



**Report of Australian Delegation
to the
ISO TC215 Health Informatics
Standards Meetings
in Gothenburg, Sweden
May-June 2008**

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

June 2008

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List of Acronyms

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

List of Acronyms (continued)

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

Acknowledgements

Standards are central to Australia's national e-health agenda, and 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 ISO TC215 plenary and working group meetings and attendees at the 4th Global Health IT Summit 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. Executive Summary

The 2008 Plenary Meeting of ISO's Health Informatics Technical Committee, TC215, was held in Gothenburg (Göteborg), Sweden on 30 May to 2 June. It was preceded by the 4th Health Information Technology Global Summit with a focus on health informatics standards in support of consumers.

There were 200 attendees registered from 22 countries, including an Australian delegation of 7 people and many sessions at the meeting were held jointly with the equivalent European CEN /TC251 Working Groups, facilitating harmonisation and common understanding between European interests and the wider international community.

Among the major issues addressed at the Gothenburg meeting were the following.

Health Information Technology Global Summit IV on consumer health issues

Key trends and needs emerging from this event included the following:

- The need for trusted signposts to help citizens negotiate the online health information maze to find accurate, unbiased and safe information on health care issues that is relevant to their personal circumstances.
- Public health information utilities, content quality standards and accreditation/referral services (including the "Knowledge Prescription" or "Information Prescription" all potentially have a role to play in meeting this need.
- There is growing interest and demand for institutional EHR systems to interoperate with Personal Health Record (PHR) owned and controlled by the consumer.
- This trend raises the need for strategies to handle citizen supplied data, addressing issues of: truth, trust, provenance, user skill levels, incorporation of such data into records and accurate identification of consumers and/or their authorised proxies.

More detailed information on the HIT Global Summit (including links to individual presentations) is provided in section 15 below.

International Harmonization Activities

The Joint Initiative Council (JIC) for global health informatics standardisation now consists of three representatives each from HL7, ISO TC215, CEN TC 251 and CDISC, following the decision at the February JIC meeting to give CDISC probationary membership for six months. The JIC held a closed meeting at Gothenburg, which was also attended by Elizabeth Hanley in her role as Secretariat to the Joint Initiative Joint Working Group – SDO Harmonisation. Ed Hammond, Chair of HL7, is the Chair of the JIC and the ISO TC215 secretariat provides secretariat to the JIC.

Presentations to the JIC meeting were provided by Rebecca Kush, CEO of CDISC, and Jennifer Zelmer, CEO of IHTSDO. Both organisations are keen to work together with the harmonisation initiative. The JIC in turn emphasised its receptiveness to including further Standards Development Organisations (SDO)s other than the three original participants, that are the signatories to the JIC Charter agreed in August 2007.

The Gothenburg JIC meeting focussed largely on discussion of Joint Initiative processes and procedures, and clarification of the Joint Initiative Work Program pharmacy and medication work items. The JIC is the decision maker for the Joint Initiative, and the processes and joint work items now being developed and discussed in the Joint Working Group will be referred to the JIC at future meetings for endorsement. The JIC will meet by monthly teleconference to progress matters between face to face meetings.

The Joint Working Group Meeting held an open meeting on Friday evening, which was attended by more than eighty people, and was lead by the three co-chairs, Don Newsham (ISO TC215), Charles Jaffe (HL7) and Melvin Reynolds (CEN TC 251). Matters discussed at this meeting included the following:

- The joint SDO work program inventory
 - At end May there were 220 active work items being undertaken by HL7, ISO TC215 and/or CEN TC 251.
 - All CDISC and HL7 work items are still to be included in the inventory.
 - Next steps were outlined for analysis of overlaps, duplications and issues.
 - Further discussion is needed on how to undertake the Gap Analysis.
- Joint Work Program
 - 13606, specifically parts 1 and 5 for harmonisation with HL7.
 - Data types. Because of time to release of ISO ballot materials, the disposition of comments will now be commenced at the HL7 meeting in September and finalised at the October ISO TC215 meeting (Grahame Grieve is the project lead for this work and will now need to attend both meetings).
 - Pharmacovigilance and identification of medicinal products. Seven joint work items will proceed to DIS ballot in late 2008 and IHTSDO terminology interests are to be included.
- Additions to the Joint Work Program
 - Glossary project which originated in ISO TC215 Working Group 3, lead by Heather Grain, will now be undertaken as a joint ISO / CEN / HL7 / CDISC glossary project.
 - Entity Name Harmonization project to address issues and harmonisation between HL7 name identifiers, ISO identification standards, and joint Data Types standard (lead by Grahame Grieve and Heather Grain).
 - Units of measure project to formalise and jointly prepare a standard of units of measure, building from accepted proprietary work, and building on current ISO TC215 Working Group 6 and device standards projects.
- Preliminary Joint Project.
 - Detailed clinical models (lead by William Goossen). ISO TC215 Working Group 1 will refine the work item and bring back to the October JWG meeting in Istanbul.
- Joint Initiative Processes
 - Information on CDISC processes will be added to the Overview of current processes

- Both the Overview and Detailed process documents will be further reviewed and then forwarded to the JIC for approval.

The Joint Initiative website at www.global-e-health-standards has been developed by the JWG secretariat with support from Klaus Veil, Chair of HL7 Australia, and provides further information about SDO harmonisation.

Harmonised 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 being to have a single, structurally correct, internationally recognised abstract data types standard for use in healthcare information interchange. ISO 21090 is designed to be compatible with and to build on the more generic ISO/IEC 11404 Language independent datatypes standard and also to replace an earlier CEN health datatypes standard and to align with current changes in HL7 abstract datatypes.

ISO 21090 is now out for 5 months ballot in each of the three SDOs with the ISO (DIS) and CEN (prEN) ballots closing on 24 September 2008. Standards Australia along with all other ISO TC215 and CEN TC251 National Member Bodies have been requested to submit their ballot responses by 8 September 2008 (the HL7 Ballot close date) so that the results can be processed at the HL7 Plenary and Working Group Meeting in Vancouver 14-19 September 2008 at which most of those most affected by the changes in this standard are likely to be present. Subsequent ratification of ISO and CEN ballot reconciliations will occur (hopefully) at the Joint Working Group meetings taking place in Istanbul in October.

Grahame Grieve (Australia) was present at the Gothenburg meetings to report on the considerable body of work that had taken place in bringing this standard forward to this point (particularly through earlier HL7 ballots) and to seek resolution of potential residual issues. His attendance was supported by the UK NHS CfH program and his employer Jiva Medical.

Those with an interest in health Information Systems development in Australia are encouraged to review the draft standard and submit comments through Standards Australia.

Harmonisation Review - Patient and Provider Identification

Australia (through Heather Grain, Convenor of ISO TC215 WG3) has been asked to head up a review of work on Patient and Provider Identification within CEN (healthcare cards), ISO (functional requirements for identification) and HL7 (messaging, services and datatypes) and to ensure that the work and the resulting standards are consistent, taking full advantage approaches adopted in each of the other work items.

This activity will support and inform the local review of Australian Standards for Patient and Health Care Client identification currently being undertaken in Australia and will require further Australian contribution to HL7 and ISO activities, both at meetings and outside of meetings.

It would be appropriate to establish liaison with State and National identification and Provider Registry projects for this work. Further details can be obtained directly from the designated expert from Australia: Heather Grain (heather@lginformatics.com)

ISO 13606 EHR Communication

Parts 1 to 4 of EN13606 *Health Informatics – EHR Communication* have now been published as a normative European Standard and Part 1 (EHR Reference Model) was also published as an international ISO standard in February 2008.

At Gothenburg, the other two core elements of 13606, Parts 2 and 3 were both approved for release to final FDIS ballot for acceptance as a full intentional standard, with substantial acceptance now having been achieved for both of these parts in the earlier DIS ballot. However, there was a commitment given to produce an HLv3 implementation guide for ISO 13606 and this needs to be honoured to avoid any negative sentiment.

Part 4 (Security) was out for ballot as a draft Technical Specification closing on 28 June 2008. Part 5 will become increasingly important as people seek to implement 13606 in a services-oriented environment and is currently undergoing “Enquiry” balloted as a draft European Standard for adoption into ISO under the Vienna Agreement. ISO members are encouraged to participate in the current consideration.

There was some news of uptake and implementations of EN 13606-based on archetypes and templates for clinical information representation – including a decision on 14 February by the county councils across Sweden to use EN 13606 Parts 1, 2 and 3 within their health systems and Parts 1, 2 and 5 for communication of EHR information.

With the final form of ISO 13606 now emerging, the next few months would be an appropriate time for IT-014 to progress the project for production of a miscellaneous publication on EN 13606, deferred from last year because of uncertainty as to the outcomes of the ISO ballots.

Glossary of terms for health informatics

Significant support was given to a project to be led by Australia, and supported by Canada to further develop the glossary of terms and definitions used in international health informatics standards documents with management and harmonization of these terms being facilitated by use of an open-source, open access on-line tool. The glossary will not just list terms and definitions, but will indicate the standard definition to be used, or where differences cannot be avoided, to declare the specific context in which the different definitions apply.

The initiative is also reported to have the support of CEN TC251, HL7 and WHO representatives; however, progress will be slow if additional funding (for an estimated at 3 months full-time work) cannot be found and the required information management work is all to be done on a volunteer basis.

Patient Safety - Health Software

Within the next month or two, Australia will be required to vote on the following two health software safety standards:

- 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.*

The standards are intended to be applied where a software artefact may affect patient safety and is not explicitly covered by existing medical device regulatory regimes (e.g. a clinical decision support tool). Although strongly supported by the UK-NHS, heated debate in the committee preparatory stages has indicated that some suppliers are strongly opposed to any standard that may be used for safety compliance regimes beyond existing medical device regimes.

It is considered important that Australia's vote on this matter needs to be appropriately informed by consideration of the documents and balanced debate of the issues including inputs from 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.

Work on Pharmacy and Medications

Following requests from ICH and an EC contract with CEN for some standards development work to support EMeA, significant work by over 60 people is currently underway in defining information structures, data elements, terminology/vocabulary and test units for use in pharmacovigilance (Individual Case Safety Reporting – ICSR) and for the identification of medicinal products (IDMP). The work is being progressed via a combination of teleconferences, email exchanges and face-to-face meetings at, and in conjunction with ISO, IEC and other health informatics meetings.

This work provided a learning experience as one of the first activities to become a “Joint Project” under the ISO-CEN-HL7 Joint Initiative Council and revealed some key issues of direction and communication that need to be addressed in such projects. As a result of initial complexity and some overlap with US work being progressed by HL7 and FDA, the scope of this work has been modified (with a reduced contractual component) but now has stronger input from regulators and the pharmaceutical industry; indeed, greater clinical balance would probably be beneficial.

Australia does not presently have any regular involvement in this work even though the resulting standards appear to be relevant to NEHTA, jurisdictions, local clinical providers and drug information services. It is recommended that consideration be given to Australia having a greater involvement – at least having a regular presence in the main WG6 meetings.

ISO TC215/WG3 - Health concept representation

Heather Grain, Chair of the Standards Australia IT-014 Health Informatics committee, has recently been appointed as Convenor of ISO TC215/WG3 (Health concept representation) for an initial period of 3 years (renewable for a second 3-year term). The WG3 meeting in Gothenburg was very well attended with representatives of many countries, IHTSDO and WHO being present. The meeting was held jointly with the European CEN /TC 251 /WG 2 Terminology working group and a strong desire to collaborate closely without duplication or overlap was evident from all present. As a result, many of the following projects will be done jointly by the relevant ISO and CEN groups working together:

- Review of standard on categorical structures for terminologies of procedures (EN 1828)
- Adoption of EN 13940 - System of concepts to support continuity of care
- Clinical knowledge resources – Metadata (CEN/TS 15699)

- Categorical structures for systems of concepts – Model for representation of semantics (EN 12264)
- Syntax to represent the content of medical classification systems (EN 14463:2007)
- Categorical structure for terminologies of human anatomy (EN 15521:2007)
- Criteria for the categorisation and evaluation of terminological systems (ISO/DTS 17117)
- New project - Health informatics – Guidelines for international healthcare terminology standardisation (ISO/NP TR 12309)
- Mapping of terminologies to classifications (ISO/NP TR 12300)
- OID Registration Problem – referred from HL7
- New project – Principles and guidelines for the measurement of conformance in the implementation of terminological systems (ISO/NP TR 12310)

A potential increase in WG3's scope is also under consideration to address the areas of: common user interface specifications, and clinical decision support but these are likely to involve joint activities and, given the above lost of projects

Personal Health Record (PHR)

While there continues to be considerable interest among the health informatics community in progressing the development of shareable personal health records (PHRs) it seems increasingly likely that ISO TC215 will be a follower, rather than a leader, in progressing standards for this field.

Nevertheless, as discussed at some length in the Gothenburg HIT Global Summit sessions, the emergence and promise of PHR solutions is already leading to a demand for greater connectivity and associated standards. It is in this area that ISO TC215, in collaboration with other members of the Joint Initiative, is likely to make contributions as PHR technologies and requirements stabilise. However, current commercial offerings are very much based on proprietary solutions.

The ISO TC215 Task Force on personal health records has been disbanded but John Ritter, who is also leading HL7's work on the PHR Functional Model, has undertaken to complete an internal report on PHR standards needs for use within TC215. ISO TC Working Group 8 has taken a "watching brief" for PHR, based on advice from the Executive Council.

From Australia's perspective, one of the benefits of separate streams of work on PHRs emerging internationally is that they provide another way of communicating the connectivity requirements needed to implement the Australian "Shared EHR" concept as proposed by NEHTA (and previously *HealthConnect*). Many of those in the US EHR system vendor community have difficulty relating to this concept, because in their eyes an "EHR" is purely an in-house clinical records system; however, we may be able to get them to accept much of the required functionality for shared EHR under the PHR banner.

General TC 215 activity

Membership of TC215 currently comprises 24 participating countries (P-Members) and 21 observing countries (O-Members).

At the Gothenburg meeting, the TC215 Secretariat reported that, since the previous plenary in Montreal in March 2007, 32 New Work Items (with draft documents), 28 voting results, 6 sets of requested informal comments and 17 ballots for draft International Standards or for final publication as were completed by the Technical Committee and its experts.

ISO TC215 also provides Secretariat services for the Joint Initiative Council (JIC) with the Joint Working Group (JWG) that supports the JIC being constituted as ISO TC251 WG9, where Australia plays a major role by providing the Secretariat.

Participation by China (PRC)

The PRC currently has Observer status within ISO TC215 with five delegates at the Gothenburg meeting. They have announced their intention to seek full P-Member status. This move parallels the development of national and regional programs to use relevant international/global health informatics standards (including HL7v2.x and CDA) and a need to see that such standards can appropriately address the full range of clinical services delivered in the Chinese health system including Traditional Chinese Medicine (TCM), particularly in the areas of terminology and vocabulary.

In recent years, Australian delegations have been active in supportive and encouraging PRC engagement in international health informatics programs and, through personal contact, were again able to be supportive of PRC involvement.

Formation of Traditional Oriental Medicine (TOM) Group

At Gothenburg it was agreed to form an Ad-hoc Group to investigate issues related to application of health informatics in Traditional Oriental Medicine (including TCM) and to propose an action plan for consideration at the April 2009 plenary in Edinburgh. It is a significant credit to Australia that Heather Grain (Chair of IT-014) has been asked to be the rapporteur for the Ad-hoc Group.

Technical liaison between JTC1 and ISO TC215

Many of TC215's individual working groups have formal technical liaisons with subcommittees of ISO/IEC JTC1, the peak committee responsible for ICT standardisation within the international ISO and IEC standards communities; however, there was no equivalent liaison between the parent JTC1 and ISO TC215 committees. At its plenary meeting in held in Australia last year, JTC1 identified a growing overlap in its activities and those of ISO TC215 and sought a formal technical liaison at committee to committee level.

At its Gothenburg meeting, ISO TC215 approved establishment of a Category A Technical Liaison with JTC1 with Richard Dixon Hughes (Australia) providing liaison from JTC1 to ISO TC215 and Dr Adrian V. Stokes (UK) providing liaison from ISO TC215 to JTC1. Mr Dixon Hughes and Dr Stokes had preliminary discussions in Gothenburg on how the liaison might be best progressed in light of their respective involvements, commitments and access to relevant individuals.

Work Program

The entire ISO TC215 work program is appended as Attachment 5.

Forthcoming Meetings

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

Dates	Location	Meeting Type/ Comment
12-15 Oct 2008	Istanbul, Turkey	JWG Meetings
27-30 Apr 2009	Edinburgh, Scotland (UK)	Plenary
Oct 2009 (dates tbc)	Durham, North Carolina, USA	JWG Meetings+ Summit V
Apr 2010 (dates tbc)	Brazil	Plenary (w DICOM conf)
Sep 2010 (dates tbc)	Cape Town, South Africa	JWG with MedInfo 2010

2. Introduction

The International Organization for Standardization (ISO) develops health informatics standards through its Health Informatics Technical Committee (ISO TC215). The responsibilities of this TC are mirrored in Australia by Standards Australia's Health Informatics Technical Committee (IT-014).

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. The second meeting, the "Joint Working Group Meeting" usually comprises meetings of the working groups only.

In 2008, the Plenary Meeting was held in Gothenburg, Sweden with activities running from Wednesday, 27 May through to Monday 2 June 2008. On four of these days nine concurrent work sessions were scheduled. The daily schedule was as follows:

Wed 28 May	TC215 Convenors meeting (1300-1600) [ISO-CEN-HL7] Joint Interoperability Council (Closed Meeting 1630-1800) WG6 (Pharmacy) ICSR and IDMP Task Group meetings (in parallel)
Thu 29 May	Health Information Standards Technology Global Summit (0800 – 1700) WG6 (Pharmacy) ICSR and IDMP Task Group meetings (in parallel)
Fri 30 May	TC215 Convenors meeting (0700–0830) Working Group meetings (0900–1700) (9 concurrent sessions) ISO TC215 /WG9 SDO Harmonization (JWG) Meeting (1730-2130)
Sat 31 May	Working Group meetings (0900–1700) (9 concurrent sessions) ISO TC215 Executive Council Meeting (1800-2030)
Sun 01 Jun	Working Group meetings (0900 – 1700) (9 concurrent sessions) Meeting of ISO TC215 WG Secretariats
Mon 02 Jun	ISO TC215 Plenary meeting to coordinate and discuss major decisions and work programs for the working groups – and pass formal resolutions. ISO WG 7 meeting (0800 – 1200) (in parallel with Plenary).

The main working sessions occupied 4 days from 30 May to 2 June 2008.

The fourth in a series of Health Information Technology Global Summits jointly organised with HIMSS took place on Thursday, 29 May with the focus on this occasion being health informatics standards in support of consumers.

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

The Australian delegation consisted of the following seven representatives, most of whom were supported by funding provided by the Australian Government Department of Health and Ageing (DoHA) through Standards Australia:

- Richard Dixon Hughes (Head of Delegation)
- Heather Grain (Chair IT-014 and Convener ISO TC215 WG3)
- Elizabeth Hanley (Standards Australia – Secretariat ISO TC215 WG8 and WG9)

- Prof Evelyn Hovenga
- Prof Anthony Maeder
- Dr Heather Leslie
- Grahame Grieve (with support from Jiva Medical and UK NHS)

Since the ISO meetings generally consist of up to eight concurrent streams of meetings, the delegation necessarily covers some areas in greater depth than others, taking into account 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).

Heads of Delegation, Working Group Convenors and Secretariats (in this case, three out of the seven Australian delegates) also attended various TC215 strategic management and organisational meetings and the Joint Working Group (of ISO, CEN and HL7). Some of these additional meetings were held prior to commencement of the main Gothenburg meeting with others being held as evening and early-morning sessions.

This report addresses the main matters that arose at both the 4th HIT Global Summit and the ISO TC215 Plenary and Working Group meetings. Resolutions taken by TC215 at the plenary meeting are 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. This is then circulated as a Draft International Standard (DIS) to 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 Reports produced by ISO committees.

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 4, 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 8 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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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: 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>A/Convenor: Marion Lyver (Canada) Vice Convenor: Vacant Secretariat: Elizabeth Hanley (Australia)</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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At Gothenburg, the TC215 Secretariat reported that, since the previous plenary in Montreal in March 2007, 32 NWIP and CD ballots with 28 voting results, 6 sets of requested informal comments and 17 DIS/FDIS ballots were completed by the Technical Committee and its experts.

ISO TC215 also 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: Elizabeth Hanley (Standards Australia)</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 to four times per year concurrently with meetings of each of the participating organisations and conduct business by teleconference in between these meetings.

Further information on current activity and outcomes in relation to ISO-CEN-HL7 collaboration in health informatics is further reported in section 5.1 below.

4.2 TC215 Scope, Organisation, and Work Program

Internal closed meetings of TC215's Working Group conveners and vice-conveners were held on Wednesday, 28 May (from 1200 to 1700) and were continued from 0700 to 0830 on Saturday 30 May to consider each of the working group scopes and work plans, including identification of longer term objectives and any potential changes.

The requirement for a closer and more coordinated approach to harmonization of work initiatives between ISO TC215 and the related European CEN /TC251 committee and HL7 were clear and were taken into account through the deliberations.

Each working group presented their current work plan outline and considered whether their scope needed to be modified. Interestingly there were few suggested modifications, with the following exceptions:

- WG3 (Health Concept Representation - terminology) currently have a full work program but propose to bring forward NWIPs for standards on common user interface specifications and clinical decision support in 2010;
- WG4 (Security) wished to have its coverage of safety and privacy issues more explicitly recognised in both its title and its statement of scope – following

considerable debate within WG4 itself, a proposal was put forward to name the committee “Security, Safety and Privacy” with greater elaboration of the privacy and safety aspects of scope but the Plenary noted that a final decision on this has been deferred to the Istanbul meeting to allow NMBs more time for consideration.

- WG5 (Patient Data Card) sought an extension of scope to consider different devices to carry health identifying and care data, such as portals, using new technology such as RFID, USB sticks, mobile phones etc. The request to extend the work of WG5 was discussed and will not be extended beyond the requirement for card use at this time, but a watch on alternative technologies will be maintained.

The entire ISO TC215 work program is appended as Attachment 5.

4.3 Forthcoming Meetings

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

12-15 Oct 2008	Istanbul, Turkey	JWG Meetings
27-30 Apr 2009	Edinburgh, Scotland (UK)	Plenary
Oct 2009 (dates tbc)	Durham, North Carolina, USA	JWG Meetings+ Summit V
Apr 2010 (dates tbc)	Brazil	Plenary (w DICOM conf)
Sep 2010 (dates tbc)	Cape Town, South Africa	JWG with MedInfo 2010

5. Major Issues

Several of the more significant topics addressed at the Gothenburg meetings included the following:

- ISO-CEN-HL7 Collaboration
- Glossary of terms for health informatics
- ISO 13606 – EHR Communication
- ISO 21090 - Harmonized Data Types
- Harmonization of Patient and Provider Identification
- Pharmacy and Medications Standards
- Safety Standards for Health Software

In many cases these matters were dealt with at the level of TC215 itself or in joint sessions across several of the working groups, so these topics have been reported ahead of providing further information on the activities and Australian involvement with the individual ISO TC215 Working Groups.

5.1 ISO-CEN-HL7 Collaboration

At the TC215 meeting in Geneva In October 2006, the three main world-wide health informatics standards development organisations (SDOs): ISO TC215, CEN TC251 and HL7 agreed in principle to a Charter for a *Joint Initiative on SDO Global Health Informatics Standardization* by which they would collaborate with the 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 being guided by a Joint Initiative Council (of SDO leaders) (JIC), supported by an open Joint Working Group (JWG) that will coordinate planning, etc. activities (and which has been formally constituted as ISO TC215 WG9).

Working arrangements for SDO Harmonization were significantly progressed during the Brisbane Meetings, 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 (in conjunction with the CEN TC251 meeting in November 2007) and at the HIMSS meeting held in Orlando, Florida in February 2008.

Nevertheless, while there is considerable goodwill, each of the SDOs primarily addresses the needs of different groups within the overall e-health stakeholder communities and the barriers to seamless collaboration remain many. 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 standards development and balloting processes of the three organisations 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 is proving to be a logistical challenge (which will become even more complicated if more organisations join the JI)
- Shortly after the JIC was formed, some interests with particular agendas petitioned the JIC to rule against other projects already underway – leading to disputation rather than collaboration.
- 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 for 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 the potential that they may become involved in the future for example, IHTSDO
- Development of Joint Initiative processes for common / harmonised standards development (for Normative Standards)
- Joint SDO work program inventory listing all current ISO TC215 and CEN TC 251 work items
- Improved communications between and within the three SDOs with each nominating an appropriate contact point for formal communication and to educate their respective members and stakeholders about the JI and its activities.
- Constitution of the JWG as ISO TC215 WG9 with Standards Australia (Elizabeth Hanley) 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/>.

5.2 Glossary of terms for health informatics

The Gothenburg meeting gave significant support to the further development of a glossary of terms and definitions used in international health informatics standards documents and to develop an approach to the management and harmonization of these terms via an on-line tool. At the meeting, CEN TC251 determined to join this initiative, along with HL7 and all of the ISO, though there is still considerable discussion needed to determine the mechanism for managing this harmonized glossary.

It should be noted that the glossary does not simply intend to provide a list of the terms and definitions, but to indicate 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 contribute to this process.

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

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

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). Three months of 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.

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.

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.

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

5.3 ISO 13606 – EHR Communication

Dr Dipak Kalra of UCL, project lead on 13606 gave an update on progress with the balloting of the 13606 as a European CEN standard and its adoption as an international ISO standard, which may be summarised in terms of the following table (courtesy Dr Kalra):

13606 Part Standard	Status in CEN	Status in ISO
1: EHR Reference Model	EN published in February 2007	Published in February 2008
2: Archetype Interchange Specification	EN published in July 2007	Passed DIS ballot: editorial changes and minor technical typos. FDIS draft ready
3: Reference Archetypes and Term Lists	EN published in February 2008	Passed DIS ballot: comments to be discussed in Goteborg
4: Security	EN published in March 2007	Passed NWIP ballot: editorial changes made, now out for DTS ballot
5: Interface Specification	Out for ENQ/DIS ballot, under Vienna Agreement (CEN lead)	

More detailed information on the progress of each part 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

Part 2 passed DIS ballot with 15 members out of 16 in favour. The status as presented to WG1 in Gothenburg was:

- Editorial comments, mainly to add clarity or adjust for a more international (not just European) perspective
- A few typos in the ADL examples (but not in the formal specification wording)
- Final disposition and FDIS draft circulated in March 2008 to experts
- Disposition has been distributed to WG1 members in advance of this meeting

Following discussion in WG1 in Gothenburg, TC215 resolved that Part 2 could be circulated for Final FDIS ballot with a view to becoming full international standard.

In addition to detailed technical points, there was some general discussion of uptake of EN 13606 archetypes (and *openEHR* templates). 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.

Part 3. Reference Archetypes and Term Lists

Part 3 also passed DIS ballot with 15 members out of 16 in favour. The status as presented to WG1 in Gothenburg was:

- Minor changes:
 - Editorial and clarification comments on the term list sections
 - Need to update the Barthel example

- Need to update the HL7 Clinical Statement model and mapping to the published DSTU version
 - More importantly, the actRelationship.typeCode table is incomplete and cannot be significantly updated at this stage. The question was raised as to whether it should be removed entirely. After much debate, it was resolved to retain the table but be clearer as to the informative nature of some of the codes provided and the need to maintain these in a more dynamic environment.

In its ballot comments, Canada stressed the importance of keeping track of both the harmonization process and the resulting products so that those intending to adopt can refer to the most recent work. Given that standardization processes take time, during which the contents of standards evolve independently, it would be beneficial to add language that gives implementers some hint that it would be prudent for them to refer to the most recent versions of the related harmonization efforts.

The UK review identified some technical and editorial points. Nevertheless the UK preference was to remain supportive of this standard provided timely and appropriately resourced efforts for detailed harmonisation are made with the relevant work of other standard bodies (that is, HL7).

In discussing these comments, Ron Parker (Canada) noted the dynamic nature of clinical/ - concept expression and description. Given that they reflect clinical activity he regards archetypes as closer to terminology (knowledge archetype) than information models. It was noted that the UK NHS have been corresponding with IHTSDO seeking to investigate opportunities for openEHR collaborating with them on:

- 1) Terminology binding
- 2) Governance process – certification
- 3) Management of archetype artefacts

On the technical side, collaborative arrangements include work with Open Health Tooling (OHT). It was also note that:

- Local adoption can make additional implementation information available on a local basis, and
- The tables in Part 3 are essentially vocabulary and many relate to HL7 code sets.

Part 4. Security

Part 4 (Security) passed NWIP and CD ballot (7 in favour, 3 abstentions and 1 against) and is being progressed separately through ISO TC215/WG4. The thrust of technical and editorial comments was to adjust for a more international (not just European) perspective, to add clarity and to align some descriptive text with other ISO security standards (e.g. 27799).

Part 4 was out for DTS ballot to become a Technical Specification with the ballot closing on 28 June 2008.

Part 5. Interface Specification

This part is currently out for DIS/enquiry ballot and comments through CEN and will become increasingly important as people seek to implement 13606 in a services-oriented environment. Collaboration has been established with the Technical Services committee in

HL7 to work on harmonisation between EN/IS 13606 and HI7, particularly in relation to Part 5 and implementation in a services environment.

Way forward

In discussing the way forward, WG1 urged ISO TC/215 to urgently identify a web-based mechanism which could be used as a definitive resource:

- 1) for maintaining technical artefacts supporting standards use including updates to frequently changing reference tables
- 2) to aid implementation and share knowledge (e.g. through FAQ)
- 3) publishing guidance noted and other supportive materials
- 4) that included facilities for these to be uploaded by authorised users from the adopting community.

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.

With the final form of ISO 13606 now emerging, the next few months would also be an appropriate time for IT-014 to progress the project to produce a miscellaneous publication on EN 13606 - an activity which was deferred from last year partly because of uncertainty as to the outcomes of the ISO ballots.

5.4 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 standard for abstract data types to be use in healthcare information interchange.

ISO 21090 is designed to be compatible with and to build on the more generic ISO/IEC 11404 Language independent datatypes standard and also to replace an earlier CEN health datatypes standard and to align with current changes in HL7 abstract datatypes.

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

ISO 21090 is now out for 5 months ballot in each of the three SDOs with the ISO (DIS) and CEN (prEN) ballots closing on 24 September 2008.

Standards Australia along with all other ISO TC215 and CEN TC251 National Member Bodies have been requested to submit their ballot responses by 8 September 2008 (the HL7 Ballot close date) so that the results can be processed at the HL7 Plenary and Working Group Meeting in Vancouver 14-19 September 2008 at which most of those most affected by the changes in this standard are likely to be present. Subsequent ratification of ISO and CEN ballot reconciliations will occur (hopefully) at the Joint Working Group meetings taking place in Istanbul in October.

Grahame Grieve (Australia) and Tom Marley (University of Salford, UK) were present at the Gothenburg meeting to report on the considerable body of work that had taken place in bringing this standard forward to this point. Grahame Grieve had particularly been involved in more

recent integration of the work with activity on R2 of the HL7 abstract data types and seeking resolution of residual issues. His attendance in Gothenburg was supported by the UK NHS CfH program and Jiva Medical. The following points were noted in a reasonably well-attended joint meeting of ISO TC215 WG2 and CEN TC251 WG1:

1. Grahame had tried to be as inclusive as possible in taking on board the stated needs of various users.
2. The proposed standard covers needs for static view of data as well as the dynamic messaging view – although the title of the standard focuses on its dynamic use in information interchange.
3. Any given domain (eg Swedish Health Authorities) may decide that they don't need all of the detail – and may restrict the application of the standard by using profiles (with consequential implications for interoperability between domains).
4. Tom Marley stressed the importance of taking on board the concept of PROFILING (as initially defined in the underlying ISO/IEC 11404 standard) as part of considering and using this standard. Others agreed on the strength of profiling – but considered that it must be more explicitly covered in the document and, of course, the profiles must include the required conformance statements.
5. There was some concern to ensure that the pre-existing European CEN/TS 14796 health data types technical specification was also mentioned – this was acknowledged, added and agreed.

Publication Issues

6. **Format.** Earlier formatting problems appeared to have been resolved but there remained several issues about the final form of the publication.

Should the standard be published in HTML (following HL7 precedent), rather than in MS-Word (as used in ISO/CEN)? It was noted that it is difficult to manage paging in HTML but the same document needs to be issued in HL7.

HL7 has agreed to use the ISO document (subject being able to link into the right place in the document) and despite the document in its present form being very large and tending to crash people's versions of MS-Word.

Dr Dipak Kalra noted from his experience with ISO/EN 13606 that there are some tricks to getting the document done and out the door in an acceptable ISO/CEN format without loss of fidelity in graphics etc. He and the team at CHIME/UCL will assist with this finalisation work.

7. **Normative Annexes.** Are Annexes to the standard allowed to be normative and, if so, which of them should be normative? It was resolved that Annexes A and B will be normative and C, D and E are informative.
8. **Schema status.** Given the size and use of the schema in Annex E, consideration was given to the question of whether the standard should be published as a single specification, as two parts or as two separate documents (potentially one web-based).

It was agreed that the XML schema in Annex E is an important tool in judging compliance and should be part of the standard – particularly given the difficulty of testing compliance against UML specifications; however, HL7 experience has found

that different XML tools give different answers regarding compliance of schemas and therefore are extremely reluctant to set an XML schema as the primary source of normative specification.

Dipak Kalra pointed out that there are other implementations and architectures that may or may not use XML and the logical content of those representations should still comply with the text and UML of the standard.

It was agreed to publish the standard as one document and confirm that Annex E remains informative.

9. Examples. It was agreed that inline examples were valuable for implementation guidance and can be published as informative material

Conformance and adoption questions

10. ISO 21090 Conformance is based on the concept of an “Information Processing Entity”, which is anything which processes information and contains the concept of data type. Examples may include:
 - other standards or specifications
 - data handling facilities and services
11. To claim conformance, any “Information Processing Entity” (IPE) must make a “conformance statement” indicating that it is conformant to ISO 21090 either
 - Directly, or
 - Indirectly
12. To claim Direct Conformance an IPE is required to use healthcare data types as defined in ISO 21090 including implementing their: - attributes, invariants, operations, conformance statements and XML format rules (may define namespace); however, IPE’s claiming direct conformance may:
 - Constrain the data types (e.g. validTimeLow & validTimeHigh SHALL be null)
 - Not make use of some data types (e.g. “Do not use URG”)
 - Add other operations to data types (e.g. Decorate ST with java.lang.String operations)
 - Use other representations for the concepts as well (e.g. CEN 13606 has other ways of doing address; these are still allowed)
 - HL7 V3 claims direct conformance to ISO 21090
 - CEN 13606 will claim direct conformance to ISO 21090
 - Eclipse OHF V3 code will claim direct conformance to ISO 21090
13. To claim Indirect Conformance an IPE is required to define Mappings to Healthcare Data types as defined in ISO 21090, which includes both:
 - Inwards mappings (from 21090 to internal types)
 - Outward mappings (from internal types to 21090)

and must be specific about how the data is mapped.

- *OpenEHR* will claim indirect conformance to ISO 21090 (Grahame Grieve will publish the mappings).
14. 13606 Conformance Statement. This was discussed as a Vienna Agreement item to include production of a conformance profile of datatypes for 13606 by July for Istanbul.

Known Difficult Issues

15. **Overlap with work on HL7 Abstract Data Types.** While completion of this project had overlapped initial consideration of Release 2 of the HL7 abstract data types, Grahame Grieve reported that he had managed the situation and had brought forward as much of the proposed R2 changes as possible – despite opposition from some elements in HL7, who would probably continue to oppose; however, changes are needed for compatibility with implementation tooling, among other things.
16. **Scope of data types.** Basis for making changes to the introductory sections was discussed and agreed. In particular, wording highlighting the fact that datatypes have been defined for use in information interchange and are only normative in that context was simplified. Also statements about how to summarise the nature of the XML provided were discussed.
17. **Stability of enumerations.**
18. **Unicode.** The specification of Unicode had been the source of major concern on the part of the Japanese; however, the alternative of a state-dependent coding system did not conform to other criteria and would break some tooling. Discussed with editors group and a realm specific solution is being introduced to resolve Japanese concerns.
19. **NullFlavor/Wrapper Pattern.** Primitive data type – Boolean in a wrapper.
20. **GTS codes.** National/international holiday codes were provided primarily to manage communications with clinical providers but become nearly impossible to manage as a code set for an international standard used on a global basis (whereas the original HL7 implementation had been US-centric). The matter has been referred back to HL7 for a rational decision.
21. **Relationship with other standards (22220, CIQ etc.).**

Particular discussion had centred on the ebXML CIQ standard as this underpins a wide range of addressing applications in the postal services; however, it was found to be nested and recursive.
22. **Patterns.** The “Thing” class type has been introduced into the Identification pattern.
23. **CD [Concept Description] code / expressions.**

A major change from the earlier HL7 datatypes was allowing expressions within a formal computing language (such as a SNOMED expression) to be used in CD but the particular grammar is not normative. It was confirmed that CD entries continue to allow both a code and a free text description to elaborate on the code.
24. **CD and SC.** Woody Beeler, (HL7) explained the rationale for having both CD and SC data types and indicated that HL7 will clarify its position on this growing issue.

25. **PQ/V** [Physical Quantity/Value].
26. **Flavors (TS.Birth)**. This has been dropped and the model diagram has been simplified.
27. **XML issues associated with the Address (AD) datatype**.

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.

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

Australian review has already identified a need for reconciliation against the more recently published international standards for identification of individual subjects of care and health service providers – which now needs to be progressed.

Those with an interest in health Information Systems development in Australia are encouraged to review the standard, which is currently out to ballot and submit voting recommendations and comments through Standards Australia. Those with an interest should contact Elizabeth.Hanley@standards.org.au in the first instance to register their interest or Grahame Grieve grahame@jivamedical.com for more technical enquiries.

5.5 Harmonization of Patient and Provider Identification

Specific harmonization activities for Patient and Provider Identification have been identified. These activities learn from activities in CEN TC251, ISO TC215 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. Leader: Australia

As part of its investigation of technical methods for authentication of individual identities, ISO TC215 WG4 is planning to circulate members of ISO TC215/WG1, TC215/WG1, CEN TC251/WG1 and TC251/WGIII with:

- A DTR on patient identification
- JTC1/SC37 DTR on biometric identification (including DNA identification)

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

5.6 Pharmacy and Medications Standards

Seven projects in the Pharmacy and Medication Business WG6 work plan are being undertaken under the Vienna Agreement with CEN, with ISO TC215 as the lead SDO. These projects are on the Joint Initiative work program, and each project has an ISO/CEN lead and an HL7 co-lead (approved by HL7).

1. Health informatics – Pharmacovigilance - Structure and Data Elements for Individual Case Safety Reports (name change 2007 Brisbane) ISO 27953
2. Health informatics – Pharmacovigilance – Test names and units for reporting laboratory results (name change 2007 Brisbane) ISO 11595
3. Health Informatics – Identification of medicinal products – Data Elements and Structure for the Exchange of Product Information for Drug Dictionaries (name change 2007 Brisbane) ISO 11615
4. Health informatics – Identification of Medicinal Products – Pharmaceutical Product Identifiers (name change 2007 Brisbane) ISO 11616
5. Health informatics –Identification of Medicinal Products –Structures and Controlled Vocabularies for Ingredients ISO 11238
6. Health informatics –Identification of Medicinal Products – Structures and Controlled Vocabularies for Units of Measurement ISO 11240
7. Health informatics – Identification of Medicinal Products – Structures and Controlled Vocabularies for Pharmaceutical Dose Form, Units of Presentation and Routes of Administration ISO 11239

These projects have been progressing rapidly with weekly teleconferences leading up to the Gothenburg meeting. Issues that emerged at Gothenburg related to the tight timeframes; concerns that comments were not being reflected in updated documents; the need for alignment between the individual case safety report project and the identification of medicinal products (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. Concerns were expressed about the current focus of IDMP work on business requirements for regulatory use cases without giving attention to clinical use cases. All seven projects will remain on the agenda for future Joint Working Group meetings to facilitate discussion of issues and process.

At the Joint Working Group meeting, it was agreed that a work item on Units of Measure would be added to the Joint Initiative Work Program, building on WG6 work and device standards.

5.7 Safety Standards for Health Software

After much debate in WG4 and WG7 recommendations were put and passed at the ISO TC215 Plenary resulting in:

- ISO/DTS 29321 *Health informatics – Application of clinical risk management to the manufacture of health software* being released to ballot of National Member Bodies (NMBs) for agreement to publish 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 released to ballot of National Member Bodies (NMBs) for agreement to publish as a Technical Report.

ISO/DTS29321 is intended to provide for clinical risk management being applied to health software not explicitly covered by regimes for clinical risk management of medical devices, which are covered by ISO 14971, which covers Medical Devices (including software) as defined by regulatory authorities. Some further convergence of ISO/TS 29321, ISO 14971 has been anticipated at their next review cycle, which suggests that close liaison between ISO TC215/WG4 (and WG7), ISO TC210 and the relevant IEC technical subcommittee is desirable.

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 makes an argument for how the level of safety is achieved.

NHS has operated with 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, as the product environment is defined as non-regulatory. Nevertheless, debate on the merits, costs, and appropriateness of having such a standard that might be imposed has been heated at times.

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 WG7 (although WG4 has principal carriage of this particular item). Accordingly, ISO TC215 also resolved:

- that the principles expressed in DTS 29321 and DTR 29322 be communicated to ISO/TC210 and IEC SC62A for harmonization and incorporation into ISO 14971, IEC 62304, draft IEC 80001, and draft IEC 80002; and
- that ISO TC215/WG4 liaise with these standards committees to further this harmonization.

Implications for Australia

The upcoming ballot on acceptance of ISO/DTS 29321 and ISO/DTR 29322 for ballot and, if passed, potential adoption is relevant to many Australian interests including from 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.

Given the level of debate on these documents in the committee stages, it is important that Australia's votes on them are appropriately informed by consideration of the documents and balanced debate of the issues by those affected. Such debate should also pave the way for adoption, implementation and possibly local adoption, if appropriate.

Working Group Reports

6. WG1 – Data Structure

Of the matters addressed by WG1 at the Gothenburg meeting, the following have been reported either separately as major issues or under other working groups (where indicated) and are not further considered in this section of the report:

- Glossary of terms for health informatics
- ISO 21090 - Harmonized Data Types
- ISO 13606 – EHR Communication
- ISO/TS 18308 (see notes on WG8)
- ISO/TS 10781EHR functional model (see notes on WG8)
- The proposed PHR functional model (see notes on WG8)
- Future review of patient and provider Identification (see major issues)
- Personal Health Task Force (joint with WG7, WG8 and CEN TC251) (see WG8).

6.1 Provider Identification (ISO/TS 27527)

Heather Grain reported to a combined meeting of WG1, WG4 and WG8 and CEN TC251 WGI and WGIII on the progress of the ISO/TS 27527 Provider identification technical specification. Points noted included:

- Comments from the DTS ballot and subsequent discussions have now been resolved with the document receiving approval to be submitted for publication as an ISO Technical Specification – as soon as the final edited version is submitted to the TC215 Secretariat.
- The objective was to identify all the data elements that can be used for the identification of providers in the healthcare environment. It is a maximum data set that you don't need to use all of.
- The standard caters for identification of health care providers, noting that health care professionals are health care providers but not all HC Providers are necessarily professionals.
- Value domains. Some commentators have indicated that they need more.
- Privacy. It was suggested that additional explanatory information may be needed to tailor the information set to the needs of individual organisations and situations.
- Bernd Blobel supported the idea of a maximum data set but also considered that the minimum data set for safe identification is required. Heather Grain considered that the TS already addresses this in functional terms.
- In response to another query, it was noted that this work had been cross-checked against the V3 provider registry in Canada.
- Where there is a national identifier – can't an OID just be concatenated to yield a relevant identifier. Yes – the standard does support this for computer to computer applications but the standard also needs to support humans.

6.2 Health Information Services Architecture (HISA)

Pier-Angelo Sottile (Italy) gave the presentation on ISO 12967 health information services architecture (HISA) to a joint meeting of ISO TC215/WG1 and WG8.

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

NWI ballot for adoption as an ISO standard opened in October 2007 and closed Jan 2008 with the item being approved. It is now being developed using a fast-track approach with all three parts currently being out for DIS ballot which opened on 3 March 2008 and closes on 28 August 2008.

Rationale for HISA

Health care organisations have a large number of specialised units with domain-specific systems that need to interoperate with each other and with external information providers to share common data sets - otherwise they become islands.

In order to support such sharing, they need to share a common information model and a common service model – which needs to be provided in technology independent ways.

ODP has identified the viewpoints that are required – enterprise viewpoint, information viewpoint, computational viewpoint. Basically the organisation needs to use them to define the general principles and general services that can be translated into detailed application implementations.

ODP also has an engineering viewpoint and a technical viewpoint. These are much closer to the actual implementation solution. The vendor takes the higher levels as defined.

An HL7 informative mapping document is also being prepared under direction of a Task Force (led by Frederik Endsleff).

Summary of purpose and application

- 1) Identify a methodology to describe healthcare information systems
- 2) Identify the fundamental architectural aspects
- 3) Architecture is therefore intended as a basis both for working with existing systems as well as for the planning and construction of new ones
- 4) HISA takes care of identifying a Service architecture comprising the information model and the services model required in a healthcare enterprise for handling its common information and functionality both at local and territorial level
- 5) General principles:
 - Information must be separated from specific application and accessible through services
 - Services logic must be independent from technological issues
 - HISA integrates and makes available the existing information assets, facilitating the interoperability of applications

- It specifies a unified, open architecture based on a middleware of information services independent from specific applications/technology
 - Capability for integrating the common and basic information set and business logic.
 - These services are available to diverse, multi-vendor applications through many types of implementations
- 6) Provides formal basis for specifying:
- Fundamental elements of a comprehensive information model capable of supporting the whole healthcare organisation in terms of managing the common and basic information set
 - Fundamental characteristics of a set of services for managing common information and for performing common business logic.

The approach has been implemented in Denmark, Italy and other countries.

Comments:

- Canada, US, Denmark, Sweden were all largely positive - links to HI7 mapping document
- The Netherlands voted negatively (only negative vote) - no need for a standard as it is just the application of ODP. Rejected – a majority has agreed to go forward.
- Dipak Kalra of the UK noted that this work could inform the broader issue of an EHR blueprint in a couple of years time, and further iteration is worthwhile.
- A UK expert commented - ?hospital-based only; ?business processes/workflow esp. community initiation and discharge back to community. Needs to support the wider picture.

Next steps

Gunner Klein, the Japanese and others will author an informational document to put this into a broader perspective for the next Istanbul meeting (which will include Ken Rubin's SOA meeting)

Implications for Australia

HISA is focussed on providing an appropriate standardized framework for a health interoperability architecture. It is gaining greater acceptance in both Europe and North America. It would be of benefit to Australian interests including NEHTA and the jurisdictions to consider the suitability and whether they can leverage benefits for this standard. The most beneficial time to do this is as part of the current DIS ballot process (which has only 2 months left to run).

6.3 Other WG1 matters

Other matters progressed by WG1 included:

- Clinical data warehouse (ISO 29585).
- Progress reporting on detailed clinical modelling issues

- Archetypes and clusters (for device interfaces).

Melvin Reynolds (WG7) led this joint session of working groups 1, 2, 7, 8 and CEN TC251 which was considering whether the archetype or cluster concept might be used to define elemental information components for transfer of information to/from automated medical devices. A session had been conducted on this topic in Brisbane in August 2007, led by Dr Sam Heard and Melvyn Reynolds.

Device manufacturers have to submit their interface information structures to regulators to get approval – therefore they are unable to ‘do in the field’ transforms to devices. Therefore they are seeking one global system of information representation perhaps with different front ends able to manage small fixed information components that can be approved and then mixed and matched as required. It is a difficulty for them if they have to be separately certified against both HL7 and 13606/*openEHR* approaches.

Investigating an approach based on 13606 with some of the contemporary tooling is one possible approach.

- Participation in discussions on semantic harmonisation hosted by WG3.
- Validation of Human Identities. Prof. Bryan.R.M.Manning (UK) presented research observations on the reliability and uniqueness of different human biometric indicators and concluded that an examination of multi-factorial DNA markers provided the best approach.
- Country Identifier Standards (ISO/TS 17120)

A systematic review of this standard had been conducted and, following consideration it was decided to recommend that it be withdrawn from the ISO TC215 program of work. The recommendation to withdraw was made with the following considerations:

- ISO 3166 *Codes for the representation of names of countries and their subdivisions*, and its supporting maintenance agency are available to support ISO TC215s country code needs.
- ISO TC215 and ISO/TC46 *Information and documentation* (which oversees ISO 3166) have a liaison to effect any future changes required by ISO TC215.
- Health Indicators Conceptual Framework (ISO/TS 21667). This standard was also up for review and, following consideration, It was agreed to confirm this as a work item and initiate a project to develop it up to a full International Standard at the current level of granularity.

Canadian Institute for Health Information (CIHI) is willing to lead – WG experts invited to participate.

7. WG2 – Data Interchange

Of the matters addressed by WG2 at the Gothenburg meeting, the following have been reported either separately as major issues or under other working groups (where indicated) and are not further considered in this section of the report:

- ISO 21090 - Harmonized Data Types
- ISO 13606 – EHR Communication

- Safety Standards for Health Software

The use of some material from draft minutes for the ISO TC215/WG2 meeting in Gothenburg circulated by Dr Adrian Stokes (UK) is gratefully acknowledged.

7.1 Web access to DICOM persistent objects (WADO)

The DICOM (Digital Image Communication in Medicine) standard is one of many standards produced and maintained by the NEMA consortium (a US-based electrical equipment manufacturers association with global presence). Despite originating from a national industry consortium, DICOM standards have widespread acceptance around the globe as the principal means of representing and communicating medical images in digital format and is supported by secondary specification such as IHE interoperability profiles and RANZCR/NATA accreditation rule. DICOM is also prominent for management of images and related metadata in other application areas including cardiology, radiotherapy and pathology laboratory imaging.

WG2 originally developed ISO 17432:2004: *Health informatics — Messages and communication — Web access to DICOM persistent objects (WADO)* as a standard to provide requesters of medical imaging studies and care providers rapid and reliable access to reports and images without duplication of the data objects via web-based technologies.

Some clinicians (or their clinical applications) need to have access to the original data in native DICOM format that allows extensive manipulation using specialized software using DICOM meta-data, while others need them rendered into generic format s(e.g. JPEG, PDF) that can be presented with off-the-shelf applications.

ISO 17432 specifies the means whereby a request for access to a DICOM persistent object is expressed as an HTTP URL/URI (see IETF RFC2396) request which includes a pointer to a specific DICOM persistent object in the form of its instance UID. The request also specifies the format of the result to be returned in response to the request (which includes an ability to obtain reports as HL7/CDA Level 1 documents).

Given the need for all International Standards to be subjected to periodic review (and especially those reliant on contemporary ICT functionality) the WADO standard had recently undergone its systematic review. In the review 11 P-member countries had supported continuing with the present standard as-is, while France and Sweden had voted for revision.

At the Gothenburg meeting Cor Loef (Philips Healthcare, The Netherlands) proposed 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. There was discussion as to whether this should become part of the existing WADO specification but ultimately WG2 resolved to progress this as a separate items.

Accordingly it was recommended to (and subsequently accepted by) ISO TC215 that:

- (a) The ISO 17432 WADO standard be reconfirmed without change; and
- (b) A proposal for a new work item be circulated to develop a standard entitled “*Web access to DICOM persistent objects by means of web services*” (noting that consideration subsequent to the NWIP ballot may result in this become either a new standard or an extension to WADO).

7.2 Telemedicine

WG2 was informed that Brazil had not yet been able to obtain resources for their proposed work on telemedicine/telehealth interoperability but hoped that they might be able to do so within the next six months.

Work had been undertaken in the Netherlands and Johan Beun (Johan@Beun.nl) gave a presentation on their work. The Dutch national body have offered to prepare a New Work Item Proposal together with a Committee Draft. There was support from five countries for this work - USA, Canada, Brazil, The Netherlands and Australia (with Prof Anthony Maeder to be nominated as an expert).

Telemedicine will be proposed as an area for general standardisation endeavours (e.g. scope and terminology; business processes) due to importance of establishing open and consistent practice internationally. If this is not done, we could have a situation of proliferating proprietary solutions and ad hoc practices, allowing scope creep of clinically accepted activities which are deemed telemedicine which may compromise processes such as regulation and reimbursement.

Netherlands has produced a National Technical Agreement (which will become ratified by their national SDO) outlining aspects which could be considered for standardisation, and will propose this in a new work item for WG2. Active support was noted by Australia, Brazil, Canada.

Implications for Australia

The Telehealth Standards framework produced by Standards Australia IT-14 could be contributed to this effort, and areas identified for standardisation effort by AUS (e.g. telehealth session records) could be proposed for international consideration.

Standards Australia IT-14 should take an active role in participating in this ISO Work Item, given its position of comparative strength and experience in Telemedicine.

7.3 Clinical Genomics Projects

Jun Nakaya gave a presentation on the current status of the ISO 25720: Genomics Sequence Variation Markup Language (GSVML), which is currently under DIS ballot with a deadline of 7 July 2008. The US representatives indicated that the US intended voting positively but will submit comments which were briefly discussed. The formal ballot comments would be reviewed at the Istanbul meeting.

There was discussion on the work being undertaken in the HL7 Clinical Genomics SIG (chaired by Amnon Shabo) on the Clinical Genomics - Pedigree Project. Following detailed discussion and review, it was agreed that this would be raised as a New Work Item Proposal (which was subsequently accepted by the TC215 Plenary).

7.4 IHE Integration Profiles (TR 28380)

Charles Parisot had circulated a draft of Part 2 ("Integration and Content Profiles") to a few members of the WG (excluding the Secretary!). He then gave a presentation on the document which led to considerable discussion and various changes to the document were agreed. The revised version (N0605) will be submitted to TC 215 for approval to start the DTR ballot.

Charles Parisot had not yet drafted the statement of the scope and aims for:

- “*Conformance Testing for Interoperability, Methodology, Process and Test Tools*” nor for
- “*Use cases and profiles*”.

7.5 CDISC proposal

Dave Iberson-Hurst (CDISC VP, Technical Strategy) gave a presentation on CDISC (Clinical Data Interchange Standards Consortium) and the BRIDG (Biomedical Research Integrated Domain Group) Model which is a domain analysis model.

There was considerable discussion on the best means of bringing proposed standards from CDISC into the ISO process. It was agreed that the best route into TC 215 was probably via WG2 although there was overlap with other WGs. A NWIP will be prepared for the BRIDG standard which would be progressed by the Architecture sub-group within WG2.

7.6 Document Registry Framework (TS 27790)

The Committee Draft was presented and there was discussion whether this should be submitted for ballot. Previously, it was expected that the document would be an extension to the IHE XDS profile but the new proposal was a “stand-alone” solution, external to XDS.

Charles Parisot (IHE) objected to the document being submitted for ballot without further discussions with IHE. After considerable discussion, it was decided (with one against) that the document should not be submitted for ballot and that there would be a final attempt to resolve the differences prior to the Istanbul meeting.

7.7 Progression of core HL7 standards

The following is the status of several other core HL7 standards currently being put through acceptance as full International standards:

- (a) ISO 27931: *HL7 Version 2.5*. This was under DIS ballot, terminating on 10 June 2008. It was anticipated that a disposition of comments would be available in time for the Istanbul meeting in October 2008.
- (b) ISO 27932: *Clinical Document Architecture R2*. This was also under DIS ballot, terminating on 10 June 2008. It was anticipated that a Disposition of Comments document would be available in time for the Istanbul meeting.

7.8 Other matters

- Since there had been no progress on the following items for a considerable time, it was agreed to drop them from the work programme:
 - *Meta-Data-Model for Usage in Standardisation of Class Models*
 - *Web Services Profile for Healthcare*
 - *Model of Stakeholder Roles*

- ISO/TR 21089:2004 *Trusted End-to-End Information Flows*. Periodic review and update of this published technical standard was being led by Gary Dickinson (HL7/USA) but was suspended pending completion of related work in HL7 which will be submitted to ISO
- ISO 10159: *Web Access Resource Manifest (WARM)* Nicholas Brown gave an update on this work. A proposed Committee Draft (V9) had been circulated to interested parties and it was agreed (unanimously) that the sub-group involved with this work should complete the CD then issue it for comment.
- ISO 17113: *Methodology for Development of Messages*. There had been some confusion about the location of the final draft for publication and the Disposition of Comments document. It was confirmed that Tom Marley had forwarded the final versions (N0609 and N0610 respectively) to the WG Secretary who had then forwarded them to the TC 215 Secretariat for publication.

8. WG 3 Health Concept Representation (terminology)

This working group had a very large attendance with representatives from Australia, Brazil, Germany, France, Sweden, Denmark, Finland, Netherlands, UK, USA, Canada, Japan, 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 2 Terminology working group met jointly with ISO TC215 WG3 throughout the Gothenburg meeting. This resulted in a number of new work items for ISO that will be brought forward from CEN to become full international standards and are included in the list below. This is indicative of a much closer relationship between the European and ISO working groups.

To further assist collaboration between the relevant ISO and CEN working groups, HL7 Terminology TC and WHO, it was agreed that action items will be reviewed and a day will be put aside for discussion of joint work items at the next meeting, with material being circulated prior to that meeting.

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

Of the matters addressed by WG3 at the Gothenburg meeting, the following have been reported either separately as major issues or under other working groups (where indicated) and are not further considered in this section of the report:

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

8.1 Review of standard on categorical structures for terminologies of procedures (EN 1828)

The European Standard EN 1828:2004 – Health informatics - Categorical structure for classifications and coding systems of surgical procedures is now due for review and it is

proposed that this work take place within CEN TC251/WGII as a joint activity with ISO TC215 WG3, with a view to the completed product then being accepted as a full International Standard (under the Vienna Agreement, which allows ISO to delegate the production of a standard to CEN and vice versa).

Categorical structures offer a set of categories to standardize the structure for specific types of clinical information. These support archetype development and the development of hierarchies, sub-sets and implementation strategies. Europe has developed a number of structures of this type. This standard initially considered only surgical procedures but now requires review, according to the review requirements of international standards. The intention is that the existing CEN standard will be reviewed and extended to incorporate the broader categorical structures required to represent health care actions or interventions in general.

There was some initial confusion about how categorical structures related to, and differed from, classifications and terminologies. The categorical 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. The title has been changed – new title is Categorical structures for terminologies of procedures.

This work will incorporate review of the ISO nursing terminology standard to include interventions. WHO expressed initial concern about activities that might conflict with its classifications of procedures in medicine. After discussion it became clear that this work supports WHO developments, and in fact will be likely to inform these developments. The WHO member states are seeking developments of this area and, in particular, tools for use in recording 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. Work lead by Netherlands

Implications for Australia

Potentially informing 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.

8.2 Adoption of EN 13940 - System of concepts to support continuity of care

Consideration was given to whether and how the two parts of European standard EN 13940 should be adopted within ISO.

- EN 13940-1:2007 *Health informatics – System of Concepts to Support Continuity of Care – Part 1: Basic Concepts* is 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* is in the early stages of development as a European Standard by CEN TC251 WG2.

EN 13940 Part 1 – Basic Concepts

The meeting agreed that Part 1 should be fast tracked into the ISO work area. A new work item proposal will be prepared for ballot in the next few months, with an additional explanatory document to introduce and explain the concepts contained within it. Although the document could go straight out as a Draft International Standard for 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.

This document has been produced as a pre-standard and has now been published as a full standard and has been adopted as the basis of the requirements of northern European countries, Belgium and France. The UK delegation supported the proposal but there are concerns about the applicability of the western values and process in environments such as traditional health care settings. The UK suggested that some of the questions that need to be considered when viewing the document include the international applicability of the health care service and health care organisations. Work item is lead by France.

EN 13940 Part 1 – Core process and work flow in health care

The work 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.

Implications for Australia

Given jurisdictional developments of data collections in this area it seems a logical area of interest to Australia. Liaison with groups involved in this type of data collection should be established. For example, it is known that Victoria is establishing considerable data collections in this area through the Victorian Integrated Non-Admitted Healthcare Minimum DataSet - VINAH.

Liaison with NEHTA may also be appropriate insofar as these developments may impact upon referrals.

8.3 Clinical knowledge resources – Metadata (CEN/TS 15699)

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 will be 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). It is intended that this work be forwarded for comments more than once, as significant additions/comments are expected to improve the document.

Implication for Australia

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

8.4 Categorical structures for systems of concepts – Model for representation of semantics (EN 12264)

EN 12264 - Categorical structures for systems of concepts – Model for representation of semantics is being reviewed for possible revision within CEN TC251/WG2

This is an existing European standard on how to develop categorical structures - a sister document to *ISO 17115 Vocabulary of terminological systems (VOTE)*. A review of this document will also be required soon. Noting that there are overlaps and some conflicts between these documents, it is intended to have a workshop session on this issue at the next meeting, and to investigate the place that the international health informatics glossary might be able to offer in assisting to clarify these issues. All terms from both the ISO and CEN documents are to be entered into the 'Glossary' prior to the next meeting.

Implication for Australia

This work will simplify and clarify the work in both terminology and classification initiatives and should be supported by Australia. The work is being lead by Europe, but requires support for the glossary initiative which is being managed by Australian expertise.

8.5 Syntax to represent the content of medical classification systems (EN 14463:2007)

The document EN 14463: 2007 – Health informatics – A syntax to represent the content of medical classification systems has recently been approved as a European standard.

WHO actively use this standard and recommend it for exchanging files using the formats specified in the standard. This standard also underpins the development of ICD11. It will be prepared as a New Work Item Proposal for ISO adoption via the Vienna Agreement with CEN lead. Denmark is to lead the work.

Implication for Australia

This work should be supported by Australia but will require little if any effort other than distribution of the document to identified interested parties.

8.6 EN 15521:2007 – Health informatics - Categorical structure for terminologies of human anatomy

This standard has been developed to represent the specificity of the field of the knowledge of medicine in human anatomy with embryology anatomy. It is based upon available open source anatomical systems from the International Model of Anatomy (which is being used extensively in Europe). This methodology has been applied to produce semantic categories that are taken within the hierarchy of the Family of Medical Anatomy (FMA) but not down to the cell or microbiological level as these are not yet stable. The semantic links are taken from the FMA with their definition. The domain constraint is that you must say which level of the hierarchy is to be used when referring the anatomy. IHTSDO has a plan to align SNOMED-CT to FMA. There is a working relationship between CEN and FMA to handle changes and update the CEN document. A process for ongoing control needs to be considered.

France is to lead the work on behalf of CEN and it is considered that Australia currently only needs to maintain a watching brief.

8.7 Criteria for the categorisation and evaluation of terminological systems (ISO/DTS 17117)

ISO/DTS 17117: *Health informatics – Criteria for the categorisation and evaluation of terminological systems*. This work item has passed voting for revision. There were significant technical comments and the working group proposed to the Technical Committee that these comments, in conjunction with the original modifications be used to build a more comprehensive document that broadens the scope of the work, from a simple modelling of the problems, to a more detailed solution based standard. This was accepted by the TC.

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.

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

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

This is a technical report that looks at the behaviour of the organisation of and the management requirements for standardised terminology systems. Though this has just been accepted through the voting process as a new work item the work was already a major piece of work, having been well worked up prior to going into the work item system. Discussions with the CEO of IHTSDO, Jennifer Zelmer indicated that this (and the mapping

item discussed below) is the type of work item which IHTSDO have found particularly useful. Some comments have been received and will be incorporated particularly focused on the processes for developers of terminologies. Work is being led by UK.

Implication 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. Further information can be obtained from Heather Grain at heather@lginformatics.com

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

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

- the value and purpose of mapping. What is a map and how and 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 would 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.

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.

8.10 Principles and guidelines for measuring conformance in the implementation of terminological systems (ISO/NP TR 12310)

This is another new work item. It passed ballot during the previous few months, and is now being developed through Canadian lead. There was significant international support for this work item and many comments were received. This document will focus on the best practice for implementation of terminologies in EHR systems.

An example of a conformance principle is versioning - how people should react to versioning for conformance, including appropriate management of historical information through terminology servers which apply existing standards to conformance in implementation. This work relates to the HL7 document on common terminology services. The principles included in this document will relate to terminologies and to classifications.

Implication 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.

8.11 OID Registration Problem – referred from HL7

The current ISO process for issuing OID numbers requires that a new OID be registered every time the standard or content of that OID changes.

The original OID objective of an unchangeable name for a concept is not achieved. For example, HL7 have the approach that you always call country – Country, but the values within the domain change while ISO call country, country1, country2, country3 etc changing the actual entity by changing the OID.

HL7 and the German delegation to the meeting requested that the TC put forward a request to ISO to review their current process in consideration of both the maintenance cost and safety issues inherent in this change process for health care.

8.12 Potential future activity

WG3 have a full work program at the moment, but in their longer term plan there is significant international interest in incorporation of user interface and clinical decision support standards to improve patient safety. 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.

Implications for Australia

These will advantage Australia through the availability of internationally established software standards that support safer health information representation. It will increase the quality of Australian implemented software from international vendors reducing costs of modification to comply with existing Australian standards. Progressing standards in this

area will require ongoing support of international standards development activities (attendance at meetings, as well as input to the development process within Australia).

8.13 Other matters

- ISO/HL7 DIS 27951: *Health informatics – Common terminology services*. Release 1 is currently on circulation for ISO/DIS ballot.
- ISO 18104:2003: *Health informatics – Integration of a reference terminology model for nursing*. This document is coming up for review and will be considered in depth at the next meeting to be informed by the other work items, such as categorical structures.
- ISO/TS 22789: *Health informatics – Conceptual framework for patient findings and problems in terminologies*. This technical specification has been forwarded for publication.

9. WG 4 Security

Of the matters addressed by WG4 at the Gothenburg meeting, the following have been reported either separately as major issues or under other working groups (where indicated) and are not further considered in this section of the report:

- Glossary of terms for health informatics (covered as a major issue at 5.2 above)
- Consideration (jointly with WG7) of the proposed DTS 29321 and DTR 29322 for risk management in health software (covered as a major issue at 5.7 above)
- Proposed review of identity management, provider identification and the identity management framework – progressed in joint meetings with WG1, WG8 and CEN 251 (reported as a major issue at 5.5 above).

9.1 Recent publications from WG4

Since the ISO TC215 meeting in Brisbane, the following standards had been submitted for publication:

- ISO IS 27799: *Health informatics – Security management in health using ISO/IEC 27002* (approved as full international standard with 20 countries in favour, none against, and 4 abstentions).
- ISO TS 25237 *Health informatics – Pseudonymisation*. WG4 resolved remaining comments in email discussions since its Brisbane meeting.
- DTS 21298 *Functional and structural roles*. WG4 resolved remaining comments in email discussions since its Brisbane meeting.
- ISO/TS 17090:2002 Health informatics – Public key infrastructure
 - Part 1: Framework and overview,
 - Part 2: Certificate profile,
 - Part 3: Policy management of certification authority

All three parts have now actually been published – leading to an ISO press release in March and an article in recent edition of ISO Focus.

9.2 Secure archiving of EHR data (ISO 21547)

Work in bringing this long-standing work item to ballot was progressed significantly at the Gothenburg meeting with a detailed review of drafts of the two parts and TC215 having now approved that:

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

9.3 Revision of ISO 21091: Directory services.

A request from CEN TC251 WG III to coordinate with CEN by Vienna Agreement in the revision to a full International Standard of TS 21091 *Health informatics – Directory services for health care providers, subjects of care and other entities*; with ISO TC215 in the lead was accepted.

Following review and update at the Gothenburg meeting, it was resolved to issue the updated version of this document for ballot as a Draft International Standard (DIS)

Implications for Australia

It is important that this document, which has not originated from the mainstream identity management and directory services environment be closely scrutinised by Australian interests during the upcoming DIS ballot.

9.4 Name and the scope of WG4

After considerable discussion it was decided to seek the approval of TC215 to amend the name of the WG to: “Security, Safety and Privacy” and its scope to:

“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 adversity affecting patient safety;*
- 3) *protect privacy in relation to personal information; and*
- 4) *ensure the accountability of users of health information systems.”*

The plenary noted the request but deferred its consideration to the Istanbul meeting, at which time a mini-Plenary would be held.

9.5 Other WG4 matters

Some of the other matters addressed by WG4 in Gothenburg included:

- Finalisation of the two parts of technical report ISO TR 11633 *Health informatics — Information security management systems (ISMS) for remote maintenance of medical devices and medical information systems*:

- Part 1: Requirements and Risk assessment, and
- Part 2: Implementation of ISMS

These two documents have now been released for publication and are based on existing processes and procedures that originated in Japan.

- Progression of ISO 22600: *Privilege management and access control* (PMAC) standard. The first two parts of ISO 22600 have now both been published. It was agreed in Brisbane that the finalised draft of Part 3 (Implementations) should be submitted for balloting as a Technical Specification following update but this was not completed. The proposed changes were further discussed in Gothenburg with a view to the draft being submitted for ballot by early July 2008.
- Audit trails for EHR (ISO 27789). Two sessions in Gothenburg were occupied with review, update and comment preparing the Committee Draft of this document. The TC215 plenary approved its being circulated to national member bodies for ballot and comment.
- DTS 13606-4: Health informatics – Electronic health record communication – Part 4: Security. The DTS ballot for acceptance of this standard closed on 8 June and comments from the DTS ballot will be resolved at the October meeting in Istanbul.
- Hosting a Joint meeting with WG5 on health professional cards.
- ISO 22857:2004 *Health informatics – Guidelines on data protection to facilitate trans-border flows of personal health information*. This was reviewed in Gothenburg with work planned to continue in Istanbul.
- ISO/DTR 11636 *Health Informatics – Dynamic on-demand virtual private network for health information infrastructure*. Work continues on this project, which was initially put forward by Japan in April 2006. It is now planned to have a revised draft ready for consideration by WG4 two months prior to the next WG4 meeting in Istanbul.

Implications for Australia

Standards Australia Sub-committee IT-014-04 will need to arrange for review of:

- PMAC Part 3 in the Australian context, once the DTS ballot is received in July/August.
- The Committee Draft of ISO 27789: *Audit trails for EHR*, once the Committee Draft is received for ballot and comment – this is the most influential time to insert comments on work in progress as they can be taken into account in going to the next stage – Draft International Standard

10. WG 5 Health Cards

Most parts of the ISO 21549 series of health card standards (which define clinical content as well as identification information) were completed some years ago and have been widely applied particularly in European countries. The full series of standards and proposed standards is as follows:

- Health informatics - Patient healthcard data - Part 1: General structure

This first part of the ISO 21549 international standard defines data structures held on patient healthcards compliant with the physical dimensions of ID-1 cards defined

by ISO 7810 and gives a general structure for the different types of data defined in separate parts of the standard.

- Health informatics - Patient healthcard data - Part 2: Common objects
- Health informatics - Patient healthcard data - Part 3: Limited clinical data
- Health informatics - Patient healthcard data - Part 4: Extended clinical data
- Health informatics - Patient healthcard data - Part 5: Identification data
- Health informatics - Patient healthcard data - Part 6: Administrative data
- Health informatics - Patient healthcard data - Part 7: Medication data
- Health informatics - Patient healthcard data - Part 8: Links [*See below]
- Health informatics - Patient healthcard data - Part 9: Health Data [*See below]

Most parts of the ISO 21549 series of health cards standard are stable but need periodic review.

10.1 ISO 21549 Health cards - Part 8: Links

The New Project (NP) proposal for a new Part 8 of the ISO 21549 Patient healthcard data dealing with the storage of links on the card links was put to member ballot and agreed (9: in favour, 0: against, 6: abstain).

This matter is being progressed jointly with WG III of CEN TC251 and was discussed at the CEN meeting in Dublin in October 2007, where it was agreed that some changes to the XML examples were needed. These were subsequently done and were accepted at the Gothenburg meeting.

The revised Part 8 document will now be circulated for ballot/ comment as a Committee Draft. Australia has limited expertise to contribute to this work and lacks any widespread implementations – although we did push for inclusion of the Links segment some years ago

10.2 ISO 21549 Health cards Part 9: Health data

With strong support from representatives of China (PRC), WG5 held an initial discussion on the use of health cards for recording health, wellness and lifestyle data as well as the disease information that is already accommodated.

Chinese experts have agreed to bring forward a proposal for Part 9 of ISO 21549 identifying information that might be recorded on a healthcare card for “health” purposes – such as keeping track of health education, protection or promotion information.

10.3 Other WG5 matters

Other activities undertaken by WG5 at the Gothenburg meetings included:-

- A study of emerging new types of card formats and other technologies (such as CD-ROM, DVD or USB sticks) - resulting in a suggestion that the scope of WG5 activities be broadened.
- Joint work with WG4 (Security) on developments in health professional cards and provision of specialised assistance to WG4 in their work in this area.

11. WG 6 Pharmacy and Medication Business

Of the matters addressed by WG6 at the Gothenburg meeting, the following have been reported either separately as major issues or under other working groups (where indicated) and are not further considered in this section of the report:

- Pharmacy and Medications Standards on the Joint Initiative work program (at 6.6)

Other projects on the Working Group 6 work plan were discussed as follows:

1. Business Requirements for the Reporting of Pharmacist Services TR 10895 – The project lead was not present, however input on the draft was requested.
2. Business Requirements for an International Coding System for Medicinal products TR 25257 – This was the subject of the only WG 6 resolution at Gothenburg. The project which is currently a preliminary work item will be put forward for a draft TR ballot with the New work item ballot.

Implications for Australia

Australia should increase its involvement in WG6 projects beyond the current monitoring /watching brief. Liaison for WG6 projects should include NEHTA and State representatives interested in identification of medicinal products and case safety reports. This work originated in Europe and now has gained involvement from HL7, and Australia needs to consider the implication of the draft ISO Standards on Australian medicinal initiatives.

12. WG 7 Devices

Of the matters addressed by WG7 at the Gothenburg meeting, the following have been reported either separately as major issues or under other working groups (where indicated) and are not further considered in this section of the report:

- ISO-CEN-HL7 Collaboration [through the JIC/JWG]
- Glossary of terms for health informatics
- Safety Standards for Health Software

WG7 works closely with relevant IEEE, ISO and IEC committees that deal with medical devices and interfaces.

12.1 Communications - Personal Health and Point of Care Devices

Work on standards for data formats and data communications for Personal Health Devices and Point of Care Devices are being progressed using basic technical specifications through the IEEE 11073 family of standards (where TC215 has partner SDO status within IEEE). At the Gothenburg meeting WG7 arranged for the following IEEE personal health device communication specifications to be progressed via a preliminary 30-day announcement ballot to an FDIS ballot for final acceptance as a full international standard

(with target date for paperwork to be with ISO TC215 Secretariat by 1 Aug 2008, in most cases):

- Pulse oximeter (IEEE 11073-10404)
- Blood pressure monitor IEEE (11073-10407)
- Thermometers (IEEE 11073-10408)
- Weighing scales (IEEE 11073-10415)
- Glucose meter (IEEE 11073-10417)
- Cardiovascular fitness and activity monitor (IEEE 11073-20601)
- Strength fitness equipment (IEEE 11073-10442)
- Independent living activity hub (IEEE 11073-10471)
- Medication monitor (IEEE 11073-10472)

and also:

- Point-of-care medical device communication – Ethernet Transport profile (IEEE 11073-30400)

Implications for Australia

Stakeholder groups interested in PHRs (e.g. NEHTA) need to be aware of this activity and associated discussions. There are many implications arising from the need to handle future input feeds to PHR; these need discussions - especially in terms of scope, information content (and how to summarise) and fixed versus portable technologies.

12.2 IT-networks incorporating medical devices

Incorporation of Medical Devices into IT Networks via ISO-80001 provides a framework for defining provision/collection of information for functionality, performance, security, risk management. These aspects were explored over several sessions which included liaison representatives

The Standard cannot explicitly prescribe detailed obligations on manufacturer/supplier nor customer/manager for information items, but can prescribe a minimum list of item types

The Standard allows for negotiated seeking of additional information, as well as describing a reasonable range of summary information to be given upfront (for which more detail can subsequently be sought). The Standard acknowledges agreement between parties on responsibilities.

A classification A, B, C (life-critical, mission-critical, operation-critical) of data communications and channel characteristics should be included, giving rise to control measures (e.g. segregation) as part of risk management.

Implications for Australia

Make stakeholder Health IT Network responsibility holders aware of the work taking place on this standard.

12.3 Other WG7 matters

- ECG Communications and Medical Waveforms.

ISO FDIS 11073-91064 *Standard communication protocol — Computer-assisted electrocardiography* has also been reviewed and approved for balloting (in June/July) along with a technical specification: ISO 11073-92302, “*Health informatics – Medical waveform format – Encoding rules, long term ECG*”.

US-FDA originally proposed both of these to WG7 for ISO adoption via HL7.

- Online registration of new devices/ updates.

Efforts are continuing through HL7 to allow device type and identifying information to be standardised to facilitate online electronic registration of device type information. FDA in the US are proposing process of electronic lodgement by manufacturers to populate international database. Agreement is being negotiated with Continua Alliance to allow their first interoperability standard to be contributed to ISO to assist in standardizing such processes.

All meetings of WG7 are scheduled as joint meetings of ISO TC215 WG7, IEEE 11073 and the HL7 DEV SIG (Devices SIG) held in rotation at each of these organisations' major events – increasing the work rate to around 5-6 meetings per year.

13. WG 8 Business Requirements for Electronic Health Records

13.1 EHR Classification Framework

The Working Group revisited the framework and current work underway to populate the Standards Knowledge Management Framework Tool (SKMT) with glossary terms and definitions. The Working Group also revised the decision to publish an ad hoc internal report titled “EHR Classification Framework”. It was agreed that there was value in moving this project forward as a Technical Report, and the project will be lead by Andrew Grant, of Canada, who has developed the SKMT. It is intended that the title of the project be changed to Knowledge Management of Health Information Standards. There is broad support for this move from several countries including United States, Japan, China, Sweden, Australia, Canada and the UK.

13.2 Requirements and specifications of common essential information for health summary records

The draft Technical Report *ISO DTR 12773 Business requirements for health summary records* passed ballot at the end of March 2008. This project has been lead by Marion Lyver of Canada, with earlier input from David Rowlands of Australia.

- 7 P members in favour, 2 against, 4 abstained (total 13)
- There were 81 comments, suggestions and questions – mainly editorial. The draft disposition was reviewed with Working Group 8 members.

- A motion was approved that the draft Technical Report be revised based on the final disposition of comment and finalised for publication.

13.3 Review of TS 18308:2004 Health Informatics requirements for an EHR architecture

Dipak Kalra, project lead, presented on the work to date on the review of TS 18308. Prior to the meeting, two documents were circulated to Working Group 8 members: the marked up version of the proposed revisions of 18308 (0.1 version); and a clear copy (0.2) of the above proposed revision. A substantial revision has been undertaken, with feedback to date provided by Canada and the United States. Further expert input is being sought before a review by all Working Group 8 members, to be followed by preparation of the Draft International Standard for the October meeting's discussions.

13.4 HL7 EHR System Functional Model

It was reported that the EHR System Functional Model DIS ballot opened on April 24 2008, however, the only document distributed with the ballot was the overview document. ISO Central Secretariat (CS) has now sent out all documents. It was noted that a decision was made based on advice from ISO CD to continue the ballot so that the comments would be collated for review at Istanbul, with HL7 members present. The HL7 EHR System Functional Model is being balloted under the HL7 Pilot Project agreement, using the HL7 process of comment review.

13.5 WG8 Work Program Review

The work items on the WG8 work plan are

- EHR Classification Framework
- ISO DTR 12773 Technical Report Business requirements for health summary records
- Requirements for EHR architecture (revision of ISO/TS 18308:2004, moving to DIS)
- ISO DIS 10781 HL7 EHR System Functional Model.

13.6 PHR

There was broad discussion at Working Group 8 and again in the Executive Council on Personal Health Records (PHR). The general view was that this is a rapidly evolving field and too soon for a Technical Report. It was noted that the definition of PHR varies in different countries.

The Executive Council recommended moving this to Working Group 8 as a "watching brief". Working Group 8 supported this with a number of countries offering to provide input, including Australia, US, UK and Brazil.

John Ritter of the US will complete the internal report envisaged by the Personal Health task group, which sent out a survey after the August 2007 ISO TC215 meeting, and has now been dissolved. John Ritter is also project lead at HL7 for the HL7 PHR Functional Model which has passed DSTU, and is keen to gain international view on PHR.

14. Other Matters

14.1 WHO standards collaboration

At the closing plenary, a representative of the WHO announced the organisation's intention to be more active in providing tools, facilities and expertise to coordinate health information standards implementation and share health information standards and tools. The following is a close replica of this presentation:

“WHO Collaboration on Health Information Standards

The WHO openly recognizes the leading role of ISO and its TC215 Committee, (CEN) and its TC251 committee, health level 7 (HL7) and IHTSDO. It also acknowledges the work initiated by the eHealth Standardization Coordination Group (eHSCG) in which WHO participated and which brought together representatives from ISO TC215, CEN TC251, HL7, DICOM, IEEE and ITU-T.

*Within its 2009-2015 programme of work, WHO has now merged all its activities in the field of Health Informatics within a newly established department called **Health Statistics and Informatics**. This new department is located in the **Information, Evidence and Research** cluster and is headed by Dr Ties Boerma.*

*This department will continue the traditional role of WHO compiling health statistics under a new web portal called the **World Health Observatory**.*

A new stream of work on health Informatics has been created merging WHO's previous lines of work on eHealth, knowledge communities, classifications and terminologies and GIS to have more coordination and coherence, and to benefit from critical mass. A new health information strategy is being developed in consultation with multiple parties and stakeholders around the world. A series of consultations will take place in Geneva, Bellagio, Seattle, Delhi, Jakarta and elsewhere within this year.

Under that stream of work a new activity has been formally recognised in health information standards. To that end, a systematic review of standardization and standards implementation in the health sector is currently taking place. Until recently, the main line of activities had been in the field of ICT standards for health. Health information standards, namely those relating to content knowledge like indicators, diagnostic guidelines to guide implementation of policies and the development of adequate tools have received less attention.

*In view of the digitalisation of health information services, proactive thinking is needed to establish a more comprehensive and action-oriented inventory of current health information practices and standards, together with an analysis of their actual implementation. This activity has been placed under the **Classifications, Terminologies and Standards** unit headed by Dr B Üstün.*

As a priority contribution to international work in that area, WHO considers that a global health information standards repository could serve as an access and dissemination platform for health information standards and their implementation.

*Building on work already initiated elsewhere and in partnership with leading standards development institutions, WHO would undertake to mobilise support and resources to build an international health information objects repository (**International OID Repository**) and to coordinate health information standards*

implementation on a Web-based platform. Registered users would be invited to browse, search and download standards for use in their health information systems.

As a semantic wiki with a contextual database accessible under an open access policy, and due consideration being given to the administration of socio-economic and legal issues, such as liability, intellectual property and security, the proposed platform would facilitate access to existing health information standards. It would also assist in identifying needs, priority areas and gaps in content areas where the health information standards are being contemplated, developed or tested, and assist in the harmonisation and complementary nature of the work of HIS developers. It would serve to communicate on, and promote the adoption and use of endorsed health information standards. It could also help monitor the use of health information standards, their development, uptake and implementation.

WHO, in response to its member states' requests in numerous areas relevant to public health action, invites all interested parties to join discussions to create a common roadmap for this activity, focusing on its form, functions, resources and sustainability. It should result in a joint international plan of action that would involve other UN bodies and related organisations, EU partners, excellence centres from around the world, foundations and industry partners."

Implications for Australia

There are significant issues and overlaps apparent in this initiative; however well intentioned it may be. There are also significant questions relating to intellectual property rights to standards products that WHO may wish to provide through its facility.

Standards Australia IT-014 would appreciate any further advice that DoHA International Branch may be able to offer in this regard and would be prepared to work with our national representatives and other key Australian stakeholders (including AIHW, NEHTA and NCCH) to ensure that WHO's scarce resources are well spent.

14.2 ebXML Task Force

Frans van Bommell convened a meeting to report outcomes of the ebXML Task Force which was only attended by himself, the two Russian delegates, Ivan Emelin and Olga Galinovskaya, Richard Dixon Hughes from Australia (and one other person briefly for part of the meeting).

It appears that with the migration of ebXML technology into the ISO 15000 series of standards, active work on development and maintenance of ebXML and related UN-CEFACT specifications has stabilised and continues to be concentrated in traditional areas of e-commerce with little prospect that a need will be perceived for data components in the health space – other than those being provided through ISO TC215, CEN TC251 and, particularly, HL7. The liaison arrangements are also not working well in that the nominated ebXML representative has not become involved in health informatics work.

Frans has announced that he will be retiring from his current job soon and will be stepping down from his various ISO TC215 activities at the Istanbul meeting. Nevertheless, his preference was to continue the ebXML Task Force until then. Richard Dixon Hughes indicated that the situation did not seem to be progressing.

On discussion among the Australian delegation, it was considered that the principal value is already being extracted from use of some of the ebXML secure messaging techniques

within health informatics and the more relevant applications domain questions were being addressed in existing bodies and the emerging SOA-standards space.

14.3 Participation in TC 215 by China (PRC)

The PRC currently has Observer status within ISO TC215 with a delegation of five persons at the Gothenburg meeting. On this occasion the PRC delegation included personnel from the China National Institute of Standardisation, the China Population and Development Research Centre and the Neuro Information Centre at the General Hospital of the Peoples' Liberation Army.

China has announced its intention to seek full P-Member status. This move parallels the development of national and regional programs to use relevant international/global health informatics standards (including HL7v2.x and CDA) and a need to see that such standards can appropriately address the full range of clinical services delivered in the Chinese health system including Traditional Chinese Medicine (TCM), particularly in the areas of terminology and vocabulary.

In recent years, Australian delegations have been active in supportive and encouraging PRC engagement in health informatics programs – including a visit by David Rowlands, Klaus Veil, Elizabeth Hanley and Heather Grain to Beijing prior to the first TC215 meeting that they attended (in Hamamatsu, Japan in 2005).

The Chair of IT-014, Heather Grain, is well known to many in the Chinese health informatics community through her work as a guest lecturer on Health Information Management for the Chinese national health information management program. It is interesting that the importance of the data classification and management capabilities spawned by this fledgling program has been emphasised during recent Avian Influenza and SARS epidemics.

Heather Grain and other members of the Australian delegation including Richard Dixon Hughes and Evelyn Hovenga were actively involved in occasional activities and introductions to various experts that supported the members of the PRC delegation and helped to maximise the benefit that they received from the attendance at this TC215 meeting.

14.4 Traditional Oriental Medicine Group

At Gothenburg it was agreed to form an Ad-hoc Group to investigate issues related to application of health informatics in Traditional Oriental Medicine (TOM) (including TCM) and to propose an action plan for consideration at the April 2009 plenary in Edinburgh.

During debate of this topic at the TC215 plenary session, it was clear that there are strongly different views held by the Chinese, Japanese and Korean delegations over naming, scoping and governance within this area of interest.

A meeting of the Ad-hoc Group is to be held at the next JWG meeting in Istanbul in October 2008 and a short interim report should be given to the mini-plenary session to be held at that meeting. The ISO TC215 Secretariat agreed to issue an invitation to the NMB's and other relevant bodies, including the WHO Western Pacific Office seeking nominations to the Ad-hoc Group before July 31.

15. ISO/ TC215 Health IT Global Summit IV

15.1 Introduction

The broad purposes of the **Health Information Technology Global Summits** are to better to engage standardisation stakeholder groups and to ensure that standards development organisations (SDOs) understand and are responding to their needs.

The inaugural Summit was held in Hamamatsu Japan in September 2005 and convened inputs from leaders of several national and regional e-health programs representative of activities in Australia, the USA, Canada, UK, Germany, European Commission (EC), and the World Health Organization (WHO). In summary, e-health program leaders wanted SDOs to:

- Deliver relevant, implementable international standards in a timely manner; and
- Collaborate with each other and with health IT vendors on effective standardisation.

Presentations from the inaugural Summit are available at:

http://www.himss.org/ASP/topics_FocusDynamic.asp?faid=134

The second Summit, held in Geneva Switzerland in October 2006, convened global vendors and their representative associations. These stakeholders strongly reiterated these themes and also noted that:

- Failure to standardise core business processes in healthcare also retards standardization;
- The increasing ubiquity of healthcare delivery (e.g. via mobile and wearable devices) dramatically increases the both the need for and complexity of standardization; and
- Widely accessible toolsets for consistently implementing standards are now required.

Presentations from the second Summit are available at:

http://www.himss.org/ASP/topics_FocusDynamic.asp?faid=180

The third Summit, held in Montreal, Canada in March 2007, focussed on the needs of clinicians and, to a lesser extent, consumers. The papers reviewed clinical engagement in various contexts with the following being common observations:

- Most clinicians remain sceptical that health informatics can provide health informatics community's interaction with clinicians must be relevant to clinician needs and engage with front-line clinicians in familiar, non-technical terms.
- Clinicians are prepared to support technology where there is clear evidence it improves health outcomes and supports faster, more accurate availability of relevant health information.
- Health information and communications technology needs to integrate effectively into clinical practice with minimum overhead and cost.
- The greatest potential benefit is anticipated to come from effective integration of clinical information, clinical knowledge into clinical workflow but is some way off.

- The primary role of standards is to provide effective communication and storage of information but should not constrain clinical practice.

Presentations from the third Summit are available at:

http://www.himss.org/ASP/topics_FocusDynamic.asp?faid=214

The fourth Summit in Gothenburg focused on the potential role of standards supporting consumer health needs.

To enliven points made in their presentations, speakers were asked to illustrate how their proposed approaches related to a scenario of a woman (Anja) leading an active life self-managing her health and a cardiac condition (mild pulmonary stenosis) while interacting with supporting clinical personnel and various medical devices – with the scenario presenting various use cases to highlight Anja's needs for support as a consumer of health services and of health information.

In opening the day's proceedings Dr Yun Sik Kwak, MD PhD, Chair of ISO TC215, reviewed the thrust of previous GHIT Summits and their practical outcome in terms of establishing the ISO/CEN/HL7 Joint Initiative and increasing joint activities within the three SDOs. Themes to be explored at this 4th GHIT Summit include:

- Global interoperability of eHealth and EHR solutions
- Empowering citizens for health
- The need to listen and fulfil stakeholders' needs
- Opportunities for collaboration, coordination and cooperation
- Promotion of global health IT standards

Dr Petra Wilson, Chair of the Health IT Global Summit also welcomed the delegates and introduced the *Anja's Journey* case study that would be addressed by the various speakers and sessions.

The following is a summary of the contributions to the Summit, with copies of the presentations being available at:

http://www.himss.org/ASP/topics_FocusDynamic.asp?faid=250

15.2 Session 1 – eHealth tools in developing patient-centric care

The first session moderated by Heather Grain (Australia) covered the following:

15.2.1 Mike Bainbridge, MD – UK NHS Connecting for Health Overview of Consumer Health

Dr Bainbridge highlighted some of the practical problems faced by the UK NHS in maintaining the quality and availability of adequate of health services against the backdrop of an ageing population. By the year 2050 the NHS expects to be caring for an aged population four times greater than today which would incur four times the real cost of service delivery (and assuming that the health care resources would be available). As evidence of this trend, the current cost of delivering conventional health care in developing counties is currently doubling every 10 years.

To address this problem, the health system needs to re-focus from delivery of acute care to a combined approach in which better quality of life becomes the dominant form of care delivered by the health system and will necessarily involve the consumer taking much greater responsibility for their own care. Providing state of the art care anywhere anytime: involve patient, give feedback.

The health system still manages information in a diversity of ways and continues to be far too reliant on paper records 40 years after the 1968 Tonbridge Report indicated the extensive difficulties with paper records and the need for rapid establishment of new standards for information management – including the use of automation.

Examples such as the Windscale nuclear plant incident (1957, 36 deaths, 260 radiation cancer cases), Flixborough chemical plant explosion (1974, 28 dead, 36 injured), Piper Alpha oil platform fire (1988, 167 dead, 62 rescued) and Clapham rail disaster (1988, 35 dead, 100 injured) have shown how failures leading to significant death and injury have led to enquiries that have changed the way that other industries have gone about their business – with the establishment of **safety case regimes in the** nuclear, chemical, oil and transport industries. On the other hand, equally damaging practices leading to considerably greater death and injury each year are tolerated within the health service.

For example it has now been established that 76% of adverse drug events are probably preventable through access to better information. It is therefore unethical to continue unchanged.

Standards, preferably as few as possible and applicable across the globe, are needed in the following areas, to resolve information management issues in the health services. These areas are the focus of standards development work within the UK NHS CfH:

- Terminology
- Drug Database
- Definitions - for example: 'Allergy' 'Current Medication'
- Messaging
- Logical Architecture / Archetypes
- User interface design
- Knowledge and Knowledge Authorship
- Device Interoperability

To achieve **interoperability**, it is necessary to employ *a ruthless approach to standards* (Sir John Patisson 2003). The NHS is therefore very focussed on effective integration through an **open architecture** based on a raft of standards. An open standards-based architecture also enables plurality of provision – securing an ongoing competitive market, diversity of supply and choice.

In the area of **Common User Interface**, the NHS has a partnership with Microsoft for development of a user interface architecture with three overarching drivers:

- patient safety,
- clinical utility, and
- reducing the amount of training and retraining

as well as securing a return on investment. Further information is available online from Microsoft at: www.mscai.org.

Five areas in which clinicians have greatest needs have been identified as:

- Timely access to reliable, complete medical records,
- Identity management,
- Communications (personal and work-related across voice text and bleep),
- Scheduling (including rosters and personal diary),
- Turning clinical knowledge and patient clinical information into personalised care.

There are also basic engineering, clinical and social challenges integrating ICT solutions deep into the clinical workplace, in particular:

- Avoiding device-induced infection – such as new peripherals (e.g. entry devices) that are cleanable, useable and affordable
- Cultural changes in the clinical workforce, giving healthcare professionals new skills and new ways of working with clients and information systems
- Compatibility with clinical processed and other sensitive clinical equipment

The need for a multidisciplinary shared health record (e.g. Shared EHR) is underlined by the key drivers including the following

1. To support **prevention and risk management programs**. (e.g. all of the following require a full multidisciplinary record contributed to by everyone involved including having **Secondary Use Services**:
 - Reduction in diseases through primary and secondary immunisations
 - Chronic disease
 - Genetic therapy
 - Minimising hospital acquired infection
 - Avoiding litigation costs)
2. **Connected Care for aged and recovering patients**, enabling team member involvement
3. Coupling with knowledge bases to translate care plans into road maps to be used for all kinds of activities.

With growing community awareness of the potential for Personal Health Records (PHRs) and the arrival of government and commercial PHR services such as HealthSpace (NHS), Dossia (Intel), HealthVault (Microsoft) and Google Health, strategies are needed to handle citizen supplied data, addressing issues of: truth, trust, provenance, user skill levels, and incorporation of such data into records. The major online service providers are investing billions of dollars on these products and it will become increasingly important to be able to interconnect the institutional EHR in clinical space and the personal PHR in the health space. The health informatics community and their stakeholders need to identify how personally collected data will fit into the formal institutional health record – and what the rules will be. Ensuring adequate identity management for citizens to an appropriate level of security is another challenge which requires affordable solutions.

Other challenges faced in empowering consumers to take more responsibility for their own health and treatment include: -

- finding strategies for convincing older citizens to participate in technology-driven solutions. Some success has been achieved here to the extent that technology can enhance other aspects of family life – keeping up with kids and family.
- Providing access to knowledge sources and clinical resources in appropriate form.

Concluding remarks - where will all this lead by the year 2105?

- No paper records
- Clinicians using records
- Patients contributing to the same records
- Consent to share genomic and other “omic” data
- Knowledge Authorship
- Decision support
- Knowledge support
- Active patient partners
- All images
- Automated prompts and warnings
- Wellness as well as sickness addressed
- Background data mining
- Feedback of research and evaluation into improvement of the health service

A full copy of the presentation may be found at:

<http://www.himss.org/content/files/PatientEmpowerment.pdf>

15.2.2 Sarah Cruchet - Health on the Net Foundation, Switzerland Quality standards for health Information on the Web

Sarah Cruchet presented the work of the Health On the Net (HON) Foundation which has been established as a Non Government Organisation (NGO) with a view to protecting the citizen by provision of an accredited certification process for health and medical information published on websites.

Market research has revealed that eight in every 10 Internet users go online for health information at some point for either themselves or for someone else and one in five patients go online to look for information relating to their conditions or treatment. These users face the problem of judging knowing whether health and medical information available online is authoritative. In a rapidly changing and very competitive commercial world there are a range of other factors that affect the quality and risks associated with online information providers, including their approach to: privacy, provision of contact details, information update, use and influence of advertising, and references to other information sources.

The basis for trusting information ranges commences with trust in the author (lowest level), up through use of supporting references/citations, backing of a recognised organisation, to third party validation (greatest assurance). The problem of assuring website information quality may be addressed through:

- The development of standards by government (e.g. EC), civil society or industry groups (these standards may be used for either self assessment or third party accreditation or certification);
- After implementation – through either a selection (referral) process or via an accreditation process (with education of the consumer community); or by
- Having privileged access to trustworthy information.

The principal European initiative to improve the quality of online health information involved the development of a standard: *Quality Criteria for Health related Websites*, published in November 2002 by the EC. The intention was for these criteria to be separately implemented by domestic adoption in each member state but, as of today, this has not happened. The criteria were grouped under the following 6 key headings: - (a) Transparency and honesty, (b) Authoritativeness, (c) Privacy and data protection (in accordance with EC Directives), (d) Timeliness (currency) of information, (e) Accountability, and (f) Accessibility. HON was one of the organisations that contributed to this work.

HON was formed in 1996 specifically for improving the quality of information intended for both patients and medical professionals. Its certification mark, the HONcode is aimed at supporting both users of health websites and web publishers through a process of active accreditation. Requests for accreditation may be sought by the owners of any health or medical website intended for health workers or consumers. Each request is then examined by review committee including medical professionals that subject the website a thorough examination to determine whether it meets all of the following eight ethical principles:

1. Authority - where medical advice or information is given, the website informs visitors if the advice is given by a qualified medical practitioner or not.
2. Complementarity - the website clearly states its purpose of supporting, not replacing, doctor-patient relations.
3. Confidentiality - the confidentiality of data relating to individual patients and visitors to the website, is respected and protected.
4. Attribution - the site refers properly to source information including displaying clearly the date when clinical pages were last modified or reviewed.
5. Justifiability - the website justifies its claims about the benefits and performance of specific treatment.
6. Transparency of authorship - the website identifies its developers, authors and webmaster and provides a valid, easily accessible contract address.
7. Transparency of ownership - the financial backers and owners of the site are presented.
8. Honesty in advertising and editorial policy - where advertising may be involved in funding a website, it is clearly separated from editorial content.

HONcode certification implies compliance with these principles, not a guarantee that the website contents may be trusted. Where a site falls short of the principles, they typically work through the changes required with the assessors.

On completion of HONcode certification, a seal is provided for website, which links dynamically to online information about the holder's current certification status with HON website. To provide greater benefit to both participants and the general public, HON hosts

a search engine facility across the HONcode certified sites (approx 6000) and arrangements have been made with the Google alliance to display HONcode certification .

Other organisations providing various types of website quality guidelines and assurance services were also noted and compared with HON, these others include: - OMNI (UK), Discern (UK), Netscoring (France), WebMedica (Spain), MedCertain (Germany), Toucanomètre (France), URAC (US), Content Guidelines (EU), Internet Healthcare Coalition (USA), VIPPS (USA), WebTrust (Canada) and AFGIS Code (Germany).

A full copy of the presentation may be found at:

<http://www.himss.org/content/files/CruchetGHITSS-4.pdf>

Some of the issues raised during questions included:

- Whether such a doctor-focussed approach is adaptable to lifestyle information provided by self-help groups, (e.g. diabetic patient organisations)?
- Relevance of the approach beyond Western allopathic medicine.
In response it was noted that the service is primarily focussed on health and medical information used in western societies (including various OTC drugs). The possibility of users forming their own opinions based on compliance with the 8 ethical principles was noted (although the user has less information than an evaluator).
- How consumers are being informed that the HONcode even exists and what is being done to market the service. In response, it was accepted that there had been little marketing and that was one of the reasons HON had linked in with Google.
- How HON is getting the right terms into their search engine to guide users to the right sources of information. A: we are working on question and answer process through Natural Language Processing with the aim of refining searches.
- How do they ensure that the sites are directing patients needing care to a physician? The audience noted that a person seeing a physician can be guided to the right information. The problem is the person who attempts to self-diagnose and self-treat – there is no solution for this; the aim can only be to ensure that guidance is given.
- The questionable ethics of some sites where patients are swapping notes, without being fully aware that the site owners are using their information for research.

15.3 Session 2 – Shareable EHR and empowering consumers through information

This session was moderated by John Ritter (USA), a co-chair of the HL7 EHR Technical Committee and HL7 Ambassador on the EHR and PHR Functional Models.

15.3.1 Mary Simpson, UK Department of Health Empowering Information

Mary Simpson addressed the summit on the use of ICT and health informatics to support and empower patients, in particular through the use of “**Knowledge Prescriptions**” that enable each person to seek and obtain information more relevant to their own health situation. People become empowered to play a greater role in their own health care when they can confidently marry:

- Information about available services, care, treatment and support, with

- information about “me” – my health, my care, my needs and preferences, my life.

There are currently many strategic pressures driving consumer empowerment in the area of health and wellness resulting in the following paradigm shifts:

- Greater personal responsibility of individuals for their own health,
- Health systems aim at both wellness and sickness,
- broader engagement of all society for health matters.

What consumers are seeking in their interactions with the health system may be summarised as follows:

- Getting the basics right
- Treating me as a person
- Fitting in with my life
- Working with me as a partner
- Understanding: – What are my symptoms? What do they mean?
- Communication: – What will happen next?
- Know-how on how to manage the condition: - What will you/I do to tackle pain and/or inconvenience caused by my condition? What can I/you do to prevent negative consequences in the future?
- Access to means: – Can I do this or do I need permission? Where do I get the required knowledge/skills?

However, when the consumer turns to the Internet there are many barriers to getting the advice that they need. They are surrounded by information overload, ongoing advances in medicine and growth in amount of choice. The following are some of the factors highlighted by Mary Simpson that need to be considered in addressing patient needs.

- Handling the Information Maze:
 - 77% people used info last year, 91% wanted trusted source.
 - Information Accreditation Scheme, Information Prescriptions, NHS Choices Public Site.
 - Accrediting info producers and production systems/processes with a quality mark.
- The NHS approach is evaluating and working with:
 - Information Prescriptions to guide people to reliable and relevant info, to be routine part of care.
 - Includes organisations/support mechanisms, local facilities/services eg clinics, suppliers.
 - NHS Choices to explain conditions and describe care pathways eg coronary heart disease.

- Additional approaches such as: improved decision support, health system performance evaluation, personal health managers, and use of social networking.
- HealthSpace personal health organiser, interlink with other systems (GP, hospital), e-prescription link, access to own health records and use by many parties.
- New culture of care: health is about me not services, I am a partner in care, health is 24/7.

A full copy of the presentation may be found at:

<http://www.himss.org/content/files/EmpoweringInformation.pdf>

15.3.2 Ana Estelrich, DMP Project, France The Personal Health Care Record

Ana Estelrich, who works with the French Government's Personal Health Record team reminded the Summit of the main features of the "Dossier Medical Personnel (DMP)" project and provided an update on progress:

- A central principle of the project has always been that the records belong to the patient – with each citizen being able to access, and control access to their own PHR.
- Information is linked into the DMP from various sources including GP, lab, hospital, imaging.
- There are protocols for posting of patient comments and erasure of information.
- The health care professional (HCP) decides what to contribute but the patient can restrict what HCPs can see.
- Masking and unmasking of documents, break-the-glass rights in emergency situations.
- IHE environment to allow users (white pages identifiers) to access databases via portal.
- On trial in limited areas.

Discussion was lively with some members of the French medical profession asking about recent reviews and likely changes including highlighting their understanding of shortcomings, including:

- The limited time available during a consultation for use of such a system,
- Clinician concerns about the completeness, reliability and risks of information selectively controlled by the patient, and
- As yet undisclosed factors reputedly identified during a recent review.

The final impression was that many of the lessons learnt in the Australian HealthConnect projects were only just beginning to surface in this project that has involved high cost and

possibly more “product push” than market pull and is subject to intense scrutiny following a change of administration.

A full copy of the presentation may be found at:

http://www.himss.org/content/files/A%2520Connected%2520Health%2520Story%2520Global%2520Summit%25202008_29_Mai.pdf

15.3.3 Goran Petersson, MD, PhD (Sweden) ePrescribing from the patient viewpoint

Goran Petersson, eHealth Institute, Univ of Kalmar: presented on the Swedish experience with ePrescribing and comparisons with Austria. The importance of the following was noted:

- Promotion of eHealth communication
- documentation
- competence
- evaluate, implement
- multidisciplinary, professional teams

Data reported by Dr Petersson was as follows:

- Seventy five percent of all prescriptions in Sweden are electronic; and almost one hundred percent of primary care.
- Attitudes by patients on who should see information - about 50% don't want others to see.

PDA based device for medication control eLIT. Virtual Pharmacy: shows equipment use.

A full copy of the presentation may be found at:

http://www.himss.org/content/files/GlobalSummitMay29_2008_short_upd.pdf

15.4 Session 3 – Data collection and storage – privacy, access and security

Session 3 was moderated by Todd Cooper, Convenor of ISO TC215/WG7 Medical Devices, who introduced the session by referring to the many issues and decisions that surround the interoperation of devices used for personal health and the impacts when device information is incorporated into a clinical record and relied on for the provision of treatment.

15.4.1 Ann-Sofie Bergström, RN, Sweden Data Collection and Storage Issues

Ann-Sophie Bergstrom of HLS Global Practice at SAS Inc made the following observations:

- People need:
 - the right treatment, at the right time, by the “right” people
 - high quality treatment delivered in a safe, efficient way.
- EU medical device directive regulates quality practices for direct-connected devices.

- Assuring quality of personal eHealth data requires integrity:
 - patient integrity, - controlled access to data - data integrity
 - analysis integrity - identity removal in certain cases
- Evidence-based decision-making involves being able to use data to uncover trends, and patterns in clinical errors, thereby reducing errors and improving patient safety – a capability for secondary uses.
- There is an urgent need for interoperability, so that I be sure that:
 - I can get treatment wherever I am
 - needed data is accessible and is mine
 - data transfer is secure so that only the right people get access
- Interoperability requires standards –
an open data model - XML-based – CDISC/HL7 compliant

A full copy of the presentation may be found at:

<http://www.himss.org/content/files/ISO-Bergstrom.pdf>

15.4.2 Dave Iberson-Hurst, CDISC, United Kingdom Liability for Personal Health'

David Iberson-Hurst, UK presented on liability with medical devices for personal health, noting many different factors to be considered, including the following:

- Logistics: how fast can it be delivered? How fast can it be replaced if it fails?
- Training: what training does user need?
- Does it need calibration? Connection? Checking?
- Help/support: help desk or care providers? 24/7 or work hours? Medical or technical?
- Who: who is data being gathered from? How concerned about identity? Password habits.
- Reliability: many links in the chain, mobile communications, server access, communications network, costs.
- Monitoring: is data received according to plan? Is the user and clinician looking at data?
- Interoperability: integrate multiple devices?
- Should data be seen in EHR environment?
- Accessibility/useability: can I see data when required? In meaningful form? Easy to use?
- Risk management: business, safety, data, link, decisions, patient, clinician.
- Fit for purpose determines quality and accuracy. Systems approach to risk (eg airlines).

A full copy of the presentation may be found at:

<http://www.himss.org/content/files/LiabilityforPersonalHealth.pdf>

15.4.3 Mario Romao, Continua Health Alliance (US) Personal Telehealth is Here

Mario Ramao, Intel presented on personal telehealth, noting opportunities for aged care, and wellness. The following was also noted:

- Barriers: awareness, interoperability, deployment, cost, proof, low EHR/SW uptake, legal
- First movers: USA VA (20k patients), KP (6k patients), employer programs (10k steps).
- Continua making guidelines for strict interoperability (out of the box), certification/logo.
- Version 1 device connectivity standards IEEE 11073 family (messages to hub).

A full copy of the presentation may be found at:

<http://www.himss.org/content/files/PatientEmpowerment.pdf>

15.4.4 Session 3 - discussion

John Ritter, HL7 project lead for PHR-S Functional Model moderated discussion during which the following points were made:

- PHRs will allow people to leave one state and travel to another; other stakeholders eg emergency.
- PHR-S is electronic system allowing collection of consumer oriented short and long term health records and goals.
- Universe of discourse for all stakeholders, consensus based, well defined.
- Business model: users have difficulties remembering: system must collect and provide relevant data, and interoperate with EHR systems.
- Collecting data and keeping data with the consumer would be supported: storage, portability (media?) and communication needs must be met.
- Laundry list approach allowing local/national choice of inclusions, roadmaps for future.
- Accommodate business models, promote trustworthiness and acceptance of EHRs, promote privacy/security policies, clarity for PHR market, certification.
- Enables modularity, define functionality, define interfaces, scope subsystems, services.
- Users: governments, payers (value-add), SDOs (evaluate need), consumers (expectations).
- There are three sections to Functional Model: personal health (individual), supportive (provider), info (security). (130 items). Each item has statement, description, example. Then conformance criteria (shall/may).

15.5 Session 4 – Two personal health applications

As a lead in to the final synopsis, progress in personal health care programs in Korea and in Japan were presented.

15.5.1 Soo Jun Park, ETRI Korea Making U-Health Technology into Business in Korea

Soo Jun Park of ETRI Korea spoke on the U-health business case and the trial deployment in Daegu (October, 2008).

- Standardized SW platform, allowing personalised health services, using health devices.
- Personal emergency alarming system (fall detection phone) using GPS location.
- Personal healthy lifestyle management system (life coaching) via ADL activity sensors.
- Proactive medication support and monitoring system (PROMISE) via context awareness.
- Biosignal monitoring system (BioPatch) wearable device: HR, RR, energy expenditure.
- Business models: u-Wellness: data from home and fitness centre to govt health centre.
- u-Safety: falls and ADL. Fitness Centre for Elderly (muscular and cardiovascular).
- Application services on standardised platform, run test bed to find commercial potential.

A full copy of the presentation may be found at:

<http://www.himss.org/content/files/MakingUHealthTechnology.pdf>

15.5.2 Michio Kimura, MD, PhD, Hamamatsu University Mandated Health Checkup for Aged 40-65 in Japan

Michio Kimura, Hamamatsu University Japan spoke on Mandated checkup for 40-65 year olds in Japan, as follows:

- Methodology consists of a questionnaire, physical examination/measurement, blood/urine chemistry. (Health Ins Co).
- High risk (aggressive/ motivation support) group undertake classes, receive instructions.
- Report for checkup in HL7 CDA-R2 L3 PHCS.
- Can companies misuse this info?
- Does it reduce health care costs? People might die later from more complex disease.
- Will people adopt exercise regime? Or seek medication (this may be more likely)?

A full copy of the presentation may be found at:

<http://www.himss.org/content/files/MandatedHealthCheckup.pdf>

15.6 Session 5 – Synthesis

As chairs of their respective organisations, Dr YS Kwak (ISO TC215), Dr Ed Hammond (HL7) and Kees Molenaar (CEN TC251) then provided a synthesis of the day's outcomes, making the following key observations:

- Emphasis changed from communication/connection to PHR/health knowledge.
- We should aim at certification of systems functions (software) and interoperability.
- Standards: where do they fit? Components, data elements, structures, clinical documents. Communications, transport, security/privacy, EHR content, DSS, devices, ID, profiles, intelligent queries, implement guides.
- Need infrastructure to support data aggregation.
- Interoperability? EHealth Systemic Interoperability has many components: HCI, security/privacy, business, communications, international, legal/ethical/social...
- Does PHR belong to patient/controller (motivated by privacy) or system?
- Three components: clinical data (for doctor making decisions), managing health (with prompt), access to data that is tailored to persons needs (eg screening results).
- PHR allows Personal Health Plan; data drawn from own and institutional sources.
- Connecting communities (models like Internet) needs to determine practice/systems.

A copy of presentations containing concluding observations may be found at:

<http://www.himss.org/content/files/Closing-Kwak.pdf>, and

<http://www.himss.org/content/files/Patient%2520empowerment-Molenaar.pdf>

In closing the day's discussions, Petra Wilson, Global Summit Chair noted as follows:

- Should design around consumer, not how health system works.
- Patient experience requires accredited/targeted information and greater awareness.
- Connected health: build trusted systems, cater for unique cases, agnostic to organisation structure
- Rising costs demand lower overhead and higher efficiency
- Clinicians should be virtually as good as each other.
- New focus in health care: prevention, healthy living, personal responsibility.
- Certified Health Information, healthy living information, chronic disease.

Discussion followed on whether social mechanisms (online communities, blogs etc.) should be platforms for discussing, developing, deploying standards (through community engagements), or whether technical standards making should be a bounded process with controlled inputs.

A copy of the presentation for Dr Wilson's round up may be found at:

[Dr. Petra Wilson, GS Chair, 'Global Summit Roundup' \(6/17/2008\)](#)

Attachment 1 – Participation in the May/June 2008 ISO TC215 meeting in Gothenburg, Sweden

Country (and NSB):	Attendance at Gothenburg
Participating ("P") members	
Australia (SA)	Yes (7 delegates)
Austria (ON)	Yes (2 delegates)
Belgium (NBN)	-
Brazil (ABNT)	Yes (6 delegates)
Canada (SCC)	Yes (18 delegates)
Czech Republic (CNI)	-
Denmark (DS)	Yes (3 delegates)
Finland (SFS)	Yes (5 delegates)
France (AFNOR)	Yes (6 delegates)
Germany (DIN)	Yes (15 delegates)
Italy (UNI)	Yes (3 delegates)
Japan (JISC)	Yes (26 delegates)
Korea, Republic of (KATS)	Yes (7 delegates)
Malaysia (DSM)	Yes (2 delegates)
Netherlands (NEN)	Yes (12 delegates)
New Zealand (SNZ)	-
Norway (SN)	Yes (2 delegates)
Russian Federation (GOST R)	Yes (2 delegates)
Serbia (ISS)	-
South Africa (SABS)	-
Sweden (SIS)	Yes (19 delegates)
Turkey (TSE)	Yes (1 delegate)
United Kingdom (BSI)	Yes (27 delegates)
USA (ANSI)	Yes (28 delegates)
Observing ("O") Countries	
Argentina (IRAM)	-
Bulgaria (BDS)	-
China (SAC)	Yes (5 delegates)
Croatia (HZN)	-
Cyprus (CYS)	-
Ecuador (INEN)	-
Hungary (MSZT)	-
India (BIS)	-
Iran, Islamic Republic of (ISIRI)	-
Ireland (NSAI)	-
Israel (SII)	-
Kenya (KEBS)	-
Mongolia (MASM)	-
Poland (PKN)	-
Portugal (IPQ)	-
Singapore (SPRING SG)	-

Country (and NSB):	Attendance at Gothenburg
Slovakia (SUTN)	-
Spain (AENOR)	Yes (2 delegates)
Switzerland (SNV)	Yes (2 delegates)
Thailand (TISI)	-
Zimbabwe (SAZ)	-

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 Plenary Resolutions

TC215 adopted the following resolutions in plenary session at the Gothenburg meeting.¹

1. Resolved that ISO TC215 accepts the report of the ISO/TC 215 Chairman.
2. Resolved that ISO TC215 approves the Executive Council recommendation to approve the appointment of Dr. Adrian Stokes as the active Liaison from TC 215 to JTC1.
3. Resolved that ISO TC215 accepts the JTC1 recommendation of Mr. Richard Dixon Hughes from JTC1 as the active liaison to TC 215.
4. Resolved that ISO/TC 215 executive council is recommending that work group 8 acting convener, Marion Lyver be continued until the Istanbul JWG meeting, where WG 8 will submit recommendations on the convener position to ISO/TC 215 for approval.
5. Resolved that ISO/TC 215 approves of the Executive Council recommendation of extending the e-business task force for this next year.
6. Resolved that ISO/TC 215 executive council is recommending to continue a convener –vice convener task force to review and revise work group scopes with the goal to re-write the ISO/TC 215 business plan. Conference Calls to begin in July 2008 as described in the Convener meeting.
7. Resolved that ISO/TC 215 executive council is recommending that work group convenors, Michael Glickman, Frans van Bommel and Todd Cooper be continued until the Istanbul JWG meeting, where the respective work groups will submit recommendations on the convener positions to ISO/TC 215 for approval.
8. Resolved that ISO/TC 215 executive council is recommending a change in the plenary resolution voting practice: Work Group convenors will give a report of work group activities and work group resolution recommendations. The resolutions will be voted for acceptance upon at the conclusion of each work group report. All delegations to receive materials at the same time with equal representation.
9. Resolved that ISO/TC 215 executive council is recommending a task force be formed for Global Summit #5 to be held in Durham North Carolina 2009 JWG.
10. Resolved that ISO TC215 accepts the report of ISO/TC 215 WG 1.
11. Resolved that ISO TC215 approves the WG 1 recommendation for the ISO TC215 Secretariat to forward to the ISO Central Secretariat DIS 13606-2 *Electronic Health Record Communication Part 2 Archetypes Interchange Specification* for circulation as an FDIS ballot.
12. Resolved that ISO TC215 approves the WG 1 recommendation for the ISO TC215 Secretariat to forward to the ISO Central Secretariat DIS 13606-3 *Electronic Health*

¹ Based on updated version of minutes provided by TC215 Secretariat via the TC215 website on 12 June 2008. As these resolutions as minuted have yet to be confirmed (and differ in several small ways from an earlier draft and some of the motions proposed), the final version may ultimately differ.

Record Communication Part 3 Reference Archetypes and Term Lists for circulation as an FDIS ballot.

13. Resolved that ISO TC215 accepts the WG1 recommendation to urge ISO TC/215 Executive Council to form an ad hoc group to urgently identify mechanisms that can be made available for international access by which:
 - Technical Artefacts and Tools supporting standards use
 - FAQs
 - Guidance notes and other supportive materials
 - Including facilities for these for be uploaded by authorized users from the adopting community.
14. Resolved that ISO TC215 approves the WG 1 recommendation to request the ISO/TC 215 Secretariat to forward document ISO TS 27527 "*Provider Identification*" to the ISO Central Secretariat for publication and that the document arrives at the TC Secretariat no later than 25 July 2008.
15. Resolved that ISO TC215 approves the WG 1 recommendation that ISO TS 17120 "*Country Identifier Standards*" be withdrawn from the ISO TC215 program of work.
16. Resolved that ISO TC215 approves the WG 1 recommendation that ISO TS 21667 "*Health Indicators Conceptual Framework*" be immediately confirmed and a project initiated to develop to a full International Standard at the current level of granularity.
17. Resolved that ISO TC215 accepts the report of ISO/TC 215 WG 2.
18. Resolved that ISO TC215 approves the WG 2 recommendation that, following review of the results of the systematic review of ISO 17432:2004 ("*Web Access to DICOM Persistent Objects*"), the standard be confirmed without change.
19. Resolved that ISO TC215 approves the WG 2 recommendation the for ISO TC215 Secretariat to circulate the DTR ballot of Health Informatics: 28380 "*IHE Global Standards Adoption - Part 2: Integration and Content Profiles*" for approval as a Technical Report; the document to arrive at the TC Secretariat no later than 2008-06-01 to be placed on the ISO/TC web site no later than 2008-06-15.
20. Resolved that ISO TC215 approves the WG 2 recommendation that the ISO TC215 Secretariat circulates the NWIP ballot of "*Health Informatics- Clinical Genomics Pedigree Topic*" for approval as a new work item targeting an International Standard and that the Form 4 and a document arrive at the TC Secretariat no later than 2008-06-01 to be placed on the ISO/TC web site no later than 2008-06-15.
21. Resolved that ISO TC215 approves the WG 2 recommendation that the ISO TC215 Secretariat circulates the NWIP ballot of Health Informatics - Messages Communication - Web Access to DICOM persistent Objects by means of Web Services for approval as a new work item targeting an International Standard and that the Form 4 and a document arrive at the TC Secretariat no later than 2008-06-01 to be placed on the ISO/TC web site no later than 2008-06-15.
22. Resolved that ISO/TC 215 approve the recommendation that work group convenor Michael Glickman, vice-convenor Michio Kimura be continued until the Istanbul JWG meeting, where the work group will submit recommendations on the convenor/vice-convenor positions to ISO/TC 215 for approval.

23. Resolved that ISO TC215 accepts the report of ISO/TC 215 WG 3.
24. Resolved that ISO TC215 approves the WG 3 recommendation that the ISO TC215 Secretariat circulates the NWIP ballot of *prEN 1828 -Health informatics – Categorical structure for terminologies of surgical procedures*” for approval as a new work item targeting as an International Standard via the Vienna Agreement with CEN lead and that the Form 4 and a document arrives at the TC Secretariat no later than 21 June 2008 to be placed on the ISO/TC web site no later than 5 July 2008.
25. Resolved that ISO TC215 approves the WG 3 recommendation that the ISO TC215 Secretariat circulates the NWIP ballot of EN 139401:2007 – *“Health informatics – System of concepts to support continuity of care – Part 1: Basic Concepts”* for approval as a new work item targeting as an International Standard via the Vienna Agreement with CEN lead and that the Form 4 and a document arrives at the TC Secretariat no later than 21 June 2008 to be placed on the ISO/TC web site no later than 5 July 2008.
26. Resolved that ISO TC215 approves the WG 3 recommendation that the ISO TC215 Secretariat circulates the NWIP ballot of CEN/TS 15699 – *“Clinical knowledge resources – Metadata”* for approval as a new work item targeting as an International Standard via the Vienna Agreement with CEN lead and that the Form 4 and a document arrives at the TC Secretariat no later than 21 June 2008 to be placed on the ISO/TC web site no later than 5 July 2008.
27. Resolved that ISO TC215 approves the WG 3 recommendation that the ISO TC215 Secretariat circulates the NWIP ballot of EN 14463: 2007 – *“Health informatics – A syntax to represent the content of medical classification systems”* for approval as a new work item targeting as an International Standard via the Vienna Agreement with CEN lead and that the Form 4 and a document arrives at the TC Secretariat no later than 21 June 2008 to be placed on the ISO/TC web site no later than 5 July 2008.
28. Resolved that ISO TC215 approves the WG 3 recommendation that the ISO TC215 Secretariat circulates the NWIP ballot of *“Health informatics – Principles and guidelines for the maintenance of terminological systems”* 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 21 June 2008 to be placed on the ISO/TC web site no later than 5 July 2008.
29. Resolved that ISO TC215 approves the WG3 recommendation to request the Secretariat to forward document ISO/TR 12309 – *“Health informatics – Guidelines for international healthcare terminology standardization”* sent to the TC secretariat for DTR ballot and that the document arrives at the TC Secretariat no later than 31 July 2008.
30. Resolved that ISO TC215 approves the WG 3 recommendation, following systematic review, that the ISO TC215 Secretariat circulates the NWIP ballot of ISO 17117 - *“Health informatics – Criteria for the categorisation and evaluation of terminological systems”* for approval as a new work item targeting as an International Standard, taking the current ISO/DTS, and that the Form 4 and a document arrives at the TC Secretariat no later than 21 June 2008 to be placed on the ISO/TC web site no later than 5 July 2008.
31. Resolved that ISO/TC 215 approves the WG3 recommendation that the ISO/TC 215 Secretariat seeks resolution from ISO of the following issue:

Currently ISO re-issues an OID when changes to enumerated content in a standard are made, e.g. ISO 3166: Country Codes. The impact of changing an OID is that when software is built, it uses a current version of the country code OID. Any ISO change in that standard resulting in new country codes with a totally different OID prevents existing software from being able to reference it without a software re-write. This has the potential to create a safety / efficiency problem in healthcare software. This has significant impact upon the cost of health software, and therefore be it further

32. Resolved that the ISO/TC 215 Secretariat recommends to ISO that in future ISO updates of such standards, that the Object Identifier be fixed and either the version number or issue date be a changeable identifier, and be it further
33. Resolved that the ISO/TC 215 Chairman and Secretary report back to the next meeting on the action taken.
34. Resolved that ISO/TC 215 approves the WG3 recommendation that when any document is prepared for DIS ballot, all terms be strongly recommended to be entered in the TC 215 Glossary prior to being sent to the ISO/TC 215 Secretariat, and be it further
35. Resolved that ISO/TC 215 approves the WG3 recommendation that the Joint Initiative Council (JIC) encourage CEN and HL7 to participate in populating and using the Glossary, and be it further
36. Resolved that ISO/TC 215 approves the WG3 recommendation that the Joint Initiative Council (JIC) create a task force of the participant SDOs to develop a process for resolution of conflicts between terms used by the different SDOs in the Glossary.
37. Resolved that ISO TC215 accepts the report of ISO/TC 215 WG 4.
38. Resolved that ISO/TC 215 approves the WG 4 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*, and *Part 2: Implementation of ISMS* to the TC Secretariat for DTR ballot, and that the documents arrive at the TC Secretariat no later than 9 June 2008.
39. Resolved that ISO TC215 approves the WG 4 recommendation that ISO TC215 coordinate with CEN using VA [Vienna Agreement] with ISO lead in the revision to a full International Standard of TS 21091 *Health informatics – Directory services for health care providers, subjects of care and other entities* and further
40. Approves the WG 4 recommendation for the ISO TC215 Secretariat to forward to the ISO Central Secretariat TS 21091 *Health informatics – Directory services for health care providers, subjects of care and other entities* for circulation as a DIS ballot.
41. Resolved that ISO TC215 approves the WG 4 recommendation that the ISO TC215 Secretariat circulates the DTS ballot of ISO 22600 *Health informatics – Privilege Management and Access Control Part 3: Implementations* for approval as a Technical Specification and that the document arrives at the TC Secretariat no later than 27 June 2008 to be placed on the ISO/TC web site no later than 11 July 2008.

42. Resolved that ISO TC215 approves the WG 4 recommendation that the principles expressed in DTS 29321 *Health informatics – Application of clinical risk management to the manufacture of health software* and DTR 29322 *Health informatics – Guidance on the management of risk to ensure the patient safety of health software systems in deployment and use* be communicated to ISO/TC 210 and IEC 62A for harmonization and incorporation into ISO 14971, IEC 62304, draft IEC 80001, and draft IEC 80002; and that ISO TC215/WG4 and WG 7 liaison with these standards committees to further this harmonization.
43. Resolved that ISO TC215 approves the WG 4 recommendation that the ISO TC215 Secretariat circulates the DTS ballot of ISO 29321 *Health informatics – Application of clinical risk management to the manufacture of health software* for approval as a Technical Specification and that the document arrives at the TC Secretariat no later than 27 June 2008 to be placed on the ISO/TC web site no later than 11 July 2008.
44. Resolved that ISO TC215 approves the WG 4 recommendation that the ISO TC215 Secretariat circulates the DTR ballot of ISO 29322 *Health informatics – Guidance on the management of risk to ensure the patient safety of health software systems in deployment and use* for approval as a Technical Report and that the document arrives at the TC Secretariat no later than 27 June 2008 to be placed on the ISO/TC web site no later than 11 July 2008.
45. Resolved that ISO TC215 approves the WG 4 recommendation that the ISO TC215 Secretariat circulates the CD ballot of 27789 *Health informatics – Audit Trails for Electronic Health Records* as a Committee Draft and a document arrives at the TC Secretariat no later than 27 June 2008 to be placed on the ISO/TC web site no later than 11 July 2008.
46. Resolved that ISO TC215 approves the WG 4 recommendation that the ISO TC215 Secretariat circulates the DTS ballot of ISO 21547 *Health Informatics — Security requirements for archiving of electronic health records — Part:1 Principles and requirements* for approval as a Technical Specification and that the document arrives at the TC Secretariat no later than 27 June 2008 to be placed on the ISO/TC web site no later than 11 July 2008.
47. Resolved that ISO TC215 approves the WG 4 recommendation that the ISO TC215 Secretariat circulates the DTR ballot of ISO 21547 *Health Informatics — Security requirements for archiving of electronic health records — Part 2: Guidelines* for approval as a Technical Report and that the document arrives at the TC Secretariat no later than 27 June 2008 to be placed on the ISO/TC web site no later than 11 July 2008.
48. Resolved that ISO TC215 accepts the report of ISO/TC 215 WG 5.
49. Resolved that ISO TC215 approves the WG 5 recommendation that ISO TC215 Secretariat circulates the NP ballot of ISO 21549-8 "*Health informatics — Patient healthcard data — Part 8: Links*" as a Committee Draft and a document arrives at the TC Secretariat no later than 200806-15 to be placed on the ISO/TC web site no later than 2008-06-30.
50. Resolved that ISO TC215 accepts the report of ISO/TC 215 WG 6.
51. Resolved that ISO TC215 approves the WG 6 recommendation that the ISO TC215 Secretariat circulates the DTR ballot of ISO/TR 25257 "*Health informatics - Business requirements for an international coding system for medicinal products*" and that the

document arrives at the TC Secretariat no later than 7 July 2008 to be placed on the ISO/TC web site no later than 21 July 2008.

52. Resolved that ISO/TC 215 Plenary be informed that during the 2009 Edinburgh Plenary an election/re-election will take place within WG 6. Work group convener Ian Shepherd and vice-convener LuAnn Whittenburg first term will be completed. The work group will submit recommendations on the convener/vice-convener positions to ISO/TC 215 Plenary for approval at Edinburgh 2009.
53. Resolved that ISO TC215 accepts the report of ISO/TC 215 WG 7.
54. Resolved that ISO TC215 approves the WG 7 recommendation that the ISO TC215 Secretariat circulates a preliminary IEEE 30 day announcement ballot be followed by a FDIS ballot of completed IEEE document 11073-10404, *"Health informatics – Personal health device communication – Device specialization – Pulse oximeter"* for approval as a new work item targeting an IS and that the Form 4 and a document arrives at the TC Secretariat no later than 2008-07-15 to be placed on the ISO/TC web site no later than 2008-08-01.
55. Resolved that ISO TC215 approves the WG 7 recommendation that the ISO TC215 Secretariat circulates a preliminary IEEE 30 day announcement ballot be followed by a FDIS ballot of completed IEEE document 11073-10407, *"Health informatics – Personal health device communication – Device specialization – Blood pressure monitor"* for approval as a new work item targeting an IS and that the Form 4 and a document arrives at the TC Secretariat no later than 2008-07-15 to be placed on the ISO/TC web site no later than 2008-08-01
56. Resolved that ISO/TC 215 approves the WG 7 recommendation that the ISO TC215 Secretariat circulates a preliminary IEEE 30 day announcement ballot be followed by a FDIS ballot of completed IEEE document 11073-10408 *"Health informatics – Personal health device communication – Device specialization – Thermometer"* for approval as a new work item targeting an IS and the Form 4 and a document arrives at the TC Secretariat no later than 2008-07-15 to be placed on the ISO/TC web site no later than 2008-08-01.
57. Resolved that ISO TC215 approves the WG 7 recommendation that the ISO TC215 Secretariat circulates a preliminary IEEE 30 day announcement ballot be followed by a FDIS ballot of completed IEEE document 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 2008-07-15 to be placed on the ISO/TC web site no later than 2008-08-01.
58. Resolved that ISO TC215 approves the WG 7 recommendation that the ISO TC215 Secretariat circulates a preliminary IEEE 30 day announcement ballot be followed by a FDIS ballot of completed IEEE document 11073-10417, *"Health informatics – Personal health device communication – Device specialization –Glucose meter"* 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 2008-07-15 to be placed on the ISO/TC web site no later than 2008-08-01.
59. Resolved that ISO TC215 approves the WG 7 recommendation that the ISO TC215 Secretariat circulates a preliminary IEEE 30 day announcement ballot be followed by a FDIS ballot of completed IEEE document 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 2008-07-15 to be placed on the ISO/TC web site no later than 2008-08-01.

60. Resolved that ISO TC215 approves the WG 7 recommendation that the ISO TC215 Secretariat circulates a preliminary IEEE 30 day announcement ballot be followed by a FDIS ballot of completed IEEE document 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 2008-07-15 to be placed on the ISO/TC web site no later than 2008-08-01.
61. Resolved that ISO TC215 approves the WG 7 recommendation that the ISO TC215 Secretariat circulates a preliminary IEEE 30 day announcement ballot be followed by a FDIS ballot of completed IEEE document 11073-10442, *“Health informatics - Personal health device communication - Device specialization – Strength fitness equipment”* 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 2008-07-15 to be placed on the ISO/TC web site no later than 2008-08-01.
62. Resolved that ISO TC215 approves the WG 7 recommendation that the ISO TC215 Secretariat circulates a preliminary IEEE 30 day announcement ballot be followed by a FDIS ballot of completed IEEE document 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 2008-07-15 to be placed on the ISO/TC web site no later than 2008-08-01.
63. Resolved that ISO TC215 approves the WG 7 recommendation that the ISO TC215 Secretariat circulates a preliminary IEEE 30 day announcement ballot be followed by a FDIS ballot of completed IEEE document 11073-10472, *“Health informatics - Personal health device communication - Device specialization – Medication 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 2008-07-15 to be placed on the ISO/TC web site no later than 2008-08-01.
64. Resolved that ISO TC215 approves the WG 7 recommendation that the ISO TC215 Secretariat circulates a preliminary IEEE 30 day announcement ballot be followed by a FDIS ballot of completed IEEE document 11073-30400, *“Health informatics – Point-of-care medical device communication – Transport profile – Ethernet”* 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 2008-07-15 to be placed on the ISO/TC web site no later than 2008-08-01.
65. Resolved that ISO TC215 approves the WG 7 recommendation to request the Secretariat to forward document ISO FDIS 11073-91064, *“Health informatics – Standard communication protocol – Computer-assisted electrocardiography”* to the ISO Central Secretariat for FDIS ballot and that the document arrives at the TC Secretariat no later than 2008-06-02.
66. Resolved that ISO TC215 approves the WG 7 recommendation that the ISO TC215 Secretariat circulates the DTS ballot of ISO 11073-92302, *“Health informatics – Medical waveform format – Encoding rules, long term ECG”* for approval as an NWIP/Technical Specification and that the document arrives at the TC Secretariat

no later than 200809-30 to be placed on the ISO/TC web site no later than 2008-10-14.

67. Resolved that ISO/TC 215 approve the recommendation that work group convenor Todd Cooper (USA), vice-convenor Thomas Norgall (Germany) and Melvin Reynolds (UK) be continued until the Istanbul JWG meeting, submit recommendations on the convenor/viceconvenor positions to ISO/TC 215 for approval at which time a proposal will be brought to the TC.
68. Resolved that ISO TC215 accepts the report of ISO/TC 215 WG 8.
69. Resolved that ISO TC215 approves the WG 8 recommendation to request the Secretariat to forward document ISO TR 12773 *Business requirements for health summary records* to the ISO Central Secretariat for publication and that the document arrives at the TC Secretariat no later than August 31, 2008 to be placed on the ISO/TC web site no later than September 15, 2008.
70. Resolved that ISO TC215 approves the WG 8 recommendation that ISO TC215 Secretariat circulates as a Draft International Standard a ballot for 18308 *Requirements for an electronic health record architecture* and a document arrives at the TC Secretariat no later than August 31, 2008 to be placed on the ISO/TC web site no later than September 15, 2008.
71. Resolved that ISO TC215 approves the WG 8 recommendation that the work item “*EHR Classification Framework*” is renamed *Knowledge Management of Health Information Standards*.
72. Resolved that ISO TC215 approves the WG 8 recommendation that the ISO TC215 Secretariat circulates the NWIP ballot of *Knowledge Management of Health Information Standards* for approval as a new work item targeting as a Technical Report and that the Form 4 and an outline of the document arrives at the TC Secretariat no later than June 15, 2008 to be placed on the ISO/TC web site no later than June 30, 2008.
73. Resolved that ISO TC215 approves the WG 8 and Executive Council recommendation to create a “watching brief” on *Personal Health Informatics (PHI) / Personal Health Records (PHR) systems* to inform its considerations and deliberations toward developing an International Technical Report or Technical Specification as appropriate, and further, the HL7 Personal Health Record System Functional Model standard currently in development be considered in any ISO TC215 TR or TS including PHR applications.
74. Resolved that ISO/TC 215 recommends acceptance of the following reports: Joint Working Group Report, Report of re-writing the Business Plan, Report of the task forces, Secretariat report, European project on Mandate 403 and the Report from China.
75. Resolved that ISO/TC 215 establishes an adhoc group to investigate issues related to application of health informatics in Traditional Oriental Medicine and to propose an action plan for consideration at the plenary meeting, April 2009. A meeting shall be held at the next JWG meeting in October 2008 and a short interim report should be given to the plenary. The secretariat shall issue an invitation to the NMB's and other relevant bodies as the WHO Western Pacific Office to nominate members of the group before July 31. Heather Grain is appointed to be rapporteur of the group.

76. Resolved that ISO TC215 thank its host, Swedish Standards Institute, specifically Ms. Marie Brandvold, Ms. Git Eliasson, and Despina Danoglou and their sponsors, the IT University, Jon Mjolnevik, and the IT University students for their excellent meeting arrangements and social event, as well as their assistance throughout the meeting, which contributed to a successful and productive meeting.
77. Resolved that ISO TC215 thanks the drafting committee of Sharon Stanford and Patricia Village.
78. Resolved that ISO TC215 acknowledges and thanks the countries of China, Spain, and Switzerland for the contribution of their members to the ISO TC215 Plenary meeting in Goteborg, Sweden.
79. Resolved that ISO TC215 approves that the next ISO TC215 Joint Working Groups meeting will be held in Istanbul, Turkey from 12 – 15 October 2008 and be it further resolved that a half day plenary meeting will be held in conjunction with the Joint Working Groups in Istanbul, Turkey.

Attachment 4 – 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 & WG 6]
 IFMPA (International Federation of Pharmaceutical Manufacturers & Associations) [liaison with TC215 WG3 & WG 6]
 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 5 – ISO TC215 Work Program

WG 1 Data Structure						
Grant Gillis, Convener						
ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	Next Stage	HARMONIZATION	Comment
Preliminary (Not yet ready for 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						
Deployment of a Clinical Data Warehouse	Andrew Grant	29585 (TS)	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	Publication	WG 4/5	Resolution #2 (2005) Resolution #6 (Brisbane 2007)
HI: Identification of Subjects of Health Care	H Grain/D Rowlands	ISO/TS 22220	Passed DTS ballot (2006-09-25) results distributed 30.60	Publication		Awaiting revised document and disposition of comments Resolution #2 (2006)
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)
Health Informatics - Service Architecture - Information Viewpoint	Gunnar Klein	IS 12967-2	On DIS ballot (2008-03-25 -	FDIS	CEN	Resolution #7 (Brisbane 2007)

			2008-08-25)			
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	Submitted to ISO CS for DIS Processing	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	13606-3	Passed DIS ballot 2008 - 04-16 results distributed	FDIS	SDO WG9	
EHR Communicaiton Part 2 - Archetype Interchange Specifications	Dipak Kalra	IS 13606-2 10.99	Submitted to ISO CS for FDIS Processing	FDIS	SDO WG9	
Sent for Publication						
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
Health Informatics:Country Identifier Standards	R. Alvarez/D. Newsham	ISO/TS# 17120	Published - 2004	Completed Systematic Review ballot 2007-12-17		9- Abstain 5- Confirm 3- Revise 2- Withdraw 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)
Withdrawn from active Work Program						
Framework for Emergency Data Sets	Hiroshi Takeda	ISO/TR 22219				
WG 2 Data Interchange						
Mike Gillickman, Convener						
ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	Next Stage	HARMONIZATION	Comments
Preliminary (Not yet ready for 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			
IHE Global Standards Adoption Part 2 - Integration and Content Profiles		TR 28380-2	Preliminary			Resolution #13 (Montreal 2007)
NWIP/DTR Ballot						
Active Items after NWIP Approval						

Document Registry Framework	Jong-Hyuk Lee	TS#27790	Passed NWIP ballot 2007-08-27	DTS ballot		Awaiting revised document and disposition of comments Resolution #10 (2006) Resolution #16 (Montreal 2007)
Messages and Communication - Web Access Reference Manifest	Nichols Brown	IS 10159	NWIP ballot approved (2007-06-07) 10.99	CD ballot		Awaiting revised document and disposition of comments
IHE Global Standards Adoption Part 1 - Process	Parisot	DTR - #28380-1	Passed DTR ballot 2007-08-03 30.99	Publication	IHE Liaison	Awaiting revised document and disposition of comments Resolution #7 (2006) Resolution #12 (Montreal 2007) Resolution #12 (Brisbane 2007)
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	on DIS ballot (2008-1-10 - 2008-06-10)	FDIS/Publication	ISO/HL7 agreement	Resolution #11 (2006) Resolution #14 (Brisbane 2007)
Clinical Document Architecture (Release 2)	Beeler/Hammond	IS#27932	on DIS ballot (2008-1-10 - 2008-06-10)	FDIS/Publication	ISO/HL7 agreement	Resolution #11 (2006) Resolution #15 (Brisbane 2007)
Genomic sequence variation Markup Language (name change 2006 JeJu)	JNakaya/Nsakamoto	IS #25720	on DIS ballot (2008-02-07 - 2008-07-07)	FDIS/Publication		Resolution #12 (2006) Resolution #11 (Montreal 2007)
Exchange of Information between Healthcare Information Systems - Development of Messages	Marley	IS 17113	2nd DIS ballot Approved 40.60	DIS passed 88%, FDIS, need docum		Resolution #15 (Montreal 2007)

				ents		
Sent for Publication						
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	Completed Systematic Review 2008-03-17		9- Abstain 11 - Confirm 2- Revise 0 - Withdraw
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)
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	PROJECT LEADER	DESIGNATION	CURRENT STAGE	Next Stage	HARMONIZATION	
ITEM						
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: Principles and guidelines for the maintenance of terminological systems	Julie Richards	TR	Preliminary			Resolution #21 (2005)
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)

NWIP/DTR Ballot						
HI: Principles and guidelines for the measurement of conformance in the implementation of terminological systems	Beverly Knight	TR# 12310	On NWIP ballot (2008-02-29 - 2008-05-29)	DTR ballot		Resolution #21 (2005) Resolution #18 (Brisbane 2007)
HI: Mapping of terminologies to classifications	Grain	TR# 12300	On NWIP ballot (2008-02-27 - 2008-05-27)	DTR ballot		Resolution #19 (Brisbane 2007)
HI: Guidelines for international healthcare terminology standardization	Anne Casey	TR# 12309	On NWIP ballot (2008-02-28 - 2008-05-28)	DTR ballot		Resolution #16 (2006) Resolution #23 (Montreal 2007) Resolution #17 (Brisbane 2007)
Active Items after NWIP Approval						
Common Glossary for ISO/TC 215	Grain	TS#28379	NWIP ballot Approved 2006-09-13 10.99	DTS Ballot		Awaiting revised document and disposition of comments Resolution #14 (2006)
HI: Criteria for the Categorization and Evaluation of Terminological Systems. (name change 2005 Berlin)	Anne Casey	TS (Revision of ISO/TS 17117)	Passed DTS ballot (2007-12-28)	Publication		Awaiting revisions and disposition of comments Resolution #20 (Montreal 2007)
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	Awaiting revised document and disposition of comments Resolution #11,15 (2006), Resolution #20 (2005) Resolution #21 (Montreal 2007)
Sent for Publication						

HI: Conceptual Framework for patient findings and problems in terminologies	Phil Brown	TS/ISO#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						
ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	Next Stage	HARMONIZATION	
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						
HI: Directory Services for healthcare providers, subjects of care and other entities (renamed 2007 - Brisbane)	Lori Fourquet	IS #21091 - Revision of TS 21091	On NWIP ballot (2008-03-28 - 2008-06-28)	DIS		Resolution #24, 25 (Brisbane 2007)
Active Items after NWIP						

Approval						
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		Resolution #33 (Montreal 2007)
Health informatics — Electronic health record communication — Part 4: Security	Dipak Kalra	TS 13606-4	On DTS ballot (2008-03-28 - 2008-06-28)	Publication	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	WG7	Resolution #32 (Montreal 2007)
HI: Application of clinical risk management to the manufacture of health software (name change 2007 Brisbane)	Ray Rogers	TS #29321	Informal Comments (close 2008-01-15)	DTS ballot	VA - CEN lead	Resolution #29 (Montreal 2007) Resolution #27, 29 (Brisbane 2007)
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	Informal Comments (close 2008-02-08)	DTR ballot	VA - CEN lead	Resolution #30 (Montreal 2007) Resolution #28, 30 (Brisbane 2007)
HI: Secure Archiving of electronic health records Part1 Principles and Requirements	Pekka Ruotsalainen	TS 21547-1	Passed NWIP 2006-09-11 10.99	DTS ballot		Awaiting revised document and disposition of comments Resolution #22 (2006)
HI: Secure Archiving of electronic health records Part2 Guidelines	Pekka Ruotsalainen	TR 21547-2	Passed NWIP 2006-09-11 10.99	DTR ballot		Awaiting revised document and disposition of comments Resolution #23 (2006)

HC Info Privilege Mgmt & Access Control P-3 AC Mgmt	B. Blobel	TS 22600-3	Passed NWIP 2006-09-0620.00	DTS ballot		Awaiting revised document and disposition of comments Resolution #26 (2006) Resolution #31 (Montreal 2007) Resolution #31 (Brisbane 2007)
Audit trails for Electronic Health records	Luuc Posthumus	IS #27789	Passed NIWP 2006-07-26 10.99	CD Ballot		Awaiting revised document and disposition of comments Resolution #28 (2006)
Pseudonymisation	Lori Fourquet	TS #25237	Passed DTS Ballot 30.60	Publication		Awaiting revised document and disposition of comments Resolution #25 (2005)
DIS and FDIS Ballots						
HI: Information Security Mgmt in Health using ISO/IEC 27002 (name change 2007 Montreal and Brisbane)	Fraser/Mynott	IS #27799	On FDIS ballot (2008-03-13 - 2008-05-13)	Publication	VA	Resolution #25 (2006) Resolution #27, 28 (Montreal 2007) Resolution #23 (Brisbane 2007) ISO CS Processing
Sent for Publication						
HI: Functional and Structural Roles	Blobel-Fourquet-Klein	N354/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: 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)
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)

ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	Next Stage	HARMONIZATION	
WG 5 Health Cards						
Frans Van Bommel, Convener						
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	Frans Van Bommel	TR				Resolution #36 (Montreal 2007)
Overview of National Healthcare Professional Card Projects and/or Plans	Frans Van Bommel	TR			CEN	Resolution #31 (2006)
NWIP/DTR Ballot						
Active Items after NWIP Approval						
Patient Health Card Data Part 8 Links	Van Bommel/Sembrizki	IS 21549-8	NWIP Approved 2006-12-27 10.99	CD Ballot	CEN	Awaiting revised document and disposition of comments
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			
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						
ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	Next Stage	HARMONIZATION	
Preliminary (Not yet ready for NWIP ballot)						
Business requirements for an Internat'l Coding System for Medicinal products	Ock-Hee Oh	TR#25257	Reclassified - Preliminary			Decision from Geneva (2006)
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			
HL7 Annotated ECG Waveform Data Standards	Beeler/Hammond	27933	Failed 2006-09-08			Transfer to WG7?
NWIP/DTR Ballot						
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 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)

May be combined into a single ID of Medicinal Product standard with four parts - pending resolution from Copenhagen meeting

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)
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						
ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	Next Stage	HARMONIZATION	
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 – Medical waveform format – Encoding rules, long term ECG	Hirai	11073-92302 NP/TS	pre-Preliminary	NWIP+ CD	JIS	WG Decision from Brisbane
Health informatics - 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
Health informatics - Personal health device communication - Device specialization – Strength fitness equipment	White	11073-10442 NP/IS	pre-Preliminary	NWIP+ CD	IEEE lead	WG Decision from Cologne
Health informatics - Personal health device communication - Device specialization – Independent living activity hub	White	11073-10471 NP/IS	pre-Preliminary	NWIP+ CD	IEEE lead	WG Decision from Cologne
Health informatics - Personal health device communication - Device specialization – Medication Monitor	White	11073-10472 NP/IS	pre-Preliminary	NWIP+ CD	IEEE lead	WG Decision from Cologne
Health informatics - Personal health device communication -	Bogia	11073-00103 NP/TR	pre-Preliminary	NWIP+ TR	IEEE lead	

Technical report - Overview						
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, 12-lead ECG	Hirai	11073-92301 NP/TS	Preliminary	NWIP + CD	JIS	
Health informatics – Personal health device communication – Device specialization – Common framework	Bogia	11073-10400 NP/IS	Preliminary	NWIP + CD	IEEE lead	
Health informatics – Personal health device communication – Device specialization – Pulse oximeter	Bogia	11073-10404 NP/IS	Preliminary	NWIP + CD	IEEE lead	
Health informatics – Personal health device communication – Device specialization – Heart rate monitor	Bogia	11073-10406 NP/IS	Preliminary	NWIP + CD	IEEE lead	
Health informatics – Personal health device communication – Device specialization – Blood pressure monitor	Bogia	11073-10407 NP/IS	Preliminary	NWIP + CD	IEEE lead	
Health informatics – Personal health device communication – Device specialization – Thermometer	Bogia	11073-10408 NP/IS	Preliminary	NWIP + CD	IEEE lead	
Health informatics – Personal health device communication – Device specialization – Weighing scale	Bogia	11073-10415 NP/IS	Preliminary	NWIP + CD	IEEE lead	
Health informatics – Personal health device communication – Device specialization – Glucose meter	Bogia	11073-10417 NP/IS	Preliminary	NWIP + CD	IEEE lead	

Health informatics – Point-of-care medical device communication – Application profile – Common networking infrastructure		11073-20401 NP/IS	Preliminary	NWIP + CD	IEEE lead	
Health informatics – Personal health device communication – Application profile – Optimized exchange protocol	Bogia	11073-20601 NP/IS	Preliminary	NWIP + CD	IEEE lead	
Health informatics – Point- of-care medical device communication – Transport profile – Inter-LAN		11073-30400 NP/IS	Preliminary	NWIP + CD	IEEE lead	
Health informatics – Point- of-care medical device communication – Transport profile – RF wireless – Local area network (wLAN)		11073-30503 NP/IS	Preliminary	NWIP + CD	IEEE lead	
HI: Point-of-care medical device communication – Technical report – Guidelines for the use of RF wireless technology	Morrissey/Coop er	p/NWIP/110 73-00101	Preliminary		?WG4?	
HI: Point-of-care medical device communication - Device specialization - Dialysis device	Cooper/Torrini	pNWIP/1107 3-10316:	Preliminary		IEEE lead	
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 (old # 28680)	Pased CD Ballot (2008- 03-06)	DIS	IEC lead	
HI: Point-of-care medical device communication - Application profile - Optional package, Remote control	Cooper/Reynold s	DIS/11073- 20301	CD stage or DIS	CD2 Ballot Q1 2008	IEEE lead	
HI: Point-of-care Medical Device Communication - Application gateway, HL7 (v2) observation	Harrington/Coop er	DIS/11073- 60101	CD stage or DIS	DIS Ballot Q1 2008	IEEE lead	

reporting interface						
HI: Point-of-Care Medical Device Communication - Framework & overview	Harrington/Cooper	IS/11073-00000	CD stage or DIS	DIS Ballot Q3 2008	IEEE lead	Resolution #35 (2005)
HI: Point-of-Care Medical Device Communication - Nomenclature Annotated ECG	Brown/Schluter	IS/11073-10102	CD stage or DIS	DIS Ballot Q3 2008	IEEE lead	Resolution #35 (2005)
HI: Point-of-care medical device communication - Nomenclature, Implantable Device, Cardiac	Schluter	IS/11073-10103	CD stage or DIS	CD Ballot Q2 2008	IEEE lead	Resolution #35 (2005)
HI: POC Medical Device Communication - Application profiles MIB Elements	Cooper/Wittenberger	IS/11073-20102	CD stage or DIS	CD Ballot Q2 2008	IEEE lead	Resolution #35 (2005)
HI: Point-of-care medical device communication – Application profile, Association Control Function	Cooper/Steubes and	IS/11073-20200	CD stage or DIS	DIS Ballot Q1 2008	IEEE lead	Resolution #35 (2005)
HI: Point-of-Care 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)
HI: Point-of-care 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	passed DIS ballot 2007-12-09	FDIS	CEN	Awaiting revised document and disposition of comments
Sent for Publication						

Published - Systematic Review						
Health informatics – Point-of-care medical device communication – Domain Info Model	Reynolds/Cooper	IS 11073-10201	Published/IEEE	Systematic Review	IEEE lead	
Health informatics – Point-of-care medical device communication – Application Profile - Base Standard	Reynolds/Cooper	IS 11073-20101	Published/IEEE	Systematic Review	IEEE lead	
Health informatics – Point-of-care medical device communication – Transport Profile - Infrared Wireless	Reynolds/Cooper	IS 11073-30300	Published/IEEE	Systematic Review	IEEE lead	
Health informatics – Point-of-care medical device communication – Transport Profile - Cable Connected	Reynolds/Cooper	IS 11073-30200	Published/IEEE	Systematic Review	IEEE lead	
Health informatics – Point-of-care medical device communication – Nomenclature	Reynolds/Cooper	IS 11073-10101	Published/IEEE	Systematic Review	IEEE lead	
Published Items						
HI: Point of care medical device communication - Part 90101: Analytical instruments- Point of care test	Cooper/Reynolds	IS/11073-90101	Published 2008		CLSI	
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: Point-of-care medical device communication - Medical waveform format – Encoding rules (formerly 11073-90201)	Hirai/Reynolds	TS/11073-92001	Published 2007			
WG 8 Business Requirements for an EHR						

Item	PROJECT LEADER	DESIGNATION	CURRENT STAGE	Next Stage	HARMONIZATION	
Convener - Open, Vice Convener Marion Lyver Acting Convener						
Preliminary (Not yet ready for NWIP ballot)						
Requirements for EHR reference architecture	Dipak Kalra	ISO#18308				Resolution #9, 63 (Montreal 2007)
HI: EHR standards Map	Andrew Grant			Publish Ad Hoc Report		Resolution #41 (2006), Resolution #39 (2005)
NWIP/DTR Ballot						
HI: Requirements and specifications of common essential information for health summary records	Marion Lyver	TR	Passed DTR ballot 2008-04-25	Publication		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	Awaiting revised document and disposition of comments Resolution #62 (Montreal 2007)
Sent for Publication						
Published Items						

ITEM	PROJECT LEADER	DESIGNATION	CURRENT STAGE	Next Stage	HARMONIZATION	
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		
DIS and FDIS Ballots						
Sent for Publication						
Published Items						