC and HL7. Meetings are attended by representatives of the some regulators and pharmaceutical industry bodies concerned about minimising any impacts of the standards on costs or through potential regulatory change.

The Convener, Ian Shepherd (UK), has openly advised that significant refinements in scope of individual items had been required to enable progress in a difficult political environment.

WG 6 addressed the following substantive matters at the Istanbul Meeting:

1. The first three-year term of Ian Shepherd (UK) as convener of WG 6 is expiring. He indicated his willingness to continue for a second term. There are no other nominees at this time. The final decision will be in Edinburgh. The Vice Convener is LuAnn Whittenburg (US) and the Secretary is Shirin Golyardi (Netherlands).
2. *ISO/WD 27953 Pharmacovigilance – Structure and Data Elements for Individual Case Safety Reports (ICSR)*. This work item is reported further in section 12.1 below and is controversial as it potentially cuts across many existing and proposed local incident reporting activities. In Istanbul, WG6 reported that the current working draft has been restructured into two parts, both to be submitted

to formal ballot for acceptance as Committee Drafts (CDs) before the Edinburgh TC 125 meeting in April 2009.

3. *ISO/WD 11595 Pharmacovigilance – Test names and units for reporting laboratory results.* Notwithstanding being for pharmacovigilance applications, this item is being progressed as part of package of six IDMP (Identification of Medicinal Product) standards covered in section 12.2 below.

The updated working draft of *ISO/WD 115954* will shortly be circulated in a ballot for acceptance as a Committee Draft. This is expected to occur at the same time as the associated IDMP drafts are balloted.

Compatibility with other existing ISO, CEN, HL7 and related standards for laboratory codes and data sets remains an issue (LOINC and European Standard EN 1614:2006 were particularly mentioned). From the laboratory perspective, there is a desire for all reporting applications to adopt common, standardized terminology to represent concepts such blood sodium level.

Resources for on-going maintenance of these standards are expected to be significant and their availability remains an issue.

4. Standards for Identification of Medicinal Products (IDMP). As reported further in section 12.2 below, the five IDMP standards are currently at Working Draft (WD) stage and are about to be circulated in CD ballots for their acceptance as Committee Drafts (along with the associated *ISO 11595 lab test names and units* standard). Harmonisation with other standards and terminology development activities and longer term code-set maintenance remain issues.
5. *ISO/DTR 25257 Business requirements for an international coding system for medicinal products.* This work item was originally approved without objection in 2005. A draft technical report was reviewed and approved by TC 215 at the Göteborg meeting in May and circulated for NMB ballot in July 2008. The document identifies business requirements for a coding scheme and compares several coding systems (WHO DD, GS1, NDC) with the requirements – identifying potential improvements.

The ballot for *ISO/DTR 25257* closed on 11 October 2008 with 12 NMBs in favour, 2 (Canada, UK) against and 10 abstaining or not voting. In total there were some 55 comments – mainly from Canada, UK and the US.

Canada was of the view that the original requirement for this document had been taken over by other projects, so it will need a major re-write. UK were concerned that comments provided prior to document going to ballot were not addressed. Australia had supported the work as a TR, submitting comments based on advice from NEHTA – particularly relating to the potential to build on work in AMT and need (for WHO and others) to differentiate more clearly between form of the medication and route of administration (noting that it sometimes happens that a form is administered via a different route to that originally intended.)

WG 6's program for progressing this matter is somewhat unclear. The leader of the project team, Ock Hee Oh (Korea) was unable to be present at the Istanbul Meeting, and the work of finalisation had not progressed sufficiently for a motion for finalisation and publication to be put to the mini-plenary. It is assumed that it will be resolved at the Edinburgh meeting.

6. *ISO/CD TR 10895 Business requirements for the reporting of pharmacist services.* The NWIP for this TR was approved by ballot in August 2007 (just in

time for the TC 215 meeting in Brisbane) and, at that time, Ian Todd of the Pharmacy Guild was nominated as an Australian expert.

The aim of the document appears to be a standard set of requirements for reporting clinical services provided to individual subjects of care by retail and other pharmacists (e.g. programs to quit smoking). Some of the issues are:

- Standards for such reporting should aim to utilise the same semantic frameworks, architectures and development methods as are applicable to other potential entries to an individual's EHR/PHR.
- In seeking to identify requirements and/or model a domain, some approaches and activities to be aware of include: HL7 MDF, CDA/CCD, clinical statement pattern and EHR-S FM, use of 13606/*openEHR* archetypes, standard terminologies and code sets and the DCM project (see section 6.12 above).
- The project is still immature as the relevant business processes and use cases are not yet sufficient clear.
- The project appears to overlap the interests and responsibilities of WG 1, WG 8, WG 2 and WG 3.
- There appears to be a need to undertake a survey of pharmacies re status of services delivered to assess what needs to be captured in the health record.
- There is a precedent in some of the ISO work done on nursing terminology (suggested by Prof Hovenga).

Implications for Australia. If and when the project moves to a more active plane, further input and involvement from the Pharmacy Guild of Australia would be appropriate; however, the idea of WG 6 attempting to model one of many clinical domains should be questioned – if it is to be done in isolation.

7. Other potential future items. In looking forward, the potential need for WG 6 to work on the following was noted:
 - Further implementation standards or guides flowing from recent UK national review of IT implementation;
 - Implementation of US program on public health and adverse event reporting is expected to lead to development of an IHE interoperability profile – WG 6 should be looking to provide input and harmonise with ICSR and other work;
 - The need for WG 6 to have an update on IHE and its wider role in health informatics, as many of the Pharmacy/Medications domain experts in WG 6 had not yet been exposed to IHE.

General Issues with progression of current items

The main activities being progressed by WG 6 largely originated from an eHealth contract between CEN and the European Commission, which led to joint standards development with ISO/TC 215/WG 6. A lot has happened since the beginning of the pharmacovigilance and IDMP projects in 2006 and some of the work originally conflicted with approaches used in the US under the FDA and their arrangements with HL7; however, communication is now much better (but far from perfect). The following way forward has now being foreshadowed to address some of the many issues that have arisen with the seven work items currently in development:

- Addressing the incorrect perception that EMeA has leadership of these projects, which has caused some confusion in WG 6; there is a need to progress the work as international standards and ensure that all countries recognise that their input is welcome.
- Under the guidance of the JIC - creating greater interdependency between all WG 6 work items and the activities being progressed by other TC 215 WGs and the other SDOs under the Joint initiative for Health Informatics SDO Harmonisation.
- Continuing active modelling activities.
- Consultation with IHTSDO and WG 3.
- Integration of units of measure with established work of other WGs and SDOs.
- Considering getting agreement to restrict current scope for ICSR to Europe and ISO community (outside USA).
- Obtaining more direct involvement of European competent authorities, professional societies and standards bodies in the standards development work as it is progressed.
- Resolving the question of maintaining the resulting controlled vocabularies and the resources needed to perform this function – which continues to be a major subject for discussion and decision-making within TC 215 and in all SDOs.

Implications for Australia

It has previously been recommended that Australia should increase its involvement in WG6 projects beyond the current monitoring /watching brief – this continues to be the case here and also in relation to parallel activities in the HL7 Pharmacy WG (see report on HL7 September 2008 meeting in Vancouver). Liaison for WG 6 projects should include NEHTA, TGA and State representatives interested in identification of medicinal products and case safety reports. Whilst this work originated in Europe, it has now gained attention and involvement from HL7, and Australia needs to consider the implication of the draft ISO Standards on Australian medicinal initiatives.

12.1 ISO 27953 Structure and data elements for individual case safety reports (ICSR)

It has now been decided by WG 6 and confirmed by TC 215 in mini-plenary that the ICSR standard should be progressed to publication as a two-part standard, as follows:

- *ISO/DIS 27953-1 Health informatics - Pharmacovigilance – Individual Case Safety Report – Part 1: The framework for adverse event reporting; and*
- *ISO/DIS 27953-2 Health informatics - Pharmacovigilance – Individual Case Safety Report – Part 2: Human pharmaceutical reporting requirements for ICSR.*

Re-drafting of the existing DIS documentation into two parts is planned to be completed by the end of December 2008, with a view to being released to five month DIS ballot in early 2009 – this is to be achieved without significant change to the substantive content. There was some concern within WG 6 that the separation into two parts may contravene ISO procedure as the original NWIP was for a single standard [however, most consider that this should not be a problem]. The following are some of the issues that were discussed around this item:

- The potential conflict with the previous HL7 proposal to progress the existing HL7 ICSR, which was largely based on US-FDA needs, to a full ISO International Standard was recognised.
- The scope of the ICSR work and content of the draft document is to be adjusted based on consideration of points raised by Lise Stevens on behalf of HL7 and the US-FDA, with the following being noted:
 - ISO/DIS 27953 will accommodate HL7 ICSR work on patient safety
 - It will focus on ensuring correct ICSR content requirements from underlying ICH work
 - The ISO template format will be used – which requires various publication changes
 - Challenges with terms and definitions, specifically the need to:
 - Update EMEA references in ICH E2A glossary and enter into glossary.
 - Ask WG 3 to clarify differences in definitions between US and EU for: Electronic data interchange; Individual case safety report
 - Terms in this ISO document do not overlap with HL7 glossary terms based on RIM. Need to constrain HL7 glossary terms relevant to this ISO doc.
 - A lot more discussion on story boards and use cases isw expected to show where content came from. Need to review to ensure these are generic
 - An informative annex of use cases has been suggested
 - Individual Case safety Report UML Model needs to be mapped to IDMP as well as ICSR data elements
 - Need the ability to capture multiple levels including active moiety, Pharmaceutical Product ID (PhPID), brand/product, ingredient (ie any level of information about the product.)
 - Document needs restructuring – ICH conformance profile plus other international stakeholder requirements becomes the ISO standard. It will have an informative additional part constraining some items ensuring acceptance by HL7 and ICH pertaining to issues associated with the need to reconcile/harmonise all content as some pertain only to certain jurisdictions.
 - HL7 Message Specification needs to be referenced by Part 1 of the ISO DIS but this HL7 document has no status as yet.
 - An implementation guide will be needed relating ISO Part 1 specification to ICH and ICH E2B(R3)
 - Annex A to be moved to main document, with further comments to be addressed over the next few weeks.
- Notwithstanding, their proposed specialised use, there is some concern (shared with IDMP) that adopting standards for ICSR reporting that differ from mainstream laboratory reporting is a retrograde step away from the “collect once – use many times” principle and an unwarranted source of disharmony.

Implications for Australia

Receipt of the DIS ballot will soon require a response from Australia. This activity has involved significant input from a large number of global interests and requires a response that aligns with our needs and directions of the full cross-section of stakeholders in Australia including TGA and NEHTA.

12.2 IDMP Standards for Identification of Medicinal Products

Five proposed WG 6 standards are specifically designated “Identification of Medicinal Products” (IDMP) standards:

- *ISO/WD 11615 IDMP – Data Elements and Structure for the Exchange of Product Information for Drug Dictionaries*
- *ISO/WD 11616 IDMP – Pharmaceutical Product Identifiers*
- *ISO/WD 11238 IDMP – Structures and Controlled Vocabularies for Ingredients*
- *ISO/WD 11240 IDMP – Structures and Controlled Vocabularies for Units of Measurement*
- *ISO/WD 11239 IDMP – Structures and Controlled Vocabularies for Pharmaceutical Dose Form, Units of Presentation and Routes of Administration*

A sixth standard, *ISO/WD 11595 Pharmacovigilance – Structures and Controlled Vocabularies for Laboratory Test Units for the Reporting of Laboratory Results* is being developed as a sixth member of the set; although not designated as an IDMP standard, it involves similar considerations related to vocabularies and information structures.

Drafts of all five IDMP (11615, 11616, 11238, 11239, 11240) working drafts will be shortly circulated in a ballot for acceptance as Committee Drafts (CDs) along with the associated *ISO/WD 11595*.

Having commenced some three years ago, these projects were progressed rapidly with weekly teleconferences in the lead up to the May 2008 Göteborg meeting, where the following issues emerged: tight timeframes; concerns that comments were not being reflected in updated documents; the need for better alignment between ICSR project and the IDMP projects; the need for wider circulation of drafts outside project groups; and the need to review prEN ISO 11615, prEN11238 and prEN ISO 11616 together. WG 6 has been working on addressing these issues as it moves forward with these projects.

Since Göteborg, Tom Marley (UK) has been engaged through CEN to work with WG 6 to generate a formal UML Domain Analysis Model (and sub-models) relating to 11238 (ingredients/substances), 11615 (IDMP Data elements & structures), and 11616 (PhPIDs) - identifying all the various class names associated with any medicinal product. This work has found that WG 6 needs to revisit the names used to identify classes across its own domain - carefully examining the purpose (use cases) for which each class has been identified and defined.. (E.g. active ingredient is sometimes referred to as significant clinical component or significant clinical ingredient). When formed, the resulting models will be useful for finding omissions in these documents and for broader harmonisation purposes.

The WG 6 view has traditionally been that their work is focussed on specific regulatory reporting requirements, with a special set of terminology, which is not intended for inclusion in EHR or more recording of adverse results in other contexts. This view is increasingly under challenge within the wider TC 215 and health informatics community and may be characterised as the IDMP work being too focussed on regulatory use cases, without giving attention to clinical use cases (e.g. as needed for EHR). This concern continued at the Istanbul Meeting with the following being noted:

- Models are likely to emerge from WG 6 that differ in various ways from other models (including existing models) addressing the same and similar domains – it is important that the various models be reconciled before they are implemented. For pharmacovigilance laboratory test units and reporting (11595), there may already be overlapping models for CDISC, EHR and/or laboratory result data.
- The WG 6 work also does not appear to be connected to existing e-prescribing standards or CDISC clinical data interchange standards.
- The 11595 standard was recently extended to include clinical observations as well as controlled vocabularies for the reporting of laboratory results – the potential for clash with the HL7 Clinical Statement pattern and other EHR communication and content standards is thereby enhanced.
- Compatibility with other existing ISO, CEN, HL7 and related standards for laboratory codes and data sets will remain an issue (LOINC and the European EN 1614:2006 standard were particularly mentioned). From the laboratory perspective, there is a desire for all reporting applications to adopt standard terminology to represent concepts such as blood sodium level.

During discussion at the Istanbul Meeting, other issues and activities arising from the IDMP and associated work included the following:

- There is strong pressure for closer collaboration with other WGs (potentially WG 3, WG 1 and WG 2) in ISO and, also, other health informatics SDOs currently involved in terminology and code sets.
- WG 1 is to follow up with WG 6 re the modelling approaches being used and identify potential overlaps with DCM and other WG 1 work.
- **ISO/CD 11240 Units of Measure (UOM).** This work appears to need close collaboration with WG 3, which has opposed WG 6 taking this work to the CD stage – requesting that it instead be directed to WG 3 for review and progression as a joint activity – as the content is (or should be) heavily dependent upon WG 3 terminology and, also, WG 2 data type harmonisation.

On the other hand, WG 6 do not wish to “lose 11240” considering that the six IDMP work items are interdependent on each other, and noting that WG 6 is committed to deliver for ICH, which wants to ensure that a definitive UOM standard is in place to support use of the other related standards.

- Other issues with the proposed UOM standard include:
 - SNOMED and the other leading options need additional terms to meet business requirements needs – where, how and by what authority would WG 6 source these additional terms?

- Standardisation of value sets – the (Regenstrief) UCUM⁶ code is widely supported and based on ISO 2955 but is strictly open source and cannot be licensed for incorporation, publication and sale as part of another standard – but its codes could be referenced from such a standard and are mappable to other term sets.
- Apparently there is some problem with the standard PQ data type.
- One option was for 11240 to remain as a draft for the present and not be progressed toward becoming a full standard leaving these issues unresolved. There was discussion of this during the mini-plenary, which resolved (with Australia abstaining) to allow this document to go through to CD ballot, which has the advantage of giving NMBs the opportunity to make their views known.
- **On-going Maintenance of the IDMP standards and supporting code sets.** There is likely to be significant costs in maintaining the broad range of code sets and terminology to support the IDMP standards (we are talking of an international medications database). The normal approach is to identify an ISO-approved “Registration Authority”. Possible approaches include mutual engagement with CDISC as well as building on current ICH capabilities and/or IHTSDO. There is a lot of work to be divided up among the various parties.

Canada is sceptical about the ability to finance this work and suggest that the business case and a sustainable approach to funding be confirmed before proceeding much further.

The US has suggested WG 6 focus on core frameworks rather than the maintenance of code sets and terminology – decoupling the details into appendices or other documents. Each of these standards has a set of terminology that needs to be maintained, some of which is unique for this domain and some that may need to reference other standards; however, health informatics terminologies are not the core remit of WG 6 - this belongs to WG3 (and, more widely to IHTSDO, WHO and others).

Importantly there are very specific and important maintenance requirements for this domain leading to issues of governance and process (timing etc) – remembering that ICH are already concerned at the time this is taking.

- *11595 Laboratory test units* has a significant maintenance attachment and also requires changes to body text before it is ready for the CD ballot – it may be the one on the critical path for the ballot release schedule.
- There is a risk that views expressed in WG 6 and among those attending TC may be different from what member bodies make out – especially given the importance that ICH was partly responsible for commissioning the work and have contributed strongly to most of the work in WG 6 but are not directly involved with other WGs and NMBs [the problem of a strong domain or sectoral view versus general cross-domain views of needs and approaches]. WG 6 adopted the strategy of trying to develop positions that represent broader views to increase their chance of acceptance by TC 215 and NMBs.
- Titles of work items to be reviewed so that these accurately reflect content following the proposed changes – can be done in Edinburgh, if necessary.

⁶ UCUM – Unified Code for Units of Measure.

Implications for Australia

Given the potential overlap and inconsistency with other work on clinical terminology, regulatory value sets and medication identification, Australia will need to take the time to develop an informed and considered position on the proposed CD ballot. It will need to be reviewed by those familiar with terminology, laboratory communication and contemporary trends in health informatics to confirm, that the proposed approaches align with existing practices and/or preferred future directions – or that there is a strong case for any deviations. The strength of an Australian position will require input from TGA concerning potential Australian/ICH adoption of a uniform, international, standards-based ICSR regime.

If these proposed standards do not align with other work, there needs to be some consideration as to the appropriate vote and the comments to be submitted with them.

13. WG 7 Devices

Parallel meetings of WG 7 and the CEN/TC 251/WG iv mirror group were formally convened over approximately 2 days, with experts from WG 7 also participating in joint session with WG 4 and CEN/TC 251/WG iii (on risk management) and with WG 3 and CEN/TC 251/WG ii (on device cluster archetypes and terminology mapping).

WG 7 works closely with relevant IEEE, ISO, IEC and HL7 committees that deal with medical device interfaces and is the primary vehicle by which established IEEE medical device interface standards are proposed to be fast-tracked into ISO international standards under the agreement between IEEE and ISO. Since the Continua Alliance was formed, vendor resources for work on device standards development have increasingly contributed through Continua's forums.⁷

The Australian delegation did not have an expert dedicated to WG 7 activities, although some parts of the WG 7 agenda were attended by Dr Vince McCauley and by Prof Anthony Maeder – who both provided notes used to assist in the preparation of this report.

WG 7 addressed the following substantive matters at the Istanbul Meeting, some of which have been reported in more detail in other sections of this report:

1. Todd Cooper (USA) and Thomas Norgall (Germany) were respectively confirmed as Convener and Vice-Convener of WG 7.

The position of secretary, occupied by Melvin Reynolds (UK) is currently vacant and he is also withdrawing from his position as convener of the CEN mirror group on devices (CEN/TC 251/WG iv). This apparently reflects a shift in UK NHS funding priorities for support of standards work.

⁷ For more on Continua Alliance, see: <http://www.continuaalliance.org/>

2. Representatives attending WG 7 are heavily involved in the current debate over what types of health software constitute a “medical device” and whether the proposed ISO/TS 29321 and ISO/TR 29322 documents on risk management of health software are an appropriate response to managing possible risks to patient safety. An additional session on these questions was convened for the evening of Sunday, 12 October.

Risk Management. WG 4 also hosted a joint session of ISO/TC 215 WG 4, WG 7 and CEN/TC 251 WG iii and WG iv on the subject of health software risk management and, more generally, managing all health information risks.

These activities are reported in more detail in section 6.8 above and at dot point 8 in the report on WG 4 activities in section 10 above.

3. Device interface standards. At the Göteborg meeting, the TC 215 plenary had resolved that 11 of the IEEE 11073 series of standards be progressed via a preliminary 30-day announcement ballot to an FDIS ballot for final acceptance as a full international standard (subject to receipt of the requisite specifications from IEEE). It appears that this outcome did not actually eventuate.

At the TC 215 mini plenary, WG 7 noted recent clarification of IEEE/ISO Partner SDO transition arrangements and sought TC 215 confirmation of its previous request that newly approved IEEE documents be circulated for combined NWIP/DIS ballot as joint-label standards as soon as they become available from IEEE (with similar fast-track treatment within CEN). The final position on this request was unclear but TC 215 resolved to circulate seven 11073-series specifications for NWIP ballot in receipt of the relevant drafts from IEEE:

- *ISO/IEEE 11073-10408 ... Personal health device communication – Device specialization – Thermometer*
- *ISO/IEEE 11073-10415 ... Personal health device communication – Device specialization – Weighing scale*
- *ISO/IEEE 11073-10441 ... Personal health device communication – Device specialization – Cardiovascular fitness and activity monitor*
- *ISO/IEEE 11073-10442 ... Personal health device communication – Device specialization – Strength Fitness Equipment*
- *ISO/IEEE 11073-10471 ... Personal health device communication – Device specialization – Independent Living Activity Hub*
- *ISO/IEEE 11073-20601 ... Personal health device communication – Application Profile – Optimized Exchange Protocol*

4. There appear to be some delays in the production of final specifications for balloting - this appears to be partly due to the additional involvement of the Continua Alliance in the standards development process. Continua do not publish their use cases; this was reported to be making development of the ISO standards very difficult. Also some of their technology implementations are not public.
5. It was reported that *ISO/IEEE 11073-10404 ... Personal health device communication – Device specialization – Pulse Oximeter* is progressing best of the new series of specifications; however, although it will be jointly published, it will be cheaper in the hyperlinked electronic version from IEEE than in the paper version from ISO.

6. WG 7 has recommended to TC 215 that IEEE lead systematic reviews of EN ISO/IEEE 11073 standards in the interests retaining synchronisation of maintenance and version releases. This would be followed in each case by direct adoption within ISO and CEN – whose experts would provide input to the joint WG decisions being led by IEEE.
7. ISO WG7 does not cover Lab. device or imaging (DICOM) communication but the equivalent CEN group (TC 251/WG iv) does. ISO and CEN are both considering pursuing devices activity in Project Task groups rather than WGs because of most of the issues are increasingly crossing WG boundaries.
8. Units of Measure (UOM). This is a topic of concern for several of the TC 215 Working Groups – in particular the growing desire to build on the open source UCUM code and conversions maintained by Regenstrief Institute. In relation to WG 7's activities
 - The ISO 11703.x (communication) series of standards do not reference UCUM but IHE profiles using these standards do. HL7 and DICOM both mandate use of UCUM.
 - It is currently proposed that ISO make references to UCUM rather than bringing it into ISO documents, where people would be paying for something that is otherwise available as an open source product.
 - Long-term maintenance and governance of UCUM are other issues. Maintenance presently depends on 2 people that perform this function.
9. In its presentation to the TC 215 mini-plenary, WG 7 noted the following miscellaneous matters, which it is seeking to progress:
 - A recommendation that an open resource listing of currently available biosignal data formats be compiled;
 - WG 7 is considering preparing candidate generic device clusters/archetypes that could be used to populate clinical archetypes;
 - There is a need to resolve ambiguity / inconsistency between some of the current 11073-104xx series of Personal Health Device documents.
10. Other matters discussed by WG 7 and noted by Dr Vince McCauley included:
 - (a) Prof Stefan Sauerman reporting on his current contract work for the Austrian national health agency - comparing requirements for pathology results with the capability of CDA/IHE standards to address them.
 - (b) The IHE Rosetta Project – development of a terminology map for devices, which is currently in the form of a large spreadsheet.
 - (c) The ongoing quest for an EHR-implementation-agnostic ability to export device data. Following discussions at the September 2007 TC 215 meeting in Brisbane, *openEHR* had been considered for this work, with Melvin Reynolds and Dr Heather Leslie having mapped ISO 11073 to the Blood Pressure Archetype and reported on differences.

Further work now needs to be done to expand the archetypes for device usage and map existing V2 messages specified for devices to the archetypes. The 11073 standards have a defined common Data Model, which needs to be reflected in archetypes and as HL7 clusters.
 - (d) The Japanese are working on a waveform specification expected to be received in time for review at the January 2009 HL7 Working Group

meeting in Orlando. Based on this, WG 7 plans to do a review of signal waveform specifications/formats (maybe 100) to analyse and report on known implementations and the proposed use, potential scope, and case for/against further standardisation. This preliminary assessment work is likely to be suitable for released as a Technical Report.

IEEE 11073 will also need this as input; however, FDA has already specified the HL7 ECG message for use in the USA.

Forthcoming Meetings

The next meetings of WG 7 are proposed to be held within the dates and at the locations shown in the following table:

Date	Location	Participants
11-16 Jan 2009	HL7 WGM Orlando, Florida, USA	WG 7, IEEE 11073, HL7 DEV WG
27-30 Apr 2009	TC 215 Plenary Edinburgh, Scotland, UK.	WG 7, CEN/TC251 WG iv
10-15 May 2009	HL7 WGM Kyoto, Japan	WG 7, IEEE 11073, HL7 DEV WG
20-25 Sep 2009	HL7 Plenary+WGM Atlanta, Georgia USA	WG 7, IEEE 11073, HL7 DEV WG
18-21 Oct 2009	TC 215 Durham, North Carolina, USA	WG 7

14. WG 8 Business Requirements for Electronic Health Records

Meetings of WG 8 were formally convened over 1½ days, with experts from WG 8 also attending joint sessions with WG 1 and CEN/TC251/WG I on another day. A total of around 60 experts from 16 different countries participated. Elizabeth Hanley (WG 8 Secretariat) and Richard Dixon Hughes (as Australian subject matter expert) attended all WG 8 sessions and others also attended some, including joint sessions with WG 1.

WG 8 addressed the following substantive matters at the Istanbul Meeting, some of which have been reported in more detail in other sections of this report:

1. Dr Marion Lyver (Canada) and Dr Beatriz Leao (Brazil) were respectively confirmed as Convener and Vice-Convener of WG 8.
2. Personal Health Records (PHRs). Presentations by Dr Dipak Kalra, Gora Datta and Dr Marion Lyver resulted in two potential new work items being identified as reported further in sections 14.2 and 14.3 below:
 - *Personal health records: Definition, scope and context – Definition, scope and context* – principally based on Dr Kalra's presentation, and
 - *Leveraging PHR and EHR for public health* – principally based on discussion of Gora Datta and Marion Lyver's presentations.

The outcomes of WG 8 consideration of PHR were formally shared with WG 1 at a later session in the Istanbul Meeting to avoid conflict.

3. *ISO/DIS 18308 Requirements for an EHR architecture*. Following discussion in Istanbul, this has been released for DIS ballot as reported further in section 14.1 below.

4. *ISO/DIS 10781 EHR system functional model.* The disposition of comments arising from the *ISO/DIS 10781* DIS ballot and the best means of advancing this work while harmonising with further recent development of the underlying HL7 standard were discussed in a joint session of WG 1, WG 8 and CEN/TC 251/ WG I as reported more fully in section 6.18 above.
5. *ISO/TR 13054 Knowledge management of health information standards.* As reported more fully in section **Error! Reference source not found.**, this work, which is being led by WG 8 was discussed in a joint session of WG 1, WG 8 and CEN/TC 251/ WG i.

The ISO/TR 13054 NWIP ballot reported closed on 21 November 2008. [The proposed item was passed with 12 in favour, 1 (Germany) opposed and 7 abstentions]. Heather Grain (Australia) is one of the experts nominated to work on the report.

6. *ISO/TR 12773 Business requirements for health summary records (HSR).* The recent history of this item is as follows:
 - This project is led by Dr Marion Lyver of Canada (with earlier input from David Rowlands of Australia).
 - The draft Technical Report *ISO DTR 12773* passed ballot at the end of March 2008 with 7 NMBs in favour, 2 (Germany, UK) against and 15 abstaining or failing to vote.
 - There were 81 comments, suggestions and questions – mainly editorial. The draft disposition of comments was reviewed with WG 8 members at the May 2008 TC 215 meeting in Göteborg, Sweden.
 - TC 215 approved the draft Technical Report being revised based on the final disposition of comments and then submitted for publication.
 - After the Göteborg meeting, the proposed disposition and revision was circulated to WG 8 members for a four week review in August – with no comments being received.
 - At the time of the Istanbul Meeting, the final draft was with TC 215 Secretariat for checking prior to being sent for publication.

Experts from WG 8 also participated in discussions of the following topics in joint sessions hosted by WG 1 - except where a specific reference is given below, see notes on WG 1 activity in section 7 above for more detail.

7. Detailed Clinical Modelling. [Reported in section 6.12 above]
8. CDISC proposals for the BRIDG model. These were discussed in a joint session of WG 1, WG 2, WG 8 and CEN/TC 251/ WG i and are reported in section 6.13 above.
9. *ISO 12967 - Health Informatics Service Architecture (HISA)* [see section 7.2 above]
10. *ISO/TR 20514 EHR definition, scope and context*
11. *ISO/TR 17119 Health informatics profiling framework*

12. *ISO 13606 – EHR Communication – Parts 1 to 3* as reported in section 6.3 above.
13. *ISO 13606-5 – EHR Communication – Part 5: Interface Specification* as reported in section 6.5 above.
14. Discussion on issues impacting semantic interoperability as reported in section 6.14 above.

Working documents relating to WG 8 activities are posted on the main TC 215 secure portal, which is managed by HIMSS, the TC 251 secretariat. Where required for approved standards development work, draft documents and reports produced by this Working Group may be obtained by contacting the WG 8 Secretariat led by Renati Barel at Standards Australia (renati.barel@standards.org.au).

For other queries about WG 8 and more information about its activities, contact Richard Dixon Hughes (richard@dh4.com.au).

14.1 ISO/DIS 18308 Health Informatics requirements for an EHR architecture

Following systematic review and extensive revision of *ISO/TS 18308:2004 Requirements for an EHR architecture*, action to upgrade this technical specification (TS) to a full ISO international standard was approved by ISO/TC 215 at the Göteborg meeting in May 2008 – with a final version of the revised draft to be provided by the project team for circulation to NMBs in the DIS ballot.

The revised DIS was provided in August 2008 and was released for ballot in November, closing on 22 April 2009, just prior to the Edinburgh TC 215 meeting.

Australia (through Dr Peter Schloeffel and Dr Sam Heard) contributed significantly to development of the earlier ISO/TS, which has also been adopted and published locally by Standards Australia.

Experts participating in the recent revisions to upgrade it to a DIS were: Dipak Kalra (project lead) (UK), Derek Ritz (Canada), Marion Lyver (Canada), Gary Dickinson (US), Robert Owens (US), Beatriz Leao (Brazil), William Goossen (The Netherlands), and Jan Talmon (The Netherlands).

In reporting progress to the Istanbul Meeting, Dr Kalra highlighted the following.

- *ISO 18308* focuses on the requirements for the EHR information within an EHR system - or for a logical or virtual EHR assembled in real time from records in one or more EHR systems (i.e. the EHR as an RM-ODP Information Viewpoint)
- The EHR requirements themselves form part of the RM-ODP Enterprise Viewpoint and draw on about eight years of research, including several EU Health Telematics projects
- The original *ISO/TS 18308* published in 2004 provided underlying requirements for the development of the *EN* and *ISO 13606 EHR communication* standards, and since it was published, the environment has changed:
 - There has been growing international acceptance that the Electronic Health Record is an information artefact (as distinct from an EHR system) – this is formalised in *ISO/TR 20514:2005 EHR Definition*,

- Scope and Context*, which was reviewed and reconfirmed for a further 3 years at the Istanbul Meeting;
- Considerably greater experience has been gained in designing, developing and implementing EHRs, EHR systems and related standards;
 - Development of the *EN* and *ISO 13606 EHR communication* standards highlighted additional areas of that needed to be addressed as requirements; and
 - HL7 published its *EHR System Functional Model* (EHR-S FM), firstly as a DSTU and then as a full ANSI/HL7 standard, as well as a range of supporting profiles, widely used by CCHIT in the United States – these complement ISO 18308 [in that they primarily address the higher levels of the Computational Viewpoint and some aspects of the Information Viewpoint].
- The revision of *ISO/TS 18308* has specifically sought alignment with the *HL7 EHR-S FM*, which is being progressed as an ISO international standard – currently *ISO/HL7 DIS 10781 EHR System Functional Model*.
 - The revised *ISO/TS 18308* document contains over 250 individual requirement statements.

Implications for Australia

Australian interests (led by IT-014-09 EHR Interoperability) need to review and comment on the recently released DIS in light of experience using the earlier AS ISO/TS 18308 and the extensive changes that have been made. The previous TS was used as a benchmark in several evaluation studies of various types of EHR technology – including earlier reviews for NEHTA, whose advice should now be sought on the a

Consideration also needs to be given to local adoption of the revised ISO 18308, once it finally becomes a full ISO international standard – to ensure that it is widely available at a reasonable cost to potential users in Australia.

14.2 Personal Health Record (PHR)

Dr Dipak Kalra commenced the WG 8 session on PHR with a presentation entitled *PHRs and EHRs toward harmony* in which he covered the following:

- The sharing of information is an increasingly important element in maintaining the health and wellbeing of members of the new information society – in which self care, family care and care networks are becoming increasingly important – along with the need to share relevant information with primary, acute and tertiary care services, when necessary.
- This leads to a set of shared key values that must be present in both EHR and PHR systems:
 - Person centred, but recognising that individuals are part of families and communities
 - Faithful and medico-legally rigorous
 - Comprehensive and interoperable between systems, care settings and countries
 - Life-long (and beyond)

- Respecting privacy
 - Accessible, empowering, educating and respecting
 - Collaborative: inviting active participation
 - Supporting diverse cultures and health paradigms
 - Capable of evolution
- There are many different scenarios for PHR systems, which can be characterised and analysed according to the extent to which they address the following five characteristics:
 - Axis 1: e-inclusion. Categorised on a seven point scale ranging from the PHR being purely private space to it having seamless two-way interoperability with relevant EHR systems.
 - Axis 2: Scope of the information. Characterising the PHR according to the types and sources of records held (one or more of: personally-entered data, carer/support group records, health professional records, social services records)
 - Axis 3: Access control – who has authority over access to information in the PHR-S and setting access policies? (seven point quasi-scale).
 - Axis 4: Data custodianship (who holds the data? One or more of:
 - (a) the citizen; (b) PHR service (with commercial interest);
 - (c) community PHR service (with no commercial interest);
 - (d) single healthcare provider; (e) regional/ national healthcare service;
 - (f) insurer; (g) by/on behalf of employer.
 - Axis 5: Interoperability and communication. Seven-point scale ranging from no interoperability, through various layers of proprietary or standards-based systems to live-linked, real-time systems.
 - The potential evolution of PHR systems has been examined in a report by Claudia Pagliari for the Nuffield Trust: *Electronic Personal Health Records - Emergence and Implications for the UK*. The Nuffield Trust, 2007.
 - The ability to view the provider's summary EHR, and increasing digitality does not necessarily represent greater interactivity.
 - Moving from present to future suggests moving:
 - from passive to interactive use of health information,
 - from provider controlled to patient control to sharing of PHR information under patient control,
 - from patients having the ability to view some provider records in the clinical setting to having a PHR system that they can use to organise their health information, access advice, interact with their healthcare providers and their EHRs and manage healthcare devices.

Gora Datta and Dr Marion Lyver then gave presentations both of which are reported in section 14.3 below, and there was discussion of all three presentations, during which the following points were noted in relation to the characterisation and broader evolution of PHR systems that had been introduced by Dr Kalra.

- Effective discourse on the evolution of EHR technology is being hindered by:
 - Different countries having different views on what constitutes a PHR. In particular, the US has a narrower view than Canada and many other

countries – real progress might therefore be obtained, if the broader view were to prevail – at least for international standards.

- Industry objecting to any attempt to lock down a singular definition when such a potentially large market is so immature and developing rapidly.
- Following the report of the former joint PHR Task Force to the TC 215 Plenary in Göteborg in May 2008, TC 215 noted that PHR is a rapidly evolving area, the HL7 PHR-S functional model work is the leading standards activity and that an ISO technical report on PHR was not warranted at that time given other priorities for resources. WG 8 was given a watching brief over developments in PHR, with the suggestion that the need for any other action be delayed for two years – after the market had absorbed the PHR-S FM DSTU.
- There are many initiatives commencing in this area and an increasing number of vendors and suppliers of PHR services and systems – which suggest that earlier action might be warranted. Similar integration and interoperability issues are emerging in both the US and Canada.
- Whether there is value in ISO/TC 215 producing a Technical Report for national bodies, groups and other SDOs in order to classify the PHR market, so that the users can better understand what is offered by the various PHR applications.
- What the appropriate basis for such a PHR classification scheme might be – a conceptual approach such as Dipak's axes or some other approach – how might this relate to other work on the knowledge management for health information standards?
- The PHR-S Functional Model being developed by the HL7 EHR WG provides a means of profiling and certifying various levels and types of PHR functionality (in the same way in which the EHR-S FM standard is now being used) – could this be extended to achieve the aims?
- A need to identify, clarify and be confident of the business drivers and requirements and longer-term integration requirements for PHRs.
- There appears to be a rapidly growing need for a standards-based framework to provide common interfaces for universal interoperability between PHR and EHR systems.

WG8 resolved to put forward a new work item proposal (NWIP) for a technical report on personal health records: definition, scope and context, including classifications and use cases, leveraging the HL7 PHR-S FM DSTU and other existing work. TC 215 approved the NWIP ballot being circulated to NMBs when the formal documentation has been delivered by Dipak Kalra to the TC 215 Secretariat (target 15 November 2008).

Countries and organisations expressing interest in this project were New Zealand, Japan, Canada, United States, United Kingdom, Australia, Brazil and WHO.

Implications for Australia

The concept of a "PHR" as it is emerging internationally has much in common with the Australian notion of a "Shared EHR" or "Individual EHR" as originally formulated in the former *HealthConnect* project and progressed by NEHTA today. There are still active pilots and initial implementations of these technologies in Australia. Australia was also very active in development of the earlier ISO/TR 20514 EHR definition, scope and

context document – renewed for a further three years in ISO. The definitional problems facing PHR (as discussed in the Istanbul Meeting) are somewhat different to those which faced the EHR and this needs to be appreciated.

An effective international standards framework for PHR/EHR interoperability and information exchange should benefit Australian efforts to work toward IEHR as well as other information-sharing initiatives within the broader healthcare sector – but only if the standards framework is well conceived based on broad industry input and consolidates existing health informatics standards activities.

It is also appropriate that Australia, holding the Secretariat for WG 8 be active in discussion and formulation of work in this space.

The first action will be to carefully consider the New Work Item Proposal when it issues early in 2009. IT-014-09 (EHR Interoperability) should be required to lead the development of appropriate responses, seeking input from relevant parties. NEHTA's views are important and should also be sought.

14.3 Leveraging PHR and EHR for public health

Gora Datta gave a presentation entitled “*Use of PHR/EHRs in developing and emerging (D&E) economies*” which addressed a range of topics, including the following:

- The world population is 6.7 billion people and growing rapidly:
 - Around 1 billion live in the developed world and the other 85% live in developing and emerging economies.
 - The proportion of people aged over 55 years in developed countries is 25% and growing (requiring care and contributing less to growth)
 - Around 27% of the world's population is aged 14 or less – mostly in the D&E world – child poverty, lack of education/opportunity and poor health are common.
 - Climate change, energy, communication and travel are becoming unsustainable – for both developed/developing world – but its NIMB
 - Around two-thirds live in just 15 countries: - China, India, USA, Indonesia, Brazil, Pakistan, Bangladesh, Nigeria, Russia, Japan, Mexico, Philippines, Vietnam, Germany, Egypt.
- Challenges for any D&E government include:
 - Limited collaboration and information sharing among various public sector programs
 - Unacceptable burden on reporting services and public partners
 - Protracted policy-making process and inefficient public response
 - Limited access to critical community information
 - Vast duplication of effort and incomplete, untimely data.
- The application of eHealthcare faces many competing priorities in the D&E world, specifically the need to address priorities for survival and security: poverty, food, shelter, education, high mortality risks and health.

- The prevailing culture is pencil and paper – rather than IT – there is a lack of infrastructure (e.g. telecommunications) needed to support eHealthcare. Doctors typically hand-write prescriptions and often work from their homes.
- Penetration of mobile phones ranges from around 25% in China/India to 85% for USA. However, this represents an opportunity for basic connectivity.
- Gora Datta's firm Cal2Cal seeks to overcome some of the problems by providing basic web services application functionality on low-cost portable devices attuned to local capabilities and needs – in particular coupling simple EHR/PHR application tools with collection of statistical data and evaluation measures as part of clinical care delivery in the field – using innovative portable tools such as mobile phone/PDA technology powered by solar cells.
- Client-held token – similar in concept to soldier's dog-tag or talisman – USB keys or SD memory cards – proven to have potential for managing critical health information.
- So what can be done?
 - Develop a minimal PHR/EHR dataset, profile or model suited to deployment on low-capacity configurations interoperating with common mass-produced platforms (phones, PDAs etc).
 - Phased mega-scale eHealth pilot based on deployment of PHR/EHR in, say, three developing countries each with a cluster of around 500,000 people involved comparing impact of – low/no infrastructure, some infrastructure, and good infrastructure.

In her brief presentation, Marion Lyver spoke to the information collected on current PHR initiatives in Canada, Japan and the United Kingdom, results from the HL7 survey on PHR, and various vendor solutions. Marion noted that:

- in the standards space, there are two views of PHR and requirements for PHR: one from developed countries, and the second from developing countries.
- In the view of PHR-S in developed countries, WG 8 could take the HL7 PHR System Functional Model as its main focus and look at other existing work.
- In looking at PHR in developing countries, WG 8 would need to engage with developing countries to do some of the identified work on PHR., possibly engaging with a major aid organisation to develop standards and collaborate on large scale research projects.

During discussion, the following points were noted in relation to the potential needs and contribution of EHR/PHR systems for use in conjunction with care delivery in D&E economies:

- Whether there should be a standardised PHR minimum data set, which may be equally applicable to EHR? (noting that WG 1 would be approached with any recommendations on data sets)
- Whether the existing The Health Summary Record could be used with an extension, and investigated for applicability to developing countries.
- Whether there is any need or benefit in specifying a uniform PHR minimum data set – and whether this might be equally applicable to EHR.
- Public health profiles need to address the most common diseases in developing countries – AIDS, Malaria, TB.

- Approaches may include:
 - Taking existing models and data sets and extending them for family and community care in developing countries so that data can be aggregated for indicators and funding requirements;
 - Define the PHR use cases, and how the PHR relates to the EHR;
 - Start with the business case and value for customers / users.
- A strong focus is needed on practical methods and experience in collecting data in D&E countries
- An essential focus would be for aid organisations and WHO to become more involved in ISO TC 215 PHR work – they are not presently engaged and they all require data and information – which is hindered by a lack of application integration – a technical report on health architecture may address this
- The amount of active work can realistically be done on PHR in this setting as pure standards developers was questioned – it was suggested that the potential to do standards work in collaboration with a large-scale pilot and bring knowledge of standards to real, on the ground work should be sought out and exploited – rather than working in isolation.
- There appears to be a rapidly growing need for a standards-based framework to provide common interfaces for universal interoperability between PHR and EHR systems.
- How would this relate to HL7 PHR-S FM, EHR-S FM, ISO 18308, HL7/PHER? Similar considerations also went into health cards.
- Should this work item be undertaken in collaboration with HL7? [Note: Rockefeller Foundation invited HL7 to meet WHO in Italy on subject of health information system interoperability].

WG 8 resolved to put forward a new work item proposal (NWIP) for a technical report on business requirements for public health standards to identify needs for adoption, adaptation or development of standards in public health, with a particular focus on developing countries and leveraging existing work on EHR and PHR.. TC 215 approved the NWIP ballot being circulated to NMBs when formal documentation has been delivered by Gora Datta to the TC 215 Secretariat (target 15 November 2008).

Countries and organisations expressing interest in this project were Canada, The Netherlands, United Kingdom, Australia, Brazil and WHO.

Implications for Australia

If the appropriate persons are prepared to be involved, Australia could contribute to considerations about this topic, given some of the ICT initiatives piloted and actively used in this country to support indigenous health and primary care.

By Australia participating, there is also the potential to identify new generations of technology that may be applicable in remote Australian settings, where low population density, remoteness and transient populations raise many of the same problems faced in applying technology in D&E economies.

It is also appropriate that Australia, holding the Secretariat for WG 8 be active in discussion and formulation of work in this space.

The first action will be to carefully consider the New Work Item Proposal when it issues early in 2009. IT-014-09 (EHR Interoperability) should be required to lead the development of appropriate responses, seeking input from relevant parties.

15. Other Matters

15.1 Global Health IT Summit V (GHITS V)

Further to discussion at the TC 215 Executive Council, it was agreed that the fifth Global Health IT Summit would be held in conjunction with the TC 215 Joint Working Groups Meeting scheduled for Duke University, Raleigh, North Carolina in October 2009.

The focus of this GHITS would be to review progress and re-visit the health IT needs of national health IT programs – responding to the challenges set at GHITS I in 2005. Subsequent GHITS events have focussed on the vendor, clinician/provider and consumer perspectives.

15.2 TC 215 Business Planning Task Force

Further to discussion at the TC 215 Executive Council, a TC 215 Business Planning Task Force has been established to carry out a further review of TC 215 activities and organisational structure – with a view consolidation and rationalisation.

The Business Planning TF members are:

- Melvyn Reynolds (UK and Co-chair SDO Harmonisation JWG),
- Don Newsham (Canada – and Convener SDO Harmonisation JWG),
- Dr Charles Jaffe (US, CEO HL7, and Co-chair SDO Harmonisation JWG),
- Ken Toyoda (Japan),
- Kees Molenaar (Netherlands, Chair CEN/TC251),
- Dr Chris Chute (US, Chair WHO ICD-11 Task Force) and
- Audrey Dickerson (HIMSS, US, TC 215 Secretariat)

Attachments

Attachment 1 – Participation in the October 2008 ISO TC215 meeting in Istanbul, Turkey

Country (and NSB):	Attendance at Istanbul
Participating (“P”) members	
Australia (SA)	Yes (8 delegates)
Austria (ON)	Yes (2 delegates)
Belgium (NBN)	-
Brazil (ABNT)	Yes (10 delegates)
Canada (SCC)	Yes (16 delegates)
China (SAC)	Yes (13 delegates)
Czech Republic (CNI)	-
Denmark (DS)	Yes (2 delegates)
Finland (SFS)	Yes (1 delegate)
France (AFNOR)	Yes (9 delegates)
Germany (DIN)	Yes (6 delegates)
Italy (UNI)	Yes (2 delegates)
Japan (JISC)	Yes (26 delegates)
Korea, Republic of (KATS)	Yes (8 delegates)
Malaysia (DSM)	Yes (4 delegates)
Netherlands (NEN)	Yes (12 delegates)
New Zealand (SNZ)	Yes (1 delegate)
Norway (SN)	Yes (3 delegates)
Russian Federation (GOST R)	Yes (2 delegates)
Serbia (ISS)	-
South Africa (SABS)	-
Sweden (SIS)	Yes (7 delegates)
Turkey (TSE)	Yes (26 delegates)
United Kingdom (BSI)	Yes (16 delegates)
USA (ANSI)	Yes (24 delegates)
Observing (“O”) Countries	
Argentina (IRAM)	-
Bulgaria (BDS)	-
Croatia (HZN)	-
Cyprus (CYS)	-
Ecuador (INEN)	-
Hong Kong SAR (ITCHKSAR)	Yes (2 delegates)
Hungary (MSZT)	-
India (BIS)	-
Iran, Islamic Republic of (ISIRI)	-
Ireland (NSAI)	Yes (2 delegates)
Israel (SII)	Yes (1 delegate)
Kenya (KEBS)	-
Mongolia (MASM)	-
Poland (PKN)	-
Portugal (IPQ)	-
Singapore (SPRING SG)	-
Slovakia (SUTN)	-

Report on ISO/TC215 Meeting, Istanbul, Turkey – October 2008

Country (and NSB):	Attendance at Istanbul
Spain (AENOR)	Yes (1 delegate)
Switzerland (SNV)	-
Thailand (TISI)	-
Zimbabwe (SAZ)	-
Representatives of Liaison Organisations (not elsewhere included)	
ICH	Yes (9 delegates)
DICOM	Yes (1 delegate)
GS1	Yes (1 delegate)
IHTSDO	Yes (1 delegate)
WHO	Yes (2 delegates)

Attachment 2 – IT-014 International Participation Objectives

STANDARDS AUSTRALIA IT-014 HEALTH INFORMATICS

Objectives for Australian engagement in international standards development 2007-08

Broad Objectives

Australia participates in international standards development activities in accordance with its obligations under World Trade Organisation treaties. The overarching objectives are to benefit the Australian health system and wider community by:

- (a) improving Australian capacity to apply health informatics and develop health informatics standards by expanding domestic knowledge and expertise based on international best practice.
- (b) promoting free trade and its benefits to health ICT (by lowering the cost of integrating and implementing health information systems, many of which are imported, and by reducing costs to Australian exporters) – both these outcomes require Australian requirements to be embedded into global standards so that they can be adopted in Australia, rather than having different standards across domestic and international markets, and
- (c) improving Australian health information systems by facilitating a standards-based approach to development and implementation, and achieving interoperability between systems.

Specific objectives for Australian engagement in international standardization via ISO TC215 (Health Informatics) include:

- Monitoring and influencing ISO TC215's strategic positioning and business model, encouraging it in leading collaboration with other global Standards Development Organisations (SDOs), and assessing and influencing its outputs so as to maximise Australia's capacity to ensure that our health information interchange and related requirements are supported unambiguously by international standards. A more global approach to standards development was a specific request to ISO from a range of national E-Health programs, including Australia's.
- Negotiating specific objectives for EHR, Personal Health Record (PHR) and health ICT safety standards.
- Progressing EHR Communication, Data Harmonisation, Subject of Care Identification, Provider Identification, and EHR/PHR Systems requirements standards into and through balloting, and assessing and contributing to other standards required for implementation of EHR and personal health record (PHR) applications, including updates to TS 18308.
- Advocating for consistency between major SDOs currently developing approaches to EHR interoperability, including consistency regarding data types, object constraint models, health information service architectures, and clinical information models and their representation.

- Facilitating consistency and collaboration between global SDOs in development and adoption of health informatics standards – including provision of the secretariat of the Joint Working Group (ISO TC215 /WG9) under the ISO-CENHL7 Joint Initiative.
- Leading development of consistent terminology and an approved lexicon of terms and thesaurus for use across all ISO health informatics standards.
- Progressing information security standards, including (where appropriate) encouraging finalization of standards on: Secure archiving of electronic health records; Security management in health using ISO/IEC 27002; Implementation of privilege management and access control (PMAC-3); Audit trails for electronic health records; Functional and structural roles; Information security management for remote maintenance of medical devices (guideline); Dynamic VPN access to health networks, and EN13606 Part 4 within ISO.
- Supporting the proposed liaison between ISO TC215 and ISO/IEC Joint Technical Committee 1 (JTC 1) with a view to encouraging collaboration on IT standards affecting health care delivery and avoiding duplication of work.

Specific objectives for Australian engagement in international standardization via CEN include:

- Monitoring and commenting on CEN work proposals in health informatics, encouraging collaboration with other SDOs and, where appropriate, seeking early involvement of Australia and other global stakeholders through the Joint Initiative.
- Continue progressing EHR Communication and Health Information Service Architecture standards into and through balloting procedures and into ISO.
- Negotiating specific objectives for EHR standards, including harmonization of data types and other elements needed to achieve EHR interoperability.
- Understanding, assessing and providing feedback on emerging health informatics standards trends as E-Health activities expand in Continental Europe and the UK.

Specific objectives for Australian engagement in international standardization via the HL7 global SDO include:

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

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

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

Relevance to NEHTA programs

NEHTA has endorsed a range of Australian Standards derived from international standards work by including them in the National E-Health Standards Catalogue. As the implementation of NEHTA's new domain-specific work packages are based on many of these standards, it is important that Australia continues to be involved in the international forums that develop, manage and maintain these, and other potentially relevant, health informatics standards.

Attachment 3 – TC215 Mini-Plenary Resolutions

TC215 adopted the following resolutions in the “mini-plenary” session at the Istanbul meeting.⁸

1. Resolved that ISO/TC215 accepts the Executive Council Report.
2. Resolved that ISO/TC215 executive council report recommends an amendment to the ISO/TC 215 Health Informatics Guidelines document to reflect the appropriate processing, specific timelines and designations for the in-meeting balloting of Draft Technical Reports (DTR), New Item Work Proposals (NWIP).

In Meeting Balloting:

- 1- *Materials for ballot at a plenary would be sent to the TC secretariat to send out with the Calling Notice 3-4 months in advance, not less than 3 months.*
- 2- *National Member Bodies (NMB) would receive an email with the documents (documents for ballot also posted with the meetings documents on LiveLink) and an explanation, the documents are to be balloted during the upcoming Plenary meeting.*
- 3- *The NMB's would forward any comments to the secretary. Comments would be collated and distributed by the TC secretary to all National Member bodies as part of the voting results materials.*
- 4- *Should the National Member body not be able to attend the meeting, a message should be sent to the TC secretary and an email ballot will be sent to the NMB.*
- 5- *Ballot resolutions would be listed with a heading titled Ballot resolution in the TC resolutions for each WG.*

Note: In [the Istanbul] Meeting Balloting recommendation read aloud, but not passed by the plenary. Tabled until Edinburgh 2009.

3. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG1.
4. Resolved that ISO/TC215 approves the WG1 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of *Quality requirements and methodology for detailed clinical models* for approval as a new work item targeting as an International Standard via the Vienna Agreement with ISO lead, and that the Form 4 and a draft document arrives at the TC Secretariat no later than April 1st 2009 to be placed on the ISO/TC web site no later than April 15 2009.
5. Resolved that ISO/TC 215 approves the formation of a Project Group under WG1 and 2 to work with CDISC to produce the scope of, and draft for, a new work item as recommended to the JIC, no later than February 27, 2009 to be placed on the WG1 web site no later than March 2, 2009. Reports from the Project Group will be made through WG1 and WG2.

⁸ Based on a version of minutes provided by TC215 Secretariat via the TC215 website on 31 October 2008 (reproduced with minor reformatting). As these minutes have yet to be confirmed, the final version may differ, although changes are not expected.

6. Noting the 100% approval at the DIS ballot and per ISO/IEC Directives Part 1 Clause 2.6.4 (b), resolved that ISO/TC215 approves the WG1 recommendation for the ISO/TC215 Secretariat to, subject to support of the comment disposition, forward to the ISO Central Secretariat by December 1 the *DIS 12967 Health informatics service architecture Parts 1, 2 and 3* for publication.
7. Resolved that ISO/TC 215 approves the WG1 recommendation that *ISO TR 20514 EHR Definition, scope and context* and *ISO TR 17119 Health informatics profiling framework* be confirmed for re-review no later than 2011.
8. Resolved that ISO/TC215 approves the WG1 recommendation for the *DIS 13606-5 Electronic health record communication Part 5: Interface specification* disposition of comments and revised draft be distributed by January 12th 2009 for a six week informal comment period by ISO/TC 215 WG1 and CEN/TC 251 WG1 and, given positive reception by both groups, subsequently request that ISO/TC 215 Secretariat to forward to the ISO Central Secretariat DIS 13606-5 for circulation as an FDIS ballot.
9. Resolved that ISO/TC215 accepts the report of ISO/TC 215 WG2.
10. Resolved that ISO/TC215 approves the WG2 recommendation to approve the WG2 officers as follows:
 - Michael Glickman, Convenor*
 - Michio Kimura, Vice Convenor*
 - Adrian V Stokes, Secretary*
11. Resolved that ISO/TC215 approves the WG2 recommendation for the ISO/TC215 Secretariat to forward to the ISO Central Secretariat *DIS 21090 Health informatics – Harmonized data types for information interchange* for circulation as FDIS ballot.
12. Resolved that ISO/TC215 approves the WG2 recommendation that the ISO/TC215 Secretariat circulates the DTS ballot of *ISO 27790 Document Registry Framework* for approval as a Technical Specification and that the document arrives at the TC Secretariat no later than 31 October to be placed on the ISO/TC web site no later than 14 November.
13. Resolved that ISO/TC215 approves the WG2 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of *Clinical Document Registry Federation* for approval as a new work item targeting a Technical Report and that the Form 4 and a document arrives at the TC Secretariat no later than 31 October to be placed on the ISO/TC web site no later than 14 November.
14. Resolved that ISO/TC215 approves the WG2 recommendation that ISO/TC215 Secretariat circulates the NP ballot of *10159 Web Access Reference Manifest* as a Committee Draft and a document arrives at the TC Secretariat no later than 31 October to be placed on the ISO/TC web site no later than 14 November.
15. Resolved that ISO/TC215 approves the WG2 recommendation for the ISO/TC215 Secretariat to forward *DIS 27931 HL7 Version 2.5* to the ISO Central Secretariat for Publication.
16. Resolved that ISO/TC215 approves the WG2 recommendation for the ISO/TC215 Secretariat to forward to the ISO Central Secretariat *DIS 27932 Clinical Document Architecture, Release 2* for circulation as FDIS ballot.

17. Resolved that ISO/TC215 approves the WG2 recommendation to request the Secretariat to forward document *ISO 25720 Genomic Sequence Variation Markup Language* to the ISO Central Secretariat for publication and that the document arrives at the TC Secretariat no later than 31 October.⁹
18. Resolved that ISO/TC215 approves the WG2 recommendation to request the Secretariat to forward document *ISO/TR 28380-2 IHE Global Standards Adoption – Part 2: Integration and Content Profiles* to the ISO Central Secretariat for publication and that the document arrives at the TC Secretariat no later than 31 October.
19. Resolved that ISO/TC215 approves the WG2 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of *Quality criteria for services and systems for telehealth* for approval as a new work item targeting a Technical Specification and that the Form 4 and a document arrives at the TC Secretariat no later than 31 October to be placed on the ISO/TC web site no later than 14 November.
20. Resolved that ISO/TC215 accepts the report of ISO/TC 215 WG3.
21. Resolved that ISO/TC215 approves the WG3 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of *Communication and Metadata Model and XML-interface specification for OID registries in healthcare* for approval as a new work item targeting as a Technical Specification and that the Form 4 and a document arrives at the TC Secretariat no later than 31 October 2008 to be placed on the ISO/TC web site no later than 15 November 2008
22. Resolved that ISO/TC215 approves the WG3 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of *Guidance for maintenance of object identifiers, OID* for approval as a new work item targeting as a Technical Report and that the Form 4 and a document arrives at the TC Secretariat no later than 31 October 2008 to be placed on the ISO/TC web site no later than 15 November 2008.
23. Resolved that ISO/TC215 approves the WG3 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of *Revision of ISO 18104:2003 – Health informatics – Integration of a reference terminology model for nursing* for approval as a new work item targeting as an International Standard via the Vienna Agreement with ISO lead and that the Form 4 and a document arrives at the TC Secretariat no later than 31 October 2008 to be placed on the ISO/TC web site no later than 15 November 2008.
24. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG4.
25. Resolved that ISO/TC215 approves the WG4 recommendation to request the Secretariat to forward document *ISO 22600-3 Health informatics – Privilege management and access control – Part 3: Implementations* to the ISO Central Secretariat for publication and that the document arrives at the TC Secretariat no later than November 8, 2008.
26. Resolved that ISO/TC215 approves the WG4 recommendation to request the Secretariat to forward document *ISO 21547-1 Health informatics – Secure archiving of electronic health records – Part 1: Principles and requirements* to the ISO Central Secretariat for publication and that the document arrives at the TC Secretariat no later than December 1, 2008.

⁹ Incorrectly minuted as *ISO/TS 25720* – when the document (based on a mature HL7 standard) was balloted as a DIS, not a DTS.

27. Resolved that ISO/TC215 approves the WG4 recommendation to request the Secretariat to forward document *ISO 21547-2, Health informatics – Secure archiving of electronic health records – Part 2: Guidelines* to the ISO Central Secretariat for publication and that the document arrives at the TC Secretariat no later than December 1, 2008.
28. Resolved that ISO/TC 215 approves the WG4 recommendation to request the Secretariat to forward document *ISO TR 11633 Health informatics — Information security management for remote maintenance of medical devices and medical information systems Part 1: Requirements and risk assessment*, to the NMBs of TC215 for a 1 month review prior to publication and that the documents arrive at the TC Secretariat no later than 15 October 2008.
29. Resolved that ISO/TC 215 approves the WG4 recommendation to request the Secretariat to forward document *ISO TR 11633 Health informatics — Information security management for remote maintenance of medical devices and medical information systems Part 2: Implementation of ISMS* to the NMBs of TC215 for a 1 month review prior to publications and that the documents arrive at the TC Secretariat no later than 15 October 2008.
30. Resolved that ISO/TC215 approves the WG4 recommendation to request the Secretariat to forward document *ISO DTR 11636 Health Informatics – Dynamic on-demand virtual private network for health information infrastructure* to TC215 P-members no later than January 3, 2009, to ballot for publication during the ISO/TC215 Edinburgh plenary.
31. Resolved that ISO/TC215 approves the WG4 recommendation for the ISO/TC215 Secretariat to forward to the ISO Central Secretariat revised *IS 22857 Health informatics – Guidelines on data protection to facilitate trans-border flows of personal health information* for circulation as a DIS ballot, and that the document arrives at the TC Secretariat no later than November 3, 2008.
32. Resolved that ISO/TC215 approves the WG4 recommendation that the scope of WG4 be changed to the following:
WG4 Security, Safety and Privacy
Defining health informatics security and privacy protection standards to
 - 1) *protect and enhance the confidentiality, availability, and integrity of health information;*
 - 2) *prevent health information systems from adversely affecting patient safety;*
 - 3) *protect privacy in relation to personal information; and*
 - 4) *ensure the accountability of users of health information systems.*
33. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG5.
34. Resolved that ISO/TC 215 accept a change proposed for WG5 to change from a Working Group to a Task Force Group of ISO/TC 215/WG4.

ISO/TC 215/WG5 kindly ask to change the scope of ISO/TC 215/WG4 to include the relevant items of WG5, also it could be taken into account that the work of WG5 will not be limited on the use of health cards. Other devices may be useful in the future as well.

Furthermore the Task Force shall be closely connected to other Working Groups as ISO/TC 215/WG1 or ISO/IEC JTC1/SC27 for the specific purposes of their standards.

And be it further resolved that ISO/TC215 approves the WG5 recommendation to accept Jürgen Sembritzki as Task Force Leader.

35. Resolved that ISO/TC215 approves the WG5 recommendation for the ISO/TC215 Secretariat to forward to the ISO Central Secretariat *CD 21549-8 Health informatics — Patient healthcard data — Part 8: Links* for circulation as a DIS ballot and a document arrives at the TC Secretariat no later than 2008-11-15.
36. Resolved that ISO/TC 215/WG5 will begin the review of three parts of the *ISO 21549 “Health informatics – Patient healthcard data”* (3 years systematic review) in Edinburgh:
 - *Part 1: General structure*
 - *Part 2: Common objects*
 - *Part 3: Limited clinical data*

For consistency reasons, *Part 5 Identification data* will be reviewed together with parts 1, 2 and 3.

37. Resolved that ISO/TC 215 thanks Frans van Bommel for his leadership of ISO/TC 215/WG5.
38. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG6.
39. Resolved that ISO/TC 215 approves that prEN ISO 27953 Health informatics – Pharmacovigilance – Individual case safety report will be a two-part standard with part 1 for the framework for adverse event reporting and part 2 for human pharmaceutical reporting requirements for ICSR.
40. Resolved that ISO/TC215 approves the WG6 recommendation that ISO/TC215 Secretariat sends the revised working draft of *prEN ISO 27953 Health informatics – Pharmacovigilance – Individual case safety report – Part 1: The framework for adverse event reporting and Part 2: Human pharmaceutical reporting requirements for ICSR* for DIS ballot and a document arrives at the TC Secretariat no later than 1 January.
41. Resolved that ISO/TC215 approves the WG6 recommendation that ISO/TC215 Secretariat circulates the revised working draft of *prEN ISO 11595 Health informatics – Pharmacovigilance – Structures and Controlled Vocabularies for Laboratory Test Units for the Reporting of Laboratory Results* as a Committee Draft and a document arrives at the TC Secretariat no later than 1 January 2009 to be placed on the ISO/TC web site no later than 15 January 2009.
42. Resolved that ISO/TC215 approves the WG6 recommendation that ISO/TC215 Secretariat circulates the revised working draft of *prEN ISO 11238 Health informatics – Identification of medicinal Products – Structures and Controlled Vocabularies for Ingredients (substances)* as a Committee Draft and a document arrives at the TC Secretariat no later than 1 January 2009 to be placed on the ISO/TC web site no later than 15 January 2009.

43. Resolved that ISO/TC215 approves the WG6 recommendation that ISO/TC215 Secretariat circulates the revised working draft of *prEN ISO 11239 Health informatics – Identification of medicinal Products – Structures and Controlled Vocabularies for pharmaceutical dose forms, units of presentation and routes of administration* as a Committee Draft and a document arrives at the TC Secretariat no later than 1 January 2009 to be placed on the ISO/TC web site no later than 15 January 2009.
44. Resolved that ISO/TC215 approves the WG6 recommendation that ISO/TC215 Secretariat circulates the revised working draft of *prEN ISO 11615 Health informatics – Identification of Medicinal Products – Data Elements and Structures for the Exchange of Regulated Product Information for Drug Dictionaries (MPID)* as a Committee Draft and a document arrives at the TC Secretariat no later than 1 January 2009 to be placed on the ISO/TC web site no later than 15 January 2009.
45. Resolved that ISO/TC215 approves the WG6 recommendation that ISO/TC215 Secretariat circulates the revised working draft of *prEN ISO 11616 Health informatics – Identification of medicinal products – Structures and controlled vocabularies for pharmaceutical product identifiers (PhPIDs)*, to be distributed as Committee Draft and a document arrives at the TC Secretariat no later than 1 January 2009 to be placed on the ISO/TC web site no later than 15 January 2009.
46. Resolved that ISO/TC215 approves the WG6 recommendation that ISO/TC215 Secretariat circulates the revised working draft of *prEN ISO 11240 Health informatics – Identification of medicinal Products – Structures and Controlled Vocabularies for Units of Measurement* as a Committee Draft and a document arrives at the TC Secretariat no later than 1 January 2009 to be placed on the ISO/TC web site no later than 15 January 2009.
47. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG7.
48. Resolved that ISO/TC215 approves the WG7 recommendation to approve the WG7 officers as follows:
 - Todd Cooper , Convenor*
 - Thomas Norgall , Vice Convenor*
 - Secretary – Vacant*
49. Resolved that ISO/TC215 approves the WG7 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of *11073-10408 Health informatics – Personal health device communication – Device specialization – Thermometer* for approval as a new work item targeting an International Standard and that the Form 4 and a document arrives at the TC Secretariat no later than IEEE availability permits and to be placed on the ISO/TC web site no later than thereafter.
50. Resolved that ISO/TC215 approves the WG7 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of *11073-10415 Health informatics – Personal health device communication – Device specialization – Weighing scale* for approval as a new work item targeting as an International Standard and that the Form 4 and a document arrives at the TC Secretariat no later than IEEE availability permits and to be placed on the ISO/TC web site no later than thereafter.
51. Resolved that ISO/TC215 approves the WG7 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of *11073-10441 Health informatics – Personal health device communication – Device specialization – Cardiovascular fitness and*

activity monitor for approval as a new work item targeting as an International Standard and that the Form 4 and a document arrives at the TC Secretariat no later than IEEE availability permits and to be placed on the ISO/TC web site no later than thereafter.

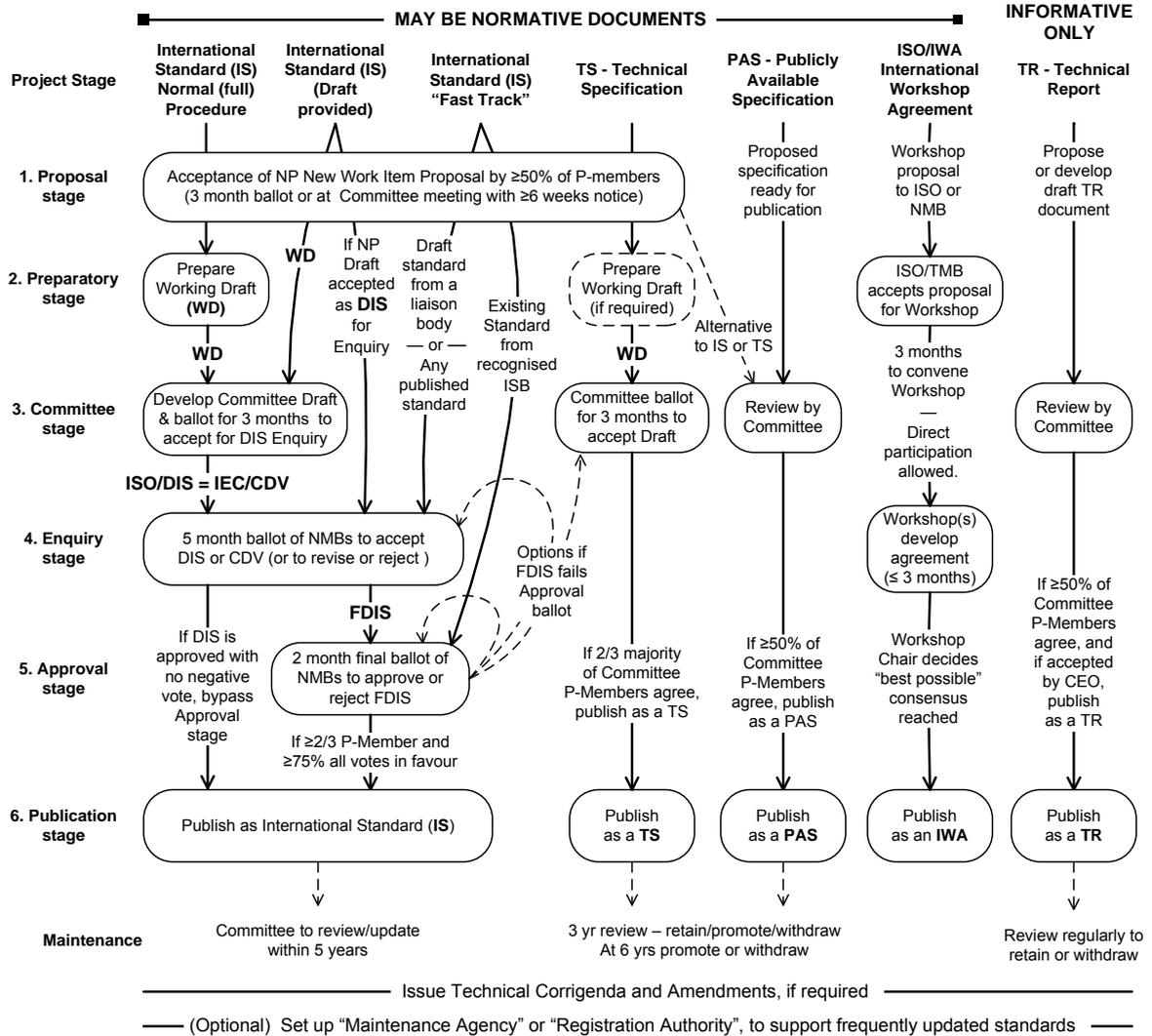
52. Resolved that ISO/TC215 approves the WG7 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of *11073-10442 Health informatics – Personal health device communication – Device specialization – Strength Fitness Equipment* for approval as a new work item targeting as (a)n International Standard and that the Form 4 and a document arrives at the TC Secretariat no later than IEEE availability permits and to be placed on the ISO/TC web site no later than thereafter.
53. Resolved that ISO/TC215 approves the WG7 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of *11073-10471 Health informatics – Personal health device communication – Device specialization – Independent Living Activity Hub* for approval as a new work item targeting as an International Standard and that the Form 4 and a document arrives at the TC Secretariat no later than IEEE availability permits and to be placed on the ISO/TC web site no later than thereafter.
54. Resolved that ISO/TC215 approves the WG7 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of *11073-20601 Health informatics – Personal health device communication – Application Profile – Optimized Exchange Protocol* for approval as a new work item targeting as an International Standard and that the Form 4 and a document arrives at the TC Secretariat no later than IEEE availability permits and to be placed on the ISO/TC web site no later than thereafter.
55. Resolved that ISO/TC 215 accepts the report of ISO/TC 215 WG8.
56. Resolved that ISO/TC215 approves the WG8 recommendation to approve the WG8 officers as follows:

Marion Lyver, Convenor
Beatriz Leao, Vice-Convenor
57. Resolved that ISO/TC215 approves the WG 8 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of *Business requirements for public health standards* for approval as a new work item targeting as a Technical Report for requirements to identify needs for adoption, adaptation or development of standards in public health, with a particular focus on developing countries and leveraging existing work on EHRs and PHRs, and that the Form 4 and a document arrives at the TC Secretariat no later than 15 November to be placed on the ISO/TC web site no later than 30 November 2008.
58. Resolved that ISO/TC215 approves the WG 8 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of *Personal Health Records: Definition, Scope and Context* for approval as a new work item targeting as a Technical Report including classifications and use cases and leveraging the HL7 PHR-S FM DSTU and other existing work, and that the Form 4 and a document arrives at the TC Secretariat no later than 15 November to be placed on the ISO/TC web site no later than 30 November 2008.
59. Resolved that the ISO/TC 215 accepts the WG8 recommendation that the draft disposition and proposed amendment of ISO/HL7 DIS 10781, based on the DIS comments supplied and further development by HL7 be reviewed by ISO/ TC 215 in

April 2009, and at the HL7 Working Group Meeting in May 2009, with a view to release a revised draft for ISO FDIS ballot in September 2009.

60. Resolved that ISO/TC215 thank its host, Turkey Standards (TSE), specifically Dr. Nihat Yurt, the Turkey Ministry of Health, the assistance of the booking agency Semor, Ms. Arzu Sarioglulil, Ms. Guniz Ercin and the Grand Cevahir Hotel for the excellent meeting arrangements and social event, as well as their assistance throughout the meeting, which contributed to a successful and productive meeting.
61. Resolved that ISO/TC 215 thanks Mr. Kees Molenaar for his assistance during the first combined plenary meeting of ISO/TC 215 and CEN/TC 251 in Istanbul.
62. Resolved that ISO/TC215 thanks the drafting committee of Patricia Village and Audrey Dickerson.
63. Resolved that ISO/TC215 acknowledges and thanks the countries of Hong Kong, Ireland, Israel for the contribution of their members to the ISO/TC215 Joint Work Group meeting in Istanbul, Turkey.
64. Resolved that ISO/TC215 approves that the next ISO/TC215 Plenary meeting will be held in Edinburgh Scotland, United Kingdom from 26 – 30 April 2009.

Attachment 4 – Diagram of ISO standards pathways



Attachment 5 – ISO TC215 Liaisons

Internal Liaisons with other ISO TCs:

ISO/IEC TC 37 (Terminology)
 TC 42 (Photography)
 TC 46 (Information and documentation)
 TC 76 (Transfusion, infusion, injection equip.)
 TC 84 (Devices for administration of medicinal products)
 TC 106 (Dentistry)
 TC 121 (Anaesthetic and respiratory equipment)
 TC 150 (Implants)
 TC 154 (Processes, data elements, etc)
 TC 168 (Prosthetics and orthotics)
 TC 170 (surgical Instruments)
 TC 171 (Document management applications)
 TC 172 (Optics and Photonics)
 TC 194 (Biological evaluation of medical devices)
 TC 198 (Sterilization of Healthcare products)
 TC 210 (Quality management for medical devices)
 TC 212 (Clinical laboratory testing)
 TC 229 Nanotechnologies

Secretariat

ON – Infoterm
 ANSI – POMA
 DIN
 DIN
 DS
 BSI
 BSI
 DIN – Pforzheim
 SNV – UN-ECE
 DIN – Pforzheim
 DIN – Pforzheim
 AFNOR
 DIN – Pforzheim
 DIN – Pforzheim
 ANSI – AAMI
 ANSI – AAMI
 ANSI – CLSI
 BSI

External (Category A) Liaisons

ISO/IEC JTC 1 [principal ISO/IEC standards body. Added Gothenburg]
 IEC/TC 62 (Electrical equipment in medical practice)
 IEC/SC 62A
 (Common aspects of electrical equipment used in medical practice)
 CDISC (Clinical Data Interchange Standards Consortium)
 DICOM (Digital Image Communication in Medicine)
 IMIA (International Medical Informatics Association)
 UN-ECE (UN Economic Commission for Europe)
 [responsible for CEFAC/EDIFACT messaging standards]
 ICN (International Council of Nurses)
 W3C (World Wide Web Consortium)
 WHO (World Health Organization)

Secretariat

ANSI
 DIN/VDE – Frankfurt, Germany:
 USA
 CDISC (USA)
 NEMA (USA)
 IMIA (Switzerland/Canada)
 UN (Geneva, Switzerland)
 ICN (Geneva, Switzerland)
 W3C (MIT, Mass, USA)
 UN (Geneva, Switzerland)

External (Category C)Liaisons:

JTC 1/SC 2 (coded character sets)
 JTC 1/SC 6 (telecommunications)
 JTC 1/SC 7 (software and systems engineering)
 JTC 1/SC 22 (Programming languages)
 JTC 1/SC 23 (Digital storage media)
 JTC 1/SC 24 (Computer graphics & image processing)
 JTC 1/SC 27 (IT security)
 JTC 1/SC 32 (Data management & interchange)

Secretariat

JISCIPSJ/ITSCJ
 ANSI – AAMI
 SCC – Bell Canada
 ANSI
 JISC – IPSJ/ITSCJ
 BSI
 DIN
 ANSI – Battelle Memorial

External (Category D)Liaisons:

ICH (Int'l Conference on Harmonisation of Technical Requirements for
 Registration of Pharmaceuticals for Human Use) [with WG3 & WG6]
 IFMPA (International Federation of Pharmaceutical Manufacturers &
 Associations) [liaison with TC215 WG3 & WG6]
 IHE (Integrating the Healthcare Enterprise) [with most TC215 WGs]

Secretariat

ICH
 IFMPA
 IHE

Pending Liaisons

ITU-T SG17 (Security, languages and telecommunication software)
 GS1 [World-wide consortium for supply chain (eg barcode) standards
 IHTSDO (International Health Terminology Standards Development
 Organization) [Now maintains SNOMED CT]

ITU-T (Geneva, Switzerland)
 GS1 (Belgium)
 IHTSDO (Denmark)

Proposed Liaisons

JTC1/SC17 (Cards and personal identification)
 JTC1/SC37 Biometrics
 CLSI –Clinical and Laboratory Standards Institute

BSI – APACS
 ANSI
 CLSI (USA)

Attachment 6 – ISO TC215 Work Program & Documents

Note – Work items are listed by stage of development within Work Group

ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
WG 1 Data Structure	Grant Gillis	Convener				
Preliminary (Pre-NWIP ballot)						
EHR Blueprint Definition			Preliminary			
Identity Management Framework Task Group	Bryan Manning					
Health Summary Record –Minimum Data Set		TBD	Preliminary	TBD		WG8?
NWIP/DTR Ballot						
Active Items after NWIP Approval						
Health Indicators for Conceptual Framework	I. Pulcins	TS 21667	Published – 2004 Completed Systematic Review ballot 2007-09-17	Waiting for document to send for DIS ballot preparation	??	Resolution #16 (Goteborg 2008)
Deployment of a Clinical Data Warehouse	Andrew Grant	TS 29585	NWI (passed NWIP ballot 2007-03-21)	DTS Ballot		Awaiting revised document and disposition of comments
HI: Provider Identification	Neil Gardner/ H Grain	TS 27527	Passed DTS ballot 2008-04-15 results distributed	Waiting for document to send to publication	WG 4/5	Resolution #2 (2005) Resolution #6 (Brisbane 2007) Resolution #14 (Goteborg2008)
DIS and FDIS Ballots						
Health Informatics – Service Architecture – Enterprise Viewpoint	Gunnar Klein	IS 12967-1	On DIS ballot (2008-03-25 – 2008-08-25)	FDIS	CEN	Resolution #7 (Brisbane 2007)

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
Health Informatics – Service Architecture – Information Viewpoint	Gunnar Klein	IS 12967-2	On DIS ballot (2008-03-25 – 2008-08-25)	FDIS	CEN	Resolution #7 (Brisbane 2007)
Health Informatics – Service Architecture – Computational Viewpoint	Gunnar Klein	IS 12967-3	On DIS ballot (2008-03-25 – 2008-08-25)	FDIS	CEN	Resolution #7 (Brisbane 2007)
EHR Communication Part 5 – Interface Specification	Dipak Kalra	IS 13606-5	On DIS ballot (2008-05-08 – 2008-10-08)	DIS	VA (CEN lead) SDO WG9	Resolution #7 (Montreal 2007) Resolution #8 (Brisbane 2007)
EHR Communication Part 3 – Archetypes and Term List Interchange Specifications	Dipak Kalra	IS 13606-3	Submitted to ISO CS for FDIS Processing	FDIS	SDO WG9	Resolution #12 (Goteborg2008)
EHR Communication Part 2 – Archetype Interchange Specifications	Dipak Kalra	IS 13606-2	Submitted to ISO CS for FDIS Processing	FDIS	SDO WG9	Resolution #11 (Goteborg2008)
Sent for Publication						
HI: Identification of Subjects of Health Care	H Grain/D Rowlands	TS 22220	Sent for Publication	Publication		Resolution #2 (2006)
Published – Systematic Review						
Health Indicators for Conceptual Framework	I. Pulcins	ISO#21667	Published – 2004	Completed Systematic Review ballot 2007-09-17		8- Abstain 8- Confirm 2- Confirm w/ correction 2- Revise waiting for WG1 decision
Published Items						
Electronic health record communication – Part 1: Reference model	D. Kalra	ISO/IS 13606-1	Published – 2008		HL7 and CEN SDO WG9	Resolution #3 (2006); Resolution #4 (2005)
EHR Definition, Scope and Context	P.Schloeffel/ K. Toyoda	TR 20514	Published - 2005			
Health Informatics: Profiling Framework	Laura Sato/ Grant Gillis	ISO 17119	Published - 2005			
HI: Good Principles and practices for a clinical data warehouse	A. Grant	ISO/TR 22221	Published – 2006			Resolution #4 (2006)

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
Withdrawn from active Work Program						
Framework for Emergency Data Sets	Hiroshi Takeda	ISO/TR 22219				
Health Informatics:Country Identifier Standards	R. Alvarez/ D. Newsham	ISO/TS# 17120	Published – 2004	Completed Systematic Review ballot 2007-12-17	Withdrawn from the WG 1 program of work	Resolution #15 (Goteborg2008)
WG 2 Data Interchange	Mike Glickman,	Convener				
Preliminary Pre-NWIP ballot)						
HI: Telehealth Systems – Teleradiology Interoperability	Pending	Pending	Pending			Pending discussion with Brazil Resolution #6 (2006) Resolution #10 (2005)
Trusted end-to-end information flows	Dickinson	DTS 21089	Preliminary			
NWIP/DTR Ballot						
HI: Messages and Communication – Web Access to DICOM persistent Objects by means of Web Services	Nick Brown	IS 12974	On NWIP ballot (2008-07-11 – 2008-10-11)			Resolution #21 Goteborg 2008
IHE Global Standards Adoption Part 2 – Integration and Content Profiles	Parisot	TR 28380-2	On DTR ballot (2008-06-13 – 2008-09-13)	Publication		Resolution #13 (Montreal 2007) Resolution #19 Goteborg 2008
Health Informatics: Clinical Genomics Pedigree Topic	Kaufman					Resolution #20 Goteborg 2008
Active Items after NWIP Approval						
Document Registry Framework	Jong-Hyuk Lee	TS#27790	Passed NWIP ballot 2007-08-27	DTS ballot. Awaiting revised document & disposition of comments		Resolution #10 (2006) Resolution #16 (Montreal 2007)

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
Messages and Communication – Web Access Reference Manifest	Nicholas Brown	IS 10159	NWIP ballot approved (2007-06-07) 10.99	CD ballot		Awaiting revised document and disposition of comments
DIS and FDIS Ballots						
Harmonized Data Types for Information Interchange (name change 2007)	Grahame Grieve/ Tom Marley	IS 21090	on DIS ballot (2008-04-24 – 2008-09-24)	FDIS/Publication	SDO WG9	Resolution #16 (2005) Resolution #14 (Montreal 2007) Resolution #13 (Brisbane 2007)
HL7 Version 2.5 messaging standard	Beeler/ Hammond	IS#27931	Passed DIS ballot 2008-06-10	DIS passed 100%, OK to publish. Awaiting revised document & disposition of comments	ISO/HL7 agreement	Resolution #11 (2006) Resolution #14 (Brisbane 2007)
Clinical Document Architecture (Release 2)	Beeler/ Hammond	IS#27932	Passed DIS ballot 2008-06-10	DIS passed 100%, OK to publish. Awaiting revised document & disposition of comments	ISO/HL7 agreement	Resolution #11 (2006) Resolution #15 (Brisbane 2007)
Genomic sequence variation Markup Language (name change 2006 JeJu)	Jnakaya/ Nsakamoto	IS #25720	Passed DIS ballot 2008-07-07	DIS passed 100%, OK to publish. Awaiting revised document & disposition of comments		Resolution #12 (2006) Resolution #11 (Montreal 2007)
Exchange of Information between Healthcare Information Systems – Development of Messages	Marley	IS 17113	2 nd DIS ballot Approved 40.60	DIS passed 88%, now to FDIS, need documents		Awaiting disposition of comments Resolution #15 (Montreal 2007)

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
Sent for Publication						
IHE Global Standards Adoption Part 1 – Process	Parisot	DTR - #28380-1	Awaiting revised draft	Publication Awaiting revised document	IHE Liaison	Resolution #7 (2006) Resolution #12 (Montreal 2007) Resolution #12 (Brisbane 2007)
Published – Systematic Review						
Clinical analyzer interfaces to laboratory information systems – Use profiles		IS 18812	Published – 2003	Systematic Review (ballot 2008-01-15 – 2008-06-16)		
Web access to DICOM Persistent Objects	Brown/Marley	IS 17432	published - 2004	Confirm without change		Resolution #18 Goteborg
Interoperability of telelearning systems	T. Craddock	TS 16058	Publication – 2004	Completed Systematic Review ballot 2007-09-17		10- Abstain 5- Confirm 4- Revise 2- Withdraw Awaiting Decision from WG2
Published Items						
Interoperability and compatibility in messaging and communication standards		TR 18307	Published – 2001			Status – maintain, revise, withdraw
Interoperability of telehealth Syst & Networks P. 1	T. Craddock	TR 16056-1	Publication – 2004			Status – maintain, revise, withdraw
Interoperability of telehealth Syst & Networks P. 2	T. Craddock	TR 16056-2	Publication – 2004			Status – maintain, revise, withdraw
Digital imaging and communication in medicine (DICOM) including workflow and data management	Parisot	IS #12052	Published – 2006		DICOM	Resolution #8,9 (2006), Resolution #11 (2005)
HL7 version 3 – Reference information model, release 1	Beeler/Hammond	IS 21731	Published – 2006			Resolution #15 (2005)
Format of length limited globally unique string identifiers	Brown/Marley	IS 18232	Published – 2006			Resolution #14 (2005)

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
Withdrawn from active Work Program						
Processes for Developing and Implementing a msg std	Emelin	TR 22599				Resolution #11 (Brisbane 2007)
WG 3 Semantic Content	Heather Grain	Convener				
Preliminary						
HI: The categorization and nomenclature of medical devices – requirements and analysis		TR	Preliminary	NWIP	VA – CEN lead	Resolution #20 (Brisbane 2007)
EHR Glossary					Resides with WG 3	
HI: Transforming clinical descriptions into higher level classification: Principles and issues	Jean Marie Rodrigues	TR	Preliminary		WG 1	Resolution #21 (2005)
HI: Harmonisation: Traditional medicine (TrM) terminologies	Kyungmo Park	TR	Preliminary			
Cross terminology referencing, including drug references in laboratory testing	To be identified	To be identified	Preliminary			
Semantic harmonization across Information Models and Terminologies	Chute/Kalra		Preliminary		WG 1	Resolution #17 (2006), Resolution #22 (2005)
HI – Categorical structure for terminologies of surgical procedures		prEN1828	preliminary	NWIP	VA – CEN lead	Resolution #24 Goteborg 2008
HI – System of concepts to support continuity of care – Part 1: Basic Concepts		EN13940	preliminary	NWIP	VA – CEN lead	Resolution #25 Goteborg 2008
Clinical knowledge resources – Metadata		CEN/TS 15699	preliminary	NWIP	VA – CEN lead	Resolution #26 Goteborg 2008
HI – A syntax to represent the content of medical classification systems		CEN/TS 14463	preliminary	NWIP	VA – CEN lead	Resolution #27 Goteborg 2008

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
HI – Guidelines for international healthcare terminology standardization		ISO/TR 12309	preliminary	DTR		Resolution #29 Goteborg 2008
NWIP/DTR Ballot						
HI: Principles and guidelines for the maintenance of terminological systems	Beverly Knight	TR #12975	On NWIP ballot (2008-07-26 – 2008-10-26)	DTR ballot		Resolution #21 (2005) Resolution #28 Goteborg 2008
HI: Criteria for the Categorization and Evaluation of Terminological Systems.	Anne Casey	IS (Revision of ISO/TS 17117)	Passed DTS ballot 2007-12-28	NWIP		(name change 2005 Berlin) Resolution #30 Goteborg 2008
Active Items after NWIP Approval						
HI: Principles and guidelines for the measurement of conformance in the implementation of terminological systems	Beverly Knight	TR# 12310	Passed NWIP ballot 2008-05-29	DTR ballot Awaiting revised document & disposition of comments		Resolution #21 (2005) Resolution #18 (Brisbane 2007)
HI: Mapping of terminologies to classifications	Grain	TR# 12300	Passed NWIP ballot 2008-05-27	DTR ballot		Awaiting revised document Resolution #19 (Brisbane 2007)
HI: Guidelines for international healthcare terminology standardization	Anne Casey	TR# 12309	Passed NWIP ballot 2008-05-28	DTR ballot Awaiting revised document & disposition of comments		Resolution #16 (2006) Resolution #23 (Montreal 2007) Resolution #17 (Brisbane 2007) Resolution #29 Goteborg 2008
Common Glossary for ISO/TC 215	Grain	TS#28379	NWIP ballot Approved 2006-09-13 10.99	DTS Ballot Awaiting revised document & disposition of comments		Resolution #14 (2006)
DIS and FDIS Ballots						
Common Terminology Services (Release 1)	Chute/ Solbrig	IS#27951	On DIS ballot (2008-04-22 – 2008-09-22)	FDIS/Publication	ISO/HL7 agreement	Resolution #11,15 (2006), Resolution #20 (2005) Resolution #21 (Montreal 2007)

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
Sent for Publication						
HI: Conceptual Framework for patient findings and problems in terminologies	Phil Brown	ISO/TS #22789	Submitted to ISOCS for publication	Publication		Resolution #22 (Montreal 2007) Resolution #21 (Brisbane 2007)
Published Items						
Vocabulary for Terminological Systems	Thurin	IS 17115	Published 2007			Resolution #18 (2006) Resolution #19 (Montreal 2007)
Cont Hlth Vocab – Vocab structure hi-level qual Indicators	Peter Elkin	TS 17117	Published – 2002	Under revision		
Integration of a reference term model for nursing	Chute/Saba	IS 18104	Published – 2003			
WG 4 Security	Ross Fraser	Convener				
Preliminary (Not yet ready for NWIP ballot)						
HI: Guidelines on data protection to facilitate trans-border flows of personal health information		TBD	Preliminary	TBD		Resolution #33 (Brisbane 2007)
HI: Guidance on the application of risk analysis and management across the health informatics domain		TR	Preliminary	NWIP		Resolution #32 (Brisbane 2007)
NWIP/DTR Ballot						
Active Items after NWIP Approval						
HI: Directory Services for healthcare providers, subjects of care and other entities (renamed 2007 – Brisbane)	Lori Fourquet	IS #21091 – Revision of TS 21091	Passed NWIP ballot 2008-06-28	DIS		Resolution #24, 25 (Brisbane 2007) Resolution #35 Goteborg 2008
Health informatics – Dynamic on-demand virtual private network for health information infrastructure	Hiroshi Shimada; Kouichi Kita	TR #11636	Passed NWIP ballot (2007-12-28)	DTR ballot Awaiting revised document & disposition of comments		Resolution #33 (Montreal 2007)

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
Health informatics — Electronic health record communication — Part 4: Security	Dipak Kalra	TS 13606-4	Passed DTS ballot 2008-06-28	Publication. Awaiting revised document & disposition of comments	SDO WG9	Resolution #34 (Montreal 2007) Resolution #26 (Brisbane 2007)
Health informatics – The Information Security Management Guidelines for Remote Maintenance Services for Medical Devices and Health Information Systems	Hideyuki Miyohara	TR 11633	Passed NWIP ballot (2007-12-13)	DTR ballot. Awaiting revised document & disposition of comments.	WG7	Resolution #32 (Montreal 2007) Resolution #34 Goteborg 2008
HI: Application of clinical risk management to the manufacture of health software (name change 2007 Brisbane)	Ray Rogers	TS 29321	Submitted to ISO for DTS ballot processing	DTS ballot	VA – CEN lead	Resolution #29 (Montreal 2007) Resolution #27, #29 (Brisbane 2007) Resolution #38 Goteborg 2008
HI: Guidance on the management of risk to ensure the patient safety of health software systems in deployment and use (name change 2007 Brisbane)	Ray Rogers	TR 29322	Submitted to ISO for DTR ballot processing	DTR ballot	VA – CEN lead	Resolution #30 (Montreal 2007) Resolution #28, 30 (Brisbane 2007) Resolution #39 Goteborg 2008
HI: Secure Archiving of electronic health records Part1 Principles and Requirements	Pekka Ruotsalainen	TS 21547-1	On DTS ballot (2008-07-01 – 2008-10-01)	Publication		Resolution #22 (2006) Resolution #41 Goteborg 2008
HI: Secure Archiving of electronic health records Part2 Guidelines	Pekka Ruotsalainen	TR 21547-2	On DTR ballot (2008-07-01 – 2008-10-01)	Publication		Resolution #23 (2006) Resolution #42 Goteborg 2008
HC Info Privilege Mgmt & Access Control P-3 AC Mgmt	B. Blobel	TS 22600-3	On DTS ballot (2008-07-04 – 2008-10-04)	Publication		Resolution #26 (2006) Resolution #31 (Montreal 2007) Resolution #31 (Brisbane 2007) Resolution #36 Goteborg 2008
Audit trails for Electronic Health records	Luuc Posthumus	IS 27789	On CD ballot (2008-07-10 – 2008-10-10)	DIS Ballot		Resolution #28 (2006) Resolution #40 Goteborg 2008
DIS and FDIS Ballots						

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
Sent for Publication						
Pseudonymisation	Lori Fourquet	TS 25237	Submitted to ISOCS for publication	Publication		Resolution #25 (2005)
HI: Functional and Structural Roles	Blobel-Fourquet-Klein	TS 21298	Submitted to ISO CS for Publication	Publication	WG 1	Resolution #27 (2006)
Published – Systematic Review						
GL on data protect to facilitate trans-border flow of p h i	Rogers/Seaton	IS 22857	Published	Under revision		7 – abs 4 – confirm 4 – revise 1- confirm with correction Resolution #33 (Brisbane 2007)
Published						
HI: Information Security Mgmt in Health using ISO/IEC 27002 (name change 2007 Montreal and Brisbane)	Fraser/Mynott	IS #27799	Published 2008		VA	Resolution #25 (2006) Resolution #27, 28 (Montreal 2007) Resolution #23 (Brisbane 2007) ISO CS Processing
HI: Public Key Infrastructure-1 Framework and Overview	Fraser	ISO 17090-1	Published 2008			Resolution #24 (2006)
HI: Public Key Infrastructure-2 Certificate Profile	Fraser	ISO 17090-2	Published 2008			Resolution #24 (2006)
HI: Public Key Infrastructure-3 Policy Mgmt of Cert Auth	Fraser	ISO 17090-3	Published 2008			Resolution #24 (2006)
Classification of Safety risks from health software	Ray Rogers	TS #25238	Published 2007			Resolution #20 (2006), Resolution #24 (2005)

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
HI: Measures for Ensuring Patient Safety of Health Software – APSOHIP	Ray Rogers	#27809 – TR	Published 2007			Resolution #21 (2006), Resolution #25 (2005) Resolution #26 (Montreal 2007)
HI: Privilege Mgmt and AC-1 Overview & Policy Mgmt	B. Blobel	TS 22600-1	Published – 2006			
HC Info Privilege Mgmt & Access Control P-2 Priv Mgmt	B. Blobel/ Klein	TS 22600-2	Published – 2006			
Health Informatics Public Key Infrastructure-1		TS- 17090-1	Published – 2002	Revised; now IS		Resolution #26 (2005)
Health Informatics Public Key Infrastructure-2		TS- 17090-2	Published – 2002	Revised; now IS		Resolution #26 (2005)
Health Informatics Public Key Infrastructure-3		TS- 17090-3	Published – 2002	Revised; now IS		Resolution #26 (2005)
Directory Services for security, communication and identification of professionals and patients.	Lori Fourquet	DTS #21091	Published	Under Revision		Resolution #25 (Brisbane 2007)
WG 5 Health Cards (TF post Oct 08)	Jürgen Sembritzki	Task Force Leader				
Preliminary (Not yet ready for NWIP ballot)						
Study for the use of cards and other technologies in the health care area, not specified as patient data cards	Van Bommel/ Sembritzki	TR				Resolution #36 (Montreal 2007)
Overview of National Healthcare Professional Card Projects and/or Plans	Van Bommel/ Sembritzki	TR			CEN	Resolution #31 (2006)
NWIP/DTR Ballot						
Active Items after NWIP Approval						
Patient Health Card Data Part 8 Links	Van Bommel/ Sembritzki	IS 21549-8	On CD ballot (2008-06-20 – 2008-09-20)	DIS Ballot	VA – ISO Lead	Resolution #44 Goteborg 2008

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
DIS and FDIS Ballots						
Sent for Publication						
Published – Systematic Review						
Patient Health Card Data Part 1 General Structure	Hopkins	IS 21549-1	Published	Completed Systematic Review ballot (2007-09-17)		8- Abstain 8- Confirm 3- Revise 1- Confirm w/ corrections Under WG5 Consideration
Patient Health Card Data Part 2 Common Objects	Hopkins	IS 21549-2	Published	Completed Systematic Review ballot (2007-09-17)		7- Abstain 7- Confirm 4- Revise 1- Confirm w/ corrections 1- Abstain w/ comment Under WG5 Consideration
Patient Health Card Data Part 3 Limited Clinical Data	Hopkins	IS 21549-3	Published	Completed Systematic Review ballot (2007-09-17)		7- Abstain 6- Confirm 6- Revise 1- Abstain w/ comment Under WG5 Consideration
Published						
Patient Health Card Data Part 6 Administrative Data	Sembritzki	IS 21549-6	Published 2008		CEN	
Patient Health Card Data Part 5 Identification Data	Sembritzki	IS 21549-5	Published 2008		CEN	
Patient Health Card Data Part 7 E-Prescription to Med Data	Shepherd	IS 21549-7	Published 2007			
Health Cards – General Characteristics	Kita	IS 20301 60.60	Published 2006			
Health Cards – Numbering System/Registration Procedure	Kita	IS 20302 60.60	Published 2006			

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
Patient Health Card Data Part 4 Extended Clinical Data	I. Emelin	IS 21549-4 60.60	Published 2006			
WG 6 Pharmacy and Medication Business	Ian Shepherd,	Convener				
Preliminary (Not yet ready for NWIP ballot)						
HL7 Structured Product Labeling standard	Beeler/ Hammond	27952	Failed 2006-09-08			w/d from WP?
HL7 Product Stability data standard	Beeler/ Hammond	27954	Failed 2006-09-08			
NWIP/DTR Ballot						
Business requirements for an International Coding System for Medicinal products	Ock-Hee Oh	TR#25257	On DTR Ballot (2008-07-11 – 2008-10-11)			Resolution #46 Goteborg 2008
Active Items after NWIP Approval						
Electronic reporting of adverse drug reactions	Hyun-taek Shin	TS#22224	Passed NWIP and DTS ballot 2007-09-18	Publication		Resolution #42 (Montreal 2007)
Health informatics – Pharmacovigilance – Structure and Data Elements for Individual Case Safety Reports (name change 2007 Brisbane)		IS#27953	Passed NWIP ballot 2007-08-18	CD	VA, ISO/HL7 agreement SDO WG9	Resolution #43 (Montreal 2007) Resolution #38 (Brisbane 2007)
Health informatics – Pharmacovigilance – Test names and units for reporting laboratory results (name change 2007 Brisbane)		IS#11595	Passed NWIP ballot 2007-08-18	CD	VA (ISO lead) SDO WG9	Resolution #44 (Montreal 2007) Resolution #36 (Brisbane 2007)
Health Informatics – Identification of medicinal products – Data Elements and Structure for the Exchange of Product Information for Drug Dictionaries (name change 2007 Brisbane)		IS#11615	Passed NWIP ballot 2007-08-18	CD	VA (ISO lead) SDO WG9	Resolution #45 (Montreal 2007) Resolution #39 (Brisbane 2007)

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
Health informatics – Identification of Medicinal Products – Pharmaceutical Product Identifiers (name change 2007 Brisbane)		IS#11616	Passed NWIP ballot 2007-08-18	CD	VA (ISO lead) SDO WG9	Resolution#46 (Montreal 2007) Resolution #37 (Brisbane 2007)
Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for Ingredients		IS #11238	Passed NWIP ballot 2007-08-18	CD	VA (ISO lead) SDO WG9	Resolution #47 (Montreal 2007)
Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for Units of Measurement		IS #11240	Passed NWIP ballot 2007-08-18	CD	VA (ISO lead) SDO WG9	Resolution #48 (Montreal 2007)
Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for Pharmaceutical Dose Form, Units of Presentation and Routes of Administration		IS #11239	Passed NWIP ballot 2007-08-18	CD	VA (ISO lead) SDO WG9	Resolution #49 (Montreal 2007)
Business Requirements for the Reporting of Pharmacist Services	Nigel Cox	TR #10895	Passed NWIP ballot 2007-08-18	DTR ballot		Resolution #40 (Montreal 2007)
DIS and FDIS Ballots						
Sent for Publication						
Published Items						
Functional Characteristics for Prescriber Support Systems (name change Apr 06)	Gunnar Klein	TR 22790	Published 2007			Resolution #33 (2006) Resolution #41 (2007)
Withdrawn from active Work Program						
Specification of a terminology model for representation of medicinal products	Ian Shepherd	TS 22226				Resolution #35 (Brisbane 2007)
Specification of a pharmacy patient record	Ian Shepherd	TR 22225				Resolution #30 (2005)

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
Business Requirements for e-transfer of Prescription event data and e-prescribing	Garry Cruickshank	TR				Decision from Geneva (2006)
WG 7 Devices	Todd Cooper	Convener				
To be submitted for Preliminary						
Health informatics – Medical waveform format – Encoding rules, DICOM-ECG	Hirai	11073-92202 NP/TS	pre-Preliminary	NWIP+CD	JIS	WG Decision from Brisbane
Health informatics – Personal health device communication – Technical report – Overview	Bogia	11073-00103 NP/TR	pre-Preliminary	NWIP+TR	IEEE lead	
HL7 Annotated ECG Waveform Data Standards	Beeler/Hammond	27933	Failed 2006-09-08			
Preliminary (Not yet ready for NWIP ballot)						
Health informatics – Medical waveform format – Encoding rules, Reporting with HL7 clinical document architecture (CDA)	Hirai	11073-92205 NP/TS	Preliminary	NWIP + CD	JIS	
Health informatics – Medical waveform format – Encoding rules, SCP-ECG	Hirai	11073-92206 NP/TS	Preliminary	NWIP + CD	JIS	
Health informatics – Medical waveform format – Encoding rules, long term ECG	Hirai	11073-92302 NP/TS	pre-Preliminary	NWIP+CD	JIS	Resolution #61 Goteborg 2008
HI – Personal health device communication – Device specialization – Common framework	Bogia	11073-10400 NP/IS	Preliminary	NWIP + CD	IEEE lead	
HI – Personal health device communication – Device specialization – Pulse oximeter	Bogia	11073-10404 NP/IS	Preliminary	NWIP + CD	IEEE lead	Resolution #49 Goteborg 2008

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
HI – Personal health device communication – Device specialization – Blood pressure monitor	Bogia	11073-10407 NP/IS	Preliminary	NWIP + CD	IEEE lead	Resolution #50 Goteborg 2008
HI – Personal health device communication – Device specialization – Thermometer	Bogia	11073-10408 NP/IS	Preliminary	NWIP + CD	IEEE lead	Resolution #51 Goteborg 2008
HI – Personal health device communication – Device specialization – Weighing scale	Bogia	11073-10415 NP/IS	Preliminary	NWIP + CD	IEEE lead	Resolution #52 Goteborg 2008
HI – Personal health device communication – Device specialization – Glucose meter	Bogia	11073-10417 NP/IS	Preliminary	NWIP + CD	IEEE lead	Resolution #53 Goteborg 2008
HI – Personal health device communication – Device specialization – Cardiovascular fitness and activity monitor	White	11073-10441 NP/IS	pre-Preliminary	NWIP+CD	IEEE lead	WG Decision from Cologne Resolution #55 Goteborg 2008
HI – Personal health device communication – Device specialization – Strength fitness equipment	White	11073-10442 NP/IS	pre-Preliminary	NWIP+CD	IEEE lead	Resolution #56 Goteborg 2008
HI – Personal health device communication – Device specialization – Independent living activity hub	White	11073-10471 NP/IS	pre-Preliminary	NWIP+CD	IEEE lead	Resolution #57 Goteborg 2008
HI – Personal health device communication – Device specialization – Medication Monitor	White	11073-10472 NP/IS	pre-Preliminary	NWIP+CD	IEEE lead	Resolution #58 Goteborg 2008
HI – PoC medical device communication – Application profile – Common networking infrastructure		11073-20401 NP/IS	Preliminary	NWIP + CD	IEEE lead	
HI – Personal health device communication – Application profile – Optimized exchange protocol	Bogia	11073-20601 NP/IS	Preliminary	NWIP + CD	IEEE lead	Resolution #54 Goteborg 2008

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
HI – PoC medical device communication – Transport profile – Ethernet		11073-30400 NP/IS	Preliminary	NWIP + CD	IEEE lead	Resolution #59 Goteborg 2008
HI – PoC medical device communication – Transport profile – RF wireless – Local area network (wLAN)		11073-30503 NP/IS	Preliminary	NWIP + CD	IEEE lead	
HI: PoC medical device communication – Technical report – Guidelines for the use of RF wireless technology	Morrissey/Cooper	p/NWIP/11073-00101	Preliminary		?WG4?	
NWIP/DTR Ballot						
Active Items after NWIP Approval						
ISO/IEC 80001 Part 1: Application of Risk Management for IT – Networks incorporating medical devices	Cooper/Eagles	ISJWG/IEC #80001 (changed from 28680)	Pased CD Ballot (2008-03-06)	DIS	IEC lead	
HI: PoC medical device communication – Application profile – Optional package, Remote control	Cooper/Reynolds	DIS/11073-20301	CD stage or DIS	CD2 Ballot Q1 2008	IEEE lead	
HI: PoC Medical Device Communication – Framework & overview	Harrington/Cooper	IS/11073-00000	CD stage or DIS	DIS Ballot Q3 2008	IEEE lead	Resolution #35 (2005)
HI: POC Medical Device Communication – Application profiles MIB Elements	Cooper/Wittenber	IS/11073-20102	CD stage or DIS	CD Ballot Q2 2008	IEEE lead	Resolution #35 (2005)
HI: PoC medical device communication – Application profile, Association Control Function	Cooper/Steubesand	IS/11073-20200	CD stage or DIS	DIS Ballot Q1 2008	IEEE lead	Resolution #35 (2005)
HI: PoC Medical Device Communication – Application profile, Polling Mode	Cooper/Hassing	IS/11073-20201	CD stage or DIS	DIS Ballot Q1 2008	IEEE lead	Resolution #35 (2005)

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
HI: PoC medical device communication – Application profile, Asynchronous Mode	Cooper/ Hassing	IS/11073-20202	CD stage or DIS	DIS Ballot Q1 2008	IEEE lead	Resolution #35 (2005)
DIS and FDIS ballots						
CEN en1064:2007, ISO 11073-91064 – Health informatics – Standard communications protocol, ECG (SCP-ECG)		IS 11073-91064	Submitted to ISO CS for FDIS Processing	FDIS	CEN	Resolution #60 Goteborg 2008
Sent for Publication						
Published – Systematic Review						
Health informatics – PoC medical device communication – Domain Info Model	Reynolds/ Cooper	IS 11073-10201	Published/IE EE	Systematic Review	IEEE lead	
Health informatics – PoC medical device communication – Application Profile – Base Standard	Reynolds/ Cooper	IS 11073-20101	Published/IE EE	Systematic Review	IEEE lead	
Health informatics – PoC medical device communication – Transport Profile – Infrared Wireless	Reynolds/ Cooper	IS 11073-30300	Published/IE EE	Systematic Review	IEEE lead	
Health informatics – PoC medical device communication – Transport Profile – Cable Connected	Reynolds/ Cooper	IS 11073-30200	Published/IE EE	Systematic Review	IEEE lead	
Health informatics – PoC medical device communication – Nomenclature	Reynolds/ Cooper	IS 11073-10101	Published/IE EE	Systematic Review	IEEE lead	
Published Items						
HI: PoC medical device communication – Part 90101: Analytical instruments- Point of care test	Cooper/ Reynolds	IS/11073-90101	Published 2008		CLSI	

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
Use of mobile wireless communication and computing technology in HC facilities recommendations for mgmt of electromagnetic interference with medical devices	Morrissey	TR#21730 60.60	Published 2007			Resolution #36 (2005)
ISO/IEEE/11073-92001 HI: PoC medical device communication – Medical waveform format – Encoding rules (formerly 11073-90201)	Hirai/ Reynolds	TS/11073- 92001	Published 2007			
Proposed to Withdraw						
Health informatics – Medical waveform format – Encoding rules, 12-lead ECG	Hirai	11073-92301 NP/TS	Preliminary	NWIP + CD	JIS	
Health informatics – Personal health device communication – Device specialization – Heart rate monitor	Bogia	11073-10406 NP/IS	Preliminary	NWIP + CD	IEEE lead	
HI: PoC medical device communication – Device specialization – Dialysis device	Cooper/ Torrini	pNWIP/1107 3-10316:	Preliminary		IEEE lead	
HI: PoC Medical Device Communication – Application gateway, HL7 (v2) observation reporting interface	Harrington/ Cooper	DIS/11073- 60101	CD stage or DIS	DIS Ballot Q1 2008	IEEE lead	
HI: PoC Medical Device Communication – Nomenclature Annotated ECG	Brown/ Schluter	IS/11073- 10102	CD stage or DIS	DIS Ballot Q3 2008	IEEE lead	
HI: PoC medical device communication – Nomenclature, Implantable Device, Cardiac	Schluter	IS/11073- 10103	CD stage or DIS	CD Ballot Q2 2008	IEEE lead	

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
WG 8 Business Requirements for an EHR	Marion Lyver	Convener				
Preliminary (Not yet ready for NWIP ballot)						
Knowledge Management of Health Information Standards				NWIP		Resolution #66, 67 (Goteborg 2008)
HI: EHR standards Map	David Rowlands			Publish Ad Hoc Report		Resolution #41 (2006), Resolution #39 (2005)
NWIP/DTR Ballot						
Requirements for EHR reference architecture		ISO#18308				Resolution #9, 63 (Montreal 2007) Resolution #65 (Goteborg 2008)
HI: Requirements and specifications of common essential information for health summary records	Marion Lyver	TR12773	Passed DTR ballot 2008-04-25	Publication. Awaiting revised document & disposition of comments		Resolution #64 Goteborg, Resolution #61 (Montreal 2007) Resolution #43 (2006) Resolution #39 (2005)
Active Items after NWIP Approval						
DIS and FDIS Ballots						
EHR System functional model	Gary Dickinson	IS# 10781	On DIS ballot (2008-04-24 – 2008-09-24)	FDIS/Publication	HL7	Resolution #62 (Montreal 2007)
Sent for Publication						
Published Items						

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ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	NEXT STAGE	HARMONIZATION	Resolution
TC215 Task Forces (ebXML and Multidisciplinary)						
Preliminary (Not yet ready for NWIP ballot)						
NWIP/DTR Ballot						
Active Items after NWIP Approval						
Clinical Stakeholder Participation in the Work of TC215		11487 TR	Passed DTR ballot 2007-12-25	Publication		Awaiting revised document and disposition of comments
DIS and FDIS Ballots						
Sent for Publication						
Published Items						

Attachment 7 – Draft Minutes of SDO Harmonization JWG



[Note: Some minor formatting changes made for inclusion in this report]



Joint Initiative on SDO Global Health Informatics Standardization

Joint Working Group (WG9) SDO Harmonization

Meeting Minutes

Meeting 6

Held at the ISO TC 215 and CEN TC 251 Working Group Meeting
Istanbul
12 October 2008

CEN Co-Chair	HL7 Co-Chair	ISO Co-Chair
Melvin Reynolds	Charles Jaffe	Don Newsham
MelvinR@AMS-Consulting.co.uk	cjaffe@hl7.org	DonNewsham@SierraSystems.com
Secretariat : Elizabeth Hanley: Elizabeth.Hanley@standards.org.au		

1. Welcome and introductions

Don Newsham, co-chair of the Joint Working Group (JWG), welcomed over ninety attendees to the sixth meeting of the JWG.

Countries with representatives at the meeting were Austria, Australia, Brazil, Canada, China, Denmark, Finland, France, Germany, Hong Kong, Japan, Korea, Malaysia, New Zealand, Russia, The Netherlands, Sweden, Turkey, United Kingdom, and the United States. The following Standards Development Organization (SDOs) and organizations were represented at the meeting: CEN TC 251, CDISC, HL7, ICH, IHTDSDO, ISO TC 215, and JTC1.

Don Newsham reported that the Joint Working Group was established in August 2007 under the Joint Initiative Charter. The JWG has held five open meetings at standards meetings hosted by ISO TC215, CEN TC 251 and HL7. There are now almost 190 people

on the JWG list. The JWG has an operational Secretariat and there is a website at <http://www.global-e-health-standards.org/> for access to public information about the Joint Initiative and JWG meetings.

It was further reported that the Joint Initiative Council (JIC) has been meeting regularly by teleconference since its last face to face meeting at Gothenburg in May to approve projects on the joint work program and to address challenges identified by the JWG. The JIC has developed and approved policies and procedures for Joint Initiative task groups and for the nomination of further international SDOs to the JIC.

2. Opening of the meeting

a. Confirmation of the agenda

The agenda was confirmed, with the addition of an item at item 8 proposed by Gary Dickinson on the path to simplification.

b. Confirmation of minutes from JWG Meeting 5 – September 2008, Vancouver – the minutes of meeting 5 were accepted.

c. Actions – See item 10.

3. SDO Work Program Harmonization

a. Joint SDO work program inventory, version 2.1

1. SKMT use / registration / term entry / follow-on discussion from Vancouver

The Joint SDO work program inventory, version 2.1 currently holds over 200 active work items under development in the four SDOs participating in the Joint Initiative (CEN TC 251, ISO TC 215, HL7 and CDISC). It was pointed out that there are approximately 40 active CDISC work items to be added. The next step is the analysis of the inventory.

Marion Lyver spoke about the ISO TC 215 Working Group 8 work on the Standards Knowledge Management Tool (SKMT), which is a web-based tool developed to manage the Common Glossary and Standards meta-data. It was reported that the SKMT design took account of the ISO 17119 Health Informatics Profiling Framework, the Zachman Framework and the Canadian Advisory Committee on Health Infrastructure framework (ACHI). The SKMT project lead, Andrew Grant is in discussion with Mark Shafarman and Bernd Blobel regarding approaches to classification of standards for the associated new work item on Knowledge Management of Health Information Standards, which is at ISO NWIP ballot until late November. Comment was requested from National Member Bodies in the ballot on the Knowledge Management of Health Information Standards work item, in particular, the outline document and project scope.

The Common Glossary project lead by Heather Grain will set out a process for entry, review and harmonization of terms used in health informatics Standards. Ongoing resourcing for the Glossary needs further investigation.

It was queried how the process within SDOs to maintain the Glossary and Standards meta-data would be linked to a process across SDOs.

b. Updates /SDO Work program harmonization issues

1. European Union ESO Mandate project update

Melvin Reynolds stated that the project report had been updated as a result of discussions held at HL7, and is currently out for comment (refer to www.ehealth-INTEROP.nen.nl for further information about the report). The Joint SDO work program inventory was used as the basis for an analysis of standards, based on a keyword approach. It was concluded that any information management approach has to be developed with the end user or procurement purposes in mind, utilizing a usable, structured set of keywords. A dynamic, accessible knowledge management tool such as the SKMT would be beneficial and ensure that currency is maintained.

2 Input to SDO Work Program Task Force on approach

Charlie McCay noted that HL7 has been focusing on projects, products and workgroups and the process and forms required to manage these, with links via URLs to information held in a repository. This will allow an accurate up-to-date view of projects and their status (preliminary / active / published). It would be helpful to have this type of information available across SDOs via a central tool which also sends out notifications about work item activity.

It was noted that providing access to information about published Standards, and work items was an important initiative, and that each SDO needs a repository to manage standards information

It was noted that there are several elements to be explored by the task force, for instance, the tooling, the information/meta-data provided about standards, approaches to classification of standards, the process for access and other process issues.

The task force will be convened to analyse the work program, and others will be added to the task force (see also action 5.1).

4 Joint Work Program – Status, Review and Discussion

a. 13606 and HL7 Version 3 implementation guide

It was reported that a Joint Initiative task group template has been submitted to the JIC for approval.

b. Data Types

Grahame Grieve reported that the joint project had now closed at DIS ballot in ISO/TC 215, with both the HL7 and CEN ballots already closed. He reported that the HL7 ballot passed, and that there were some negative ballot submissions from the editors. The ISO ballot received positive votes, and many detailed comments, which will be distributed to ISO and HL7 members for review. It was reported that there was a total of 374 detailed lined items to review, some of these are significant.

Grahame raised a number of options to move forward:

1. Now that the ISO DIS ballot has passed, that draft could be published as is without going to FDIS, noting that there are known flaws to be addressed;

2. The editorial team could make editorial corrections and re-ballot the document as FDIS and DSTU;
3. HL7 could send the data types document to a normative ballot and the document could proceed to ISO FDIS.

The intention is to seek feedback on progress from ISO TC 215 WG 2 at this meeting, and to form a resolution.

The following matters were raised:

- HL7 has a 4 month process both for DSTU(not normative) or normative Standards, if the document went back to DSTU, then that would take a TSC decision (TSC meets weekly)
- A new ballot may open new issues, and those with issues could do a profile in the expectation that these comments could be considered in the next release.
- It would be useful to achieve a simultaneous publication of the same technical content at CEN, ISO and HL7, and to keep maintenance also in synchronization. There was general and strong support for the project team to make changes and work towards a combination of options 2 and 3 in early 2009.

c. Pharmacovigilance and identification of medicinal products

Ian Shepherd, noting that this work was formally requested of CEN TC 251 and ISO TC 215, reported that ICH had developing guidelines for regulation and licensing of pharmacovigilance products, for human use. ISO TC 215 was asked to extend countries involved in the work, with the work items largely in use in the US, Japan and Europe. Ian identified that issues encountered in the project were in two categories: firstly, scope, in that it would be time consuming to cover all possible uses outside the licensing and regulation domain; secondly, being in the licensing area, the project is impacted by national differences in legislation for registering of medicines. He further reported that WG6 have been responsible for these projects for two years, which has involved changes of personnel, and some re-education of new personnel. It was reported that twenty to thirty different organizations were involved in the development of these work items to ensure compatibility with broader work. It was expected that some work items would be sent for ballot after this meeting.

d. Glossary

It was reported that a Joint Initiative task group template has been submitted to JIC for approval.

e. Entity Names Harmonization

It was reported that a Joint Initiative task group template needs to be developed for submission to the JIC for approval.

f. Units of Measure

Melvin Reynolds reported that there is a project underway in ISO/TC 215 Working Group 6 on Units of Measure, and also a new work item being discussed in Working Group 3 regarding the methodology for maintenance and publication of units of

measure. It was noted that the Regenstrief Institute produces an informal publication on Units of Measure which is mandated in HL7 Version 3.

Melvin Reynolds reported that he has held follow-up discussion on Units of Measure after Vancouver, seeking assurances there is alignment between the two work items. Areas of infrastructure, registration and maintenance need to be understood and the need for formal governance processes and a host organization for UCUM were identified.

It was noted that there is interest from CDISC, and HL7 also in this work, and that an ISO lead was needed.

The relationship with IHTSDO work was queried, and it was reported that IHT had provided some information from the SNOMED CT perspective on units of measure. The possibility of having both an ISO Standard and a IHTSDO Standard, leading to Intellectual Property issues, was raised.

g. Identification of other potential joint work items

Don Newsham raised the representation and exchange of clinical data through archetypes, templates and bindings to terminology as a potential area of joint work. It was noted that ISO TC 215 Working Group 1 has an agenda item on detailed clinical models scheduled for this week's working group meeting, and that this work will build on the work undertaken in Scotland and The Netherlands on clinical data requirements.

It was reported that HL7 have working groups for vocabulary and templates, looking at the appropriate use of clinical models, and that the Clinical Interoperability Council is drawing in clinical requirements for interoperability.

Mark Shafarman noted that this matter is related to the harmonisation between 13606, and HL7 V 3.

Action 6.1 JWG Convenor to schedule update report on detailed clinical modelling work for JWG Meeting 7.

5. Standardization processes

a. Joint Initiative Task Group Processes

Don Newsham referred to the JIC Policy and Procedures version 5. The JIC has approved this policy and procedure, which was based on the Charter, and incorporates the principles of harmonization from the Charter. The document includes the current lists of agreements between SDOs that are in force for working in the Joint Initiative task group. The approved Policy and Procedure sets out how SDOs work together in a joint initiative task group, and is a simplified version of the the current lists of agreements between SDOs that are in force for working in the Joint Initiative task group. The approved Policy and Procedure sets out how SDOs work together in a joint initiative task group, and is a simplified version of the draft detailed processes for common / harmonized standards development released for comment to JWG members earlier in the year.

A query was raised about how the process would allow the addition of another SDO to the joint task group.

Charlie McCay asked that the Joint Initiative Task Group templates be published on the website before they go to the JIC for approval.

Action 6.2 JWG secretariat to load the Joint Initiative Task Group templates proposals to website prior to submission to the JIC.

6. Harmonization Needs and Issues

It was stated that issues of maintenance, versioning and co-ordination of balloting would be covered in the discussion, and also issues surrounding intellectual property and referencing other standards.

The following issues were raised:

- How should revisions of published standards be managed to avoid multiple publications in different SDOs?
- The need to address timing of updates to standards.
- The need to have a fixed update cycle
- Should all balloting occur in the host SDO i.e. in one community?
- The need to have a stopping point, and allow countries to develop a profile
- There has been a lot of goodwill to date to deal with these issues. ISO has an inherently limited process ie DIS, FDIS, while HL7 can go through an unlimited process. Can we ask for comments to be limited in scope and defer management to a later release?
- In the device communications projects, the joint working group, using the goodwill principle, shared documents and jointly viewed documents with circulation restricted during development to the ballot group. One SDO managed the ballot process and accepted input to ballot processes from others signed up to the ballot group. The standard went straight to publication in the other SDOs as there were no further changes required.
- Is there a need for a stopping process in place i.e. if new comments come in, they are addressed in the next ballot cycle?
- In the Vocabulary area, there is a need to harmonize between ISO and HL7 i.e. discussion is held in two places which leads to two documents: one technical and one procedural, both referencing the other document. This is a cohesive answer to the two parts of the problem, and not a joint work item. There will need to be a ballot hosted by 1 SDO with other SDOs contributing, with both documents being balloted simultaneously.
- Which template should be used for Standards developed jointly?
- The need to need to have some joint documents made available electronically. With a deeply technical document, navigation and hyperlinks would be helpful.

It was noted that the guidelines for referencing other Standards varied between SDO, and that the lead SDO's guidelines should be followed.

It was further noted that concerns related to Intellectual Property, for instance, how much of a Standard could be quoted in another document, would depend on the legislative framework under which an SDO operates.

In summarising the discussion, Don Newsham suggested that the primary approach is through good will, and that a singular ballot should be hosted and managed by one SDO and all SDOs can contribute to that ballot.

Action 6.3 Bev Knight to provide an update report to JWG Meeting 7 on the Vocabulary documents being developed as separate technical and procedural documents and balloted simultaneously.

7. Communications

The Joint Working Group website is at www.global-e-health-standards.org

8. Other Business

Gary Dickinson spoke briefly on the path to simplification for analysis of standards to address the large number of standards publications and projects.

Action 6.4 JWG Convenor to schedule an out of session review of Gary Dickinson's proposal on a path to simplification and provide an update report to JWG Meeting 7.

9. Next JWG Meeting

1. HL7 (Orlando) – 11 January 2009, after international affiliates meeting (4.30pm to 6.30pm).
2. ISO TC 215 / CEN TC 251 Meeting (Edinburgh) – April 2009.

10. Actions

Number	Action	Responsibility
3.4	Update the decision tree diagram for discussion at May JWG meeting. 2008/05/30 Jeremy Thorp noted that some examples to work through would be of assistance in updating and simplifying the decision tree. Carried 2008/09/14 Carried. 2008/10/12 Carried	Jeremy Thorp
4.1	Report back on gaps and overlaps found in the joint SDO work program inventory. 2008/09/14 Carried. 2008/10/12 Carried	Melvin Reynolds
4.2	Submit items of overlap, duplication or other issues to JWG 2008/09/14 Carried. 2008/10/12 Carried	Members of ISO/secretariat. TC 215, CEN/TC251, HL7, CDISC
4.5	Submit the Joint initiative task group template for the Entity Name Harmonization project to the JIC for approval and inclusion on the joint work program. 2008/09/14 Carried. 2008/10/12 Carried	Heather Grain and Grahame Grieve

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Number	Action	Responsibility
4.6	Submit the Joint initiative task group template for the Units of Measure project to the JIC for approval and inclusion on the joint work program. 2008/09/14 Carried 2008/10/12 Carried	Ray Simkus, Gunnar Klein, Robert Owens and Grahame Grieve
5.1	Establish a taskforce to explore issues and propose next steps for standards analysis 2008/10/12 Mark Shafarman and Gary Dickinson added to taskforce Carried	Don Newsham, Melvin Reynolds, Charlie McCay, and other volunteers
5.2	Forward to the TSC process issues raised by Grahame Grieve in regard to the date types project. 2008/10/12 Carried	Charlie McCay
5.3	Forward to JWG Secretariat for circulation, details of the process for registration and entry of terms to the glossary via the SKMT 2008/10/12 Carried	Heather Grain
5.4	Forward issues related to multiple releases of a Standard to the JIC for discussion and decision making. 2008/10/12 Completed	JWG Convenor
6.1	Schedule update report on detailed clinical modeling work for JWG Meeting 7	JWG Convenor
6.2	JWG secretariat to load the Joint Initiative Task Group templates proposals to website prior to submission to the JIC.	JWG Secretariat
6.3	Provide an update report to JWG Meeting 7 on the Vocabulary documents being developed as separate technical and procedural documents and balloted simultaneously.	Bev Knight
6.4	Schedule an out of session review of Gary Dickinson's proposal on a path to simplification and provide an update report to JWG Meeting 7.	JWG Convenor

Acronyms and Abbreviations

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

List of Acronyms (continued)

NCI EVS	NCI's Enterprise Vocabulary Service
NEHTA	(Australian) National E-Health Transition Authority
NHIN	(US) National Health Information Network
NHS	(UK) National Health Service
NIH	(US) National Institutes of Health
NMB	National Member Body [of ISO or CEN]
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
PoC	Point-of-Care
RHIO	(US) Regional Health Information Organisation
RIM	(HL7) Reference Information Model
RMIM	Refined Message Information Model
SDO	Standards Development Organisation
SIG	Special Interest Group
SKMT	Standards Knowledge Management Tool
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
UCUM	Unified Code for Units of Measure [Regenstrief Institute]
UML	Unified Modelling Language
VHA	(US) Veterans' Health Administration
W3C	World Wide Web Consortium
WG	Working Group
XDS	(IHE's) cross enterprise Data Sharing protocol
XML	eXtensible Markup Language