



IT-014 Health Informatics Committee

Australian Delegation Report ISO TC215 Working Group Meeting Edinburgh, Scotland - April 2009

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Author: Richard Dixon Hughes

With input from other Australians present at the meeting:

- Heather Grain - Chair IT-014 Health Informatics
- Andrew Caswell - Standards Australia
- Janette Gogler
- Bryn Lewis
- Dr Vince McCauley
- Prof Anthony Maeder

Report on ISO TC215 Working Group Meeting Edinburgh, Scotland, April 2009

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1. Introduction

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

Australia is a strong supporter of World Trade Organization (WTO) and through the coordinated endeavours of Standards Australia as national standards body, best practice in standardization which emphasises adoption of "international standards" in preference to development of local standards. Indeed, Clause 3.4 of the Memorandum of Understanding that Standards Australia holds with The Commonwealth states that:

When preparing Australian Standards, Standards Australia will, in accordance with Articles 3 and 4 of the WTO TBT Agreement, utilise accepted international standards to the maximum extent possible and will only depart from this practice where there are compelling reasons to do so.

Within this context, trade in health information systems, supporting infrastructure such as clinical terminology and conformance testing services, and even health service provision are increasingly becoming international in their scope - emphasising the need for appropriate international health informatics standards. It is vitally important to ensure that an Australian national position is represented the development of these standards. This is most effectively achieved by ensuring that Australian delegations with appropriate mixes of skills and expertise continue to participate in the relevant international standards meetings and that priority areas are adequately addressed.

The International Organization for Standardization (ISO) develops health informatics standards through technical committee *ISO/TC 215 Health Informatics*. TC 215's activities are mirrored in Australia by Standards Australia's Technical Committee, IT-014 on Health Informatics. ISO/TC 215 has the following working groups:

WG 1 Data Structure

*WG 2 Data Interchange (which has two streams:
- Architecture and Methodology)*

WG 3 Semantic Content

WG 4 Security, Safety and Privacy (also now incorporating Health Cards)

WG 6 Pharmacy and Medication Business

WG 7 Devices

WG 8 Business Requirements for Electronic Health Records

The ISO/TC 215 Secretariat is serviced by HIMSS on behalf of the US national standards body, ANSI.

The Secretariat also services the ***Joint Initiative on Health Informatics Standards Development Organisation Harmonisation*** (JI). This initiative is realised through an executive-level **Joint Initiative Council (JIC)** that has the objectives of reducing overlap and inconsistency and promoting economy of effort in the standards development activities of ISO/TC 215, CEN/TC 251, HL7 and other health informatics standards development organisations (SDOs).

There is a Joint Working Group (JWG) that reports to the JIC for the purpose of reviewing cross-SDO work programs and making recommendations for harmonisation

to the JIC. It formally operates as an ISO/TC215 Working Group but with co-chairs drawn from HL7, ISO/TC215 and CEN/TC251.

Australia provides the convener of WG 3 (Heather Grain) and Standards Australia provides the Secretariats for WG 8 and the JWG, as well as the JI and JWG website.

The Australian Healthcare Community derives significant and ongoing. Benefit from Australian representation at international meetings such as ISO/TC 215.

2. The Edinburgh Meeting

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

The Plenary Meeting for 2009 (“Edinburgh Meeting”) was hosted by BSI, the British Standards Institution, and was held in Edinburgh, Scotland from Sunday, 26 to Thursday, 30 April (inclusive) and was attended by a total of around 220 delegates from 18 countries along with representatives of liaison organisations including CEN, HL7, IHTSDO, WHO, CDISC, IHE and IEEE.

Australian was represented by seven delegates:

- Richard Dixon Hughes, Head of Delegation
- Heather Grain, Chair IT-014, Convenor ISO/TC215/WG3 Semantic content
- Andrew Caswell
- Janette Gogler
- Bryn Lewis
- Prof Anthony Maeder
- Dr Vince McCauley

Travel and accommodation costs for the seven Australian delegates were largely met by a grant from the Australian Government Department of Health and Ageing (DoHA) with the balance of the cost being met by Standards Australia, the participants and their employers. The travel grant provided by the Department was administered by Standards Australia. The financial support of the Australian Government which made the attendance of delegates possible is gratefully acknowledged.

Standards Australia facilitated the deliberations of a Selection Panel, which included the Department, to choose appropriate applicants possessing of the appropriate skill sets to attend the meeting and deliver on the meeting objectives for Australia. The chosen Australian delegates were then notified and Standards Australia coordinated and facilitated briefing meetings where the Australian delegation could meet to discuss the strategy and prepare for the meeting together.

Work Program

As can be seen from the following timetable, the meeting took place in four main parts. The first day consisted of leadership meetings, the second day began with the opening plenary at which processes for the meeting are confirmed. Following the opening plenary, work proceeded for several days across a number of streams at Working-

Group, level. The closing plenary occurred on the final day where reports from each group were received and resolutions considered, discussed and votes taken to direct future action of the TC and its WGs.

Sat 25 Apr	1930-2000: Initial Australian team meeting.
Sun 26 Apr	0830-1100: TC215 Operations & harmonization meeting (Secretaries, Conveners and Vice-Conveners - Secretariat briefs office bearers on operational matters for the meeting) – Attended by Grain (WG3) and Caswell (WG8 & JWG). 1130-1400: ISO/TC215 Executive Council Meeting - heads of delegation and conveners review policy and planning matters requiring resolutions (Attended by Dixon Hughes, Grain, Caswell) 1430-1700: ISO TC215 JWG on SDO Harmonization meeting (Secretariat - Australia (Caswell). Also attended by Dixon Hughes, Grain.
Mon 27 Apr	0900-1000 (Q1): Opening plenary and welcome on behalf of BSI and NHS CfH 1015-1215 (Q2): Working Group meetings: 1 joint session (re DCM, M/403, CDW) + 4 separate sessions 1230-1315 (Lunch) - plus Meeting of Conveners, Vice-conveners, Secretaries 1315-1500 (Q3): Working Group meetings 1 joint session (on Identity Mgt, EHR data, CDW) + 6 separate sessions 1515-1700 (Q4): Working Group meetings (2 joint + 4 separate sessions) 1715-1815: Australian team progress meeting 1800- 2000: Leadership reception (sponsored by Microsoft + NHS) - Maeder & Grain
Tue 28 Apr	0815-0900 (Q0): Early start for WG1 & WG8 joint session - presentation by Grain 0900-1215 (Q1 & Q2): Working Group meetings (7 separate sessions) 1230-1315: (Lunch) Presentation by Dr Chris Bailey of WHO on identifiers, indicator management, transmission formats and aggregation from individual records 1315-1700 (Q3): Working Group meetings (1 joint + 5 separate sessions) 1515-1700 (Q4): Working Group meetings (2 joint + 3 separate sessions) 1700-1745: Australian team progress meeting 1800-2215: ISO/TC215 Official BSI Reception
Wed 29 Apr	0900-1015 (Q1 & Q2): Working Group meetings (5 separate sessions) 0900-1215: Meeting of the JIC (Joint Initiative Council for SDO Harmonisation) - closed to all except for SDO representatives to JIC and JWG co-chairs. 1230-1315 (Lunch) - plus Meeting of Conveners, Vice-conveners, Secretaries to discuss framing of resolutions for next meeting in October 2009 1315-1730 (Q3 & Q4): Working Group meetings (5 separate sessions) - formulation and consolidation of resolutions 1900-2200: Canada-Australia dinner function
Thu 30 Apr	0900-1700 (less lunch, tea breaks): TC215 Plenary - presentations by WG conveners, TC215 leaders and liaisons accompanied by formal resolutions. (See minutes in Attachment 1). Grain presents for WG3. Dixon Hughes presents as JTC1 liaison.

When a TC 215 meeting is held in the European region, it is normal for the relevant working groups from the European CEN/TC 251 health informatics committee to meet in joint session with their corresponding ISO/TC215 working group – a practical measure that assists in harmonising CEN and ISO health informatics standards.

Australia has strongly encouraged development of major international health informatics standards under the ISO/TC215 umbrella (rather than through regional

SDOs). It was noted that, in Edinburgh, CEN/TC251 WGi (Information Models) announced an intention to reactivate a separate work program to address specific needs of EC-stakeholders. Through the JWG and our observer status at CEN, Australia will need to be vigilant to ensure that Australian input can be made on relevant work at an appropriate time and avoid the previous situation in which it became difficult for work initially developed as a European standard

Joint work is often performed with other groups having formal liaisons with ISO – CDISC, DICOM, GS1, ICN, IHTSDO, IMIA, UNECE, WHO, IHE, CEN, IEC. The relationship between ISO and CEN is notable and formalized in the Vienna agreement.

A summary of current TC215 work is provided in Section 19 below. This includes a record of standard documents that have recently been published, recent and upcoming ballots which are expected to require Australian input, proposed new work items and other significant matters related to execution of the TC215 work program.

Draft minutes and resolutions of the plenary session, which contain formal motions relating to the progression and/or acceptance of items on the TC 215 Work Program from the Edinburgh Meeting are also provided in Attachment 1 below.

2.1 Australian participation

ISO/TC 215 generally has up to eight concurrent streams at its meetings and the actual agenda for each work group tends to vary from that published prior to the meeting. Given the limited size of the Australian delegation and the expertise and interests of the delegates, the delegation necessarily covers some areas in greater depth than others with the allocation of responsibilities taking into account and the priorities set out in IT-014's current objectives for Australian engagement in international standards development as discussed with DoHA.

To monitor and plan its involvement, the Australian delegation met on a regular basis over lunch and at the end of each day to plan which sessions should be covered that are relevant to the Standards Australia IT-014 and/or NeHTA work plans.

Usually the delegation is also in constant contact by email and Skype chat as WiFi internet access is available at all conference locations. However, on this occasion, the Wifi infrastructure proved to be extremely intermittent, which made timely intra-delegation communication difficult as well as communication with interested parties in Australia. At future meetings, it may be worth considering independent internet connectivity for the Australian delegation.

In addition to the plenary and working group sessions, most Australian delegates also participated in the JWG meeting. Three out of the seven Australian delegates were also involved in TC 215 strategic management and organisational meetings in their roles as Head of Delegation, Working Group Convenors and Secretariats.

This report was compiled by the Richard Dixon Hughes, Australian Head of Delegation at ISO/TC215, drawing heavily on contributions from all of those that attended and highlighting areas of specific concern to Australian stakeholders, and identifying priority areas for such strategic engagement from all relevant parties who have an interest in the national e-health agenda.

Substantial descriptions of many TC215 projects and related activities have been provided in recent reports of TC215 meetings. At some points in this report, the reader has been referred to such descriptions, rather than repeating material. The relevant

reports may be found archived in under “News” on the Standards Australia e-health website at: <http://e-health.standards.org.au/news.asp?area=news&Archive=true>.

Participation by people with an interest and expertise in the areas under consideration is most welcome with many of the issues being discussed in detail at upcoming IT-014 working group meetings which are open to interested parties.

For details of IT-014 subcommittees and working groups or for further information contact Andrew Caswell or Julie Lam at Standards Australia via email: Andrew.Caswell@standards.org.au or Julie.Lam@standards.org.au.

2.2 TC215 Executive Council

The TC215 Executive Council comprises the TC215 Chair, the Head of Delegation for each country, and the Convenor and Vice-Convenor of each TC215 Working Group. Its role is to consider issues of governance and process relevant to the TC. Topics discussed at its meeting in Edinburgh included:

1. Reports on the activities of the JIC and JWG and implications for the TC's involvement in health informatics harmonisation, potential impacts of new members and the importance of mounting joint projects properly by completing the joint project template.
2. Operations and harmonisation. Details were provided of publication processes and formats required by ISO. In the past, TC215's documents have not always met the format and content required by ISO. The TC secretary provided a of templates and instructions from ISO on CD-ROM and gave direction to those present on the common issues and errors in our documents with advice about how to resolve these problems.

Action: Project leads for work items being led by Australia should obtain this information from Andrew Caswell and Standards Australia.

3. Processes for management of the international health informatics glossary and document register (as discussed below).
4. Draft Business Plan. Proposed updates accepted by Exec Council including scope changes to reflect incorporation of safety issues and the role of harmonisation, joint development and adaptation of standards from the 'family of health informatics standards organisations' within the scope of the TC. A need for TC215 to engage expeditiously with others active in the field including ITU-T and IEC/SC62D (electromedical equipment) was noted.

The Exec Council resolved that the updated business plan will be packaged for consideration and discussion by NMBs up to October - for vote at next plenary.

Action: Australian interests including IT-014 and NEHTA to consider and comment on Scope and Objectives for TC215 and its WGs.

5. Changes to WG conveners and secretariats - including Andrew Caswell taking over the Secretariat of WG8 and JWG (WG9) on behalf of Standards Australia
6. Liaison proposals and arrangements for and fast track processing of established international work. Organisations proposed for liaison at TC215 level include:
 - ISO/TC37 Terminology and other language and content resources;
 - ISO/TC210 Quality management and corresponding general aspects for medical devices (including joint working groups with IEC/SC62A, JWG1 risk management, JWG2 medical device software)
 - IEC/SC62D Electromedical equipment

7. Formation of a Task Force (TF) to address standards activities affecting **safety and quality of clinical care**. The Exec Council approved putting this to the TC215 plenary. The TF's would consider (among other things): - Clinical Decision Support Systems (CDSS), related EHR-S functions and contributions and engagement with others in area of medical devices.

8. Proposed arrangements for upcoming meetings and GHITS V - with outcomes as reported below.
9. Resourcing of the Secretariat. The steadily increasing publication load of this TC along with the difficulties of the ISO publication process led the Executive Council to direct the Chair to ask HIMSS (who provide the secretariat) to consider and address this issue.

2.3 Opening Plenary

The opening plenary commenced with a welcome to all delegates from the Chair. Dr YS Kwak and from Kees Molenaar, Chair of CEN/TC251, who is also chair of the European Mandate M/403 working group. Recently returned from a meeting with EC representatives in Prague, he noted that “standards are back in fashion”.

Jeremy Thorp, Head of Delegation for the UK, added his welcome on behalf of the UK delegation and NHS Connecting for Health (CfH) - noting the record 220 registrants.

Dr Paul Woolman, Health Enterprise Information Architect at Scottish Health spoke of Scotland’s 500 year history as a centre of excellence in healthcare. He particularly noted the strong informatics forum at the University of Edinburgh and centre of excellence on IT and grid computing at the National E-Science Centre.

Ms. Breda Corish, Head of Market Development – Materials and Healthcare, ICT and Electronics, British Standards Institution (BSI) welcomed delegates on behalf of BSI and gave a presentation on BSI and its IST/35 health informatics committee.

BSI has some 300 staff; around 1,300 technical subcommittees working on 6175 projects; 30,211 current standards on its books and it publishes between 2,000 and 2,500 standards each year. BSI also provides secretariats for 202 international and European standards committees.

In health informatics, the UK NHS has been providing BSI with external secretariat services and committee leadership for IST/35 since 1991. This support, which has been provided through the Information Standards Board for Health and Social Care (ISB HaSC), has been essential to managing the committee’s workload.

As an organisation, BSI has been active in shaping the wider European standards agenda, seeking to ensure that standards are developed in a timely fashion to address real needs and that there is effective coordination between SDOs. These principles have underpinned BSI’s engagement in the following key areas:

- FLES (Future Landscape of European Standardization)
- EC ICT Standardization policy
- EC EXPRESS project

BSI supports the key theme emerging from the EC of seeking to optimise and avoid duplication between SDOs, requiring sector-specific programs to give preference to more generic cross-sectoral standards, wherever possible. This theme is echoed in EC Mandate M/403 and Health INTEROP report, which are shaping health informatics standardization in Europe and led to a major review and restructure of IST/35 and its activities in 2008. This has particularly impacted on the dilemma of balancing safety, security and privacy issues (as addressed by the ISO 27000 series) with effective clinical use of information systems and resources. In response to Mandate M/403, the eHealth INTEROP strategy report noted:

“eHealth standards, especially for safety/ security and privacy, should be developed in concert with those for other e-Processes, with a clear plan for accommodating the requirements of existing sector specific arrangements.”

In response to these drivers, the IST/35 Strategic Business Plan (covering the period April 2008 to March 2011) notes that :

“[IST/35]... stresses the importance of aligning international with national efforts, protecting the privacy and security of information in electronic information exchange, and engaging consumers and health care purchasers in improving the value of medical care while controlling costs.”

The Australian delegation noted that the eHealth INTEROP report and the response to Mandate M/403 is having a substantial influence on the thinking of CEN/TC251 member nations and their needs within the TC215 and JIC/JWG community. It also aligns with some of the requirements of Standards Australia’s new business model.

Action: IT-014 to review and report on status of eHealth INTEROP report and recommended M/403 standards activities and implications of this on Australian engagement through TC215, JIC/JWG and HL7.

SKMT. The opening plenary also discussed the potential benefits of wider adoption of the new eHealth Standards knowledge management tool for documents and terms glossary (as reported in [section 4 below](#)).

2.4 Proposed TC215 Meetings

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

18-21 Oct 2009	Durham, North Carolina, USA	JWG Meetings with ½ day plenary and Global Health IT Summit V
10-14 May 2010	Rio de Janeiro Brazil Windsor Barra Hotel & Congressos	Plenary (before HL7 meeting on 16-20 May in Rio)
10-13 Oct 2010	The Netherlands, location tbc	WGM, joint with CEN/TC251
May/June 2011	Finland, dates & location tbc	Plenary
Oct 2011	Possibly China - dates & location tbc	WGM

As 18 of the 27 ISO/TC215 P-members are from Europe, the Exec Council agreed that TC215 should try to have at least one meeting a year in Europe - to be joint with CEN/TC251.

2.5 Global Health IT Summit V (GHITS V)

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

The focus of GHITS V would be to review progress and re-visit the health IT needs of national health IT programs (and associated Provider/Enforcer Organisations) – responding to the challenges set by national programs at the first GHITS meeting, which was held in 2005 at Hamamatsu in Japan. Subsequent GHITS events have focussed on the vendor, clinician/provider and consumer perspectives.

Major Issues and Common Themes

Some of the more significant general topics addressed at the Edinburgh meeting ran across several Working Groups and related to the positioning of ISO/TC215 in relation to other SDOs and the Joint Initiative for Health Informatics SDO harmonisation.

The following have been grouped together and are presented in this part of the report:

- Progressing health informatics SDO collaboration - including commentary on the activities of the Joint Initiative Council (JIC) and the Joint Working Group (JWG) - See [section 3](#).
- International health informatics glossary and document register ([in section 4](#)) and the *ISO 13119* MetaKnow project ([in section 12.5 below](#)).
- European Mandate M/403 on e-Health Standards - and the drive toward interoperability in Europe that is expected to have an increasingly strong influence on the global health informatics standards agenda - [see section 5](#).
- Traditional Medicine (TM) Task Force ([in section 6](#)) and call for Australian CM input to development of standards on categorial structures for symptoms, signs and patterns/syndromes in traditional medicine (see [section 12.2 below](#)).
- The Detailed Clinical Models (DCM) project - which includes activity in both ISO/CEN and HL7. While Australian stakeholders have strongly supported the need for this project, we have recently become concerned at the path that the ISO/CEN has taken in emphasising a particular approach. [See section 7](#).
- Competing activities in the standardisation of units of measure and challenges facing the preferred general adoption of UCUM in international standards. [See section 8](#).
- Provider Identification (DTS 27527) and Entity Name Harmonisation. [See section 9](#).

The fact that the above commentaries have been grouped into this part of the report does not diminish the importance of some the other matters reported; however, the aim in production of this particular report has been to have a smaller group of core topics. The following topics reported in the subsequent parts of this report are among those that some may see as being equally significant:

- Clinical data warehouse (CDW) - specification of best practice for data repositories, health statistics, registries etc by developing *DTS 29585* to build on *DTR 22221*. [See section 10.1](#).
- Identity management frameworks - resolution of competing approaches to identity management in line with international developments. [See section 10.2](#).
- Health Information Services Architecture (HISA) - preparation of guidance on how to use the ISO/CEN HISA - with examples. [See section 10.3](#).
- Globally applicable measures for delivery of health on a national, regional and/or population basis *ISO/TS 21667* – Health indicators conceptual framework. [See section 10.4](#).
- *ISO/TR 28380* IHE global standards adoption - [see section 11.5](#).

- ISO/TR 13131 Best practice in telehealth/telemedicine - see section 11.6
- International endorsement of the CDISC BRIDG model for collecting, managing and sharing clinical trials and research data - see section 11.7.
- A series of activities on the management of terminology development applicable at international, national or local level, including guidelines for organizations (*ISO/DTR 12309* - in section 12.6), terminology product maintenance (in section 12.7) and conformance measurement (*ISO TR 12310* - in section 12.8).
- Proposal for ISO standard on alerts, including classifications of severity - in section 12.9.
- New guidelines to clarify the management and OID Registers for e-health interoperability (with external expert input) - see section 12.10.
- Building on leading Australian, UK and other work to produce standards for user interfaces and visual presentation for health care and best practice in clinical decision support systems - see sections 12.14, 16.4 and 16.5.
- Classification of data purposes for processing of personal health information - see section 13.3.
- Defining new global regimes for Identification of Medicinal Products (IDMP) and pharmacovigilance program and changes - in section 14.
- Health software risk management and new rules for risk management of IT networks etc. used in healthcare - in sections 15.1 and 15.2.
- Integrated eHealth architecture (for the Global South) Ensuring that health informatics standards base can be applied by developing and emerging (D&E) economies in securing better delivery of health to their populations is a rapidly increasing focus of TC215 work. WHO is supportive of the need for standards that streamline appropriate choices of standards, products and practices and ultimately markets for systems and services. See sections 16.1 and 17.
- Further endorsement and enhancement of the HL7 EHR system functional model (*ISO/HL7 DIS 10781*) as the basis for measuring systems functionality. See section 16.3.
- New approaches to classification of Personal Health Records (PHRs) plus endorsement and enhancement of the HL7 PHR system functional model within ISO - covered by several upcoming WG8 items listed in section 16.
- Progress of TC215 standards development highlighting progress and expected areas requiring Australian input. See section 19.

3. Collaboration between Health Informatics SDOs

3.1 Introduction to Joint Initiative, JIC and JWG

The Joint Initiative (JI) on Health Informatics SDO Harmonisation provides a management focus on harmonisation of SDO work programs and the adoption of improved processes and procedures for management of joint projects.

This initiative is formally guided by the **Joint Initiative Council (JIC)** which consists of the most senior office bearers and executives of the participating SDOs meeting by teleconference every month and face-to-face on 3 to 4 occasions per year. Executed by the founding members in 2006, the Charter for a *Joint Initiative on SDO Global Health Informatics Standardization* responds 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 JIC's activities are supported by an **Joint Working Group (JWG)** that provides an open forum in which joint activities are reviewed, proposals for new joint activities are considered and the detailed problems of managing the joint program (such as inconsistent balloting or publication processes) are worked through on a case-by-case basis. The quality and feasibility of SDO harmonisation depends on the JWG functioning effectively identifying and recommending potential joint work for approval by the JIC and in finding solutions to problems affecting the progression of joint work.

The original members of the JIC were ISO/TC 215, CEN/TC 251 and HL7 with CDISC and IHTSDO having been admitted as additional members.

The Standards Australia health informatics team provides the Secretariat for the JWG (which is officially constituted as ISO/TC 215/WG 9). The costs of staff time, communications and travel are borne by Standards Australia with assistance from the Australian Government Department of Health and Ageing; however, effective performance of this role depends on advice and assistance from Australian experts.

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

Action: It is important that all those involved in the Australian health informatics community work closely with the Standards Australia support team to ensure continuity in the quality of support provided to the JWG.

Background information: More detailed background on the JIC, JWG, their formation and activities is available from the JI website, maintained by Standards Australia at: <http://www.global-e-health-standards.org/> and, also, sections 5, 6.1 and Attachment 6 of the report of the October 2008 meeting of TC215 in Istanbul, available from: http://www.e-health.standards.org.au/downloads/TC215_Istanbul.pdf.

3.2 Joint Initiative Council (JIC)

The Joint Initiative Council (JIC) represents the arena for harmonising joint efforts of standards development in health informatics. Current members of the JIC are ISO/TC215, CEN/TC251, HL7, CDISC and IHTSDO.

Potential new members: organisations discussing membership include IEEE, DICOM, WHO and LOINC. The needs and relevance of each organisation is considered and where there is common interest in international activity, additional groups will be brought into the group, with each new member being admitted for a 6 month probationary period before achieving full membership.

While there is considerable goodwill, each of the SDOs in the JIC primarily addresses the needs of different groups within the overall e-health stakeholder communities and there are many practical barriers to seamless collaboration. Achievement of the JI's end-goals remains fragile; however, positive outcomes are being achieved, with the following matters being reported by Ed Hammond as the current JIC chair.

- **Key processes** have progressively been put into place, represented by:
(a) the initial JI Charter; (b) admission of other JIC members; and
(c) the JIC/JWG template for introducing joint work into the JIC.

Many issues surrounding the joint balloting process, publication process and intellectual property have also been addressed with varying levels of success in accordance with the following key elements:

- One SDO acts as the “host” and provides the project leader, with other participating SDO formally appointing co-leads with specific reporting responsibilities
 - Balloting will be simultaneous among participating SDOs, with the key feature that all ballots FINISH around the same time.
 - Comments are dealt with by a joint work group convened by the host but operating as a single unit on behalf of the JIC
 - Published standards will identify all participating SDOs and will be available from each SDO under that SDO's normal distribution arrangements
 - SDOs will only participate in projects and ballots relevant to their own scope and needs
- **Improving productivity.** The JIC is considering how to make its processes more efficient, with key elements being:
 - On-going evaluation of JIC processes to determine their effectiveness
 - Ensuring that items are distributed appropriately to all participating bodies in a timely fashion
 - Cross-organisational education and promoting an understanding of how the JIC and JWG work - and the differences between their roles
 - JWG conveners will meet as required with joint project groups to monitor progress, issues, resources, and other requirements - bringing items to JIC whenever the JIC needs to be involved for decisions.

- **Currently approved JIC work items:** The following six projects have been approved by the JIC to be conducted as approved joint projects under more recently agreed JIC/JWG harmonisation processes:
 - (a) harmonised data types (ISO 21090);
 - (b) ICSR;
 - (c) HL7v3 Implementation Guide for ISO/EN 13606;
 - (d) Glossary and document registries (using SKMT);
 - (e) Clinical trials registry and results (CTRR); and
 - (f) BRIDG model.See section [3.3 below](#) for brief comments on progress of these projects as reported to JWG and follow links to commentary elsewhere in this report for more detailed information.
- **Proposed project - Identification of Medicinal Products (IDMP).** The scope of this current work is being revised as a formal proposal for a JIC-approved project with ISO, CEN, HL7, CDISC, and IHTSDO all seeking to participate.
- **JIC Leadership.** Dr Ed Hammond has been the JIC chair, since it was formed. Commencing January 2010, the chair will rotate to a different SDO each year.
- **Future JIC meetings.** The JIC holds meetings or conference calls almost every month with the next teleconference scheduled for 10 June. Face-to-face meetings have also been planned for Wednesday, 23 September at HL7 WGM in Atlanta, GA and on Tuesday, 20 October at the TC 215 meeting Durham, NC.

3.3 Joint Working Group (JWG)

The 8th meeting of the JWG (Joint Working Group on SDO Harmonization - constituted as ISO/TC 215/WG 9) was held in Edinburgh on Sunday, 26 April 2009 from 1430 to 1700 hours and attracted over 90 attendees from 15 different countries.

The JWG meeting was attended and run by the three co-chairs: Don Newsham (ISO/TC215), Melvin Reynolds (CEN/TC251) and Charles Jaffe (HL7) - with Don Newsham presenting the final outcomes to the TC215 closing plenary.

The minutes of the previous (7th) meeting of the JWG, which had been held in conjunction with the Orlando HL7 WGM meeting in January 2009 were confirmed.

SDO Work Program Harmonisation. Under this topic, consideration was given to:

- Progress in the development of the Standards Knowledge Management Tool (SKMT) and discussion of its proposed use to assist JWG/JIC and its SDO members in managing the consistency of defined terms across health informatics standards and, also, to harmonise the overall standards portfolio. Consolidated commentary on SKMT and its use, subjects addressed in several different sessions is given in [section 4 below](#).
- Melvyn Reynolds' presentation on progress by European Standards Organisations (ESOs) in addressing the requirements of EC Mandate M/403 and the production and implications of the eHealth INTEROP report. Consolidated comments on this topic are provided in [section 5 below](#).

Progress of JIC-approved joint work items

The JWG received and considered updates on the following six projects which are progressing as JIC-approved joint projects under more recently agreed JIC/JWG processes.

- **ISO 21090 Harmonised data types** [section 11.2 below]. This work being led by HL7/Grahame Grieve of Australia is to be finalised via mid-year ISO/FDIS and HL7 normative ballots following completion of latest HL7 ballot reconciliations at the May 2009 HL7 WGM in Kyoto.
- **Individual Case Safety Report (ICSR)** for pharmacovigilance.
- **HL7 v3 Implementation Guide for ISO 13606 EHR communication** - JWG is clarifying proposed uses and scope of the work for a start in 2010. Mark Shafarman as the project lead
- **Document and Glossary Registries** [section 4 below]. This work item, started within ISO/TC215, is being led by Heather Grain of Australia and Andrew Grant of Canada.

To support this work being extended to other SDOs under JIC, a task force has been established to address issues of populating, marketing and maintaining these registries. SDOs will nominate the task group members.

- **BRIDG domain analysis model** for protocol-driven biomedical research [section 11.7 below]. The NWIP for international standardization of the existing CDISC BRIDG model was presented in Edinburgh with the project to be led by CDISC with strong HL7 support - see for more detail.
- **Clinical trials registry and results (CTRR)** - development of a new data exchange standard for registering and reporting of clinical trials and clinical outcomes. Approved as a JIC project with confirmed participation by CDISC (lead), HL7, and ISO and pending participation by CEN and IHTSDO. WHO and NLM (US) may have interest in the work and will need to be included in communications.

Proposed items for the Joint Work Program

The JWG discussed the following items, which have been proposed or suggested for approval by the JIC as potential joint projects to be conducted under JIC/JWG harmonisation processes.

- **Identification of Medicinal Products (IDMP)** [see section 14.2 below]. This work, initially proposed by ICH and CEN, has been underway for some years through ISO/TC215 /WG6. While it was intended as an early JIC project, it was never officially approved as such - with the result that there has been some miscommunication and conflict (particularly in relation to activities of HL7 Pharmacy WG).

Finalisation of IDMP work is now proposed as a JIC project with ISO, CEN, HL7, CDISC, and IHTSDO all participating. A JIC/JWG template has been prepared, based on revised versions of the existing the ISO WG6 project scope statements, which are . all JIC SDOs are reviewing IDMP project scopes with the aim of balloting the outputs jointly and resolving comments through JIC/JWG processes. The IDMP projects are expected to be formally approved by JIC the revised scopes have been agreed - with ISO to retain the project leadership.

In the meantime, WG6 has been assisting with the redefinition of these projects and their renewal on the ISO/TC215 work plan in other sections of this report.

- **Detailed clinical modelling (DCM)** [see section 7 below]. The current parallel ISO and HL7 work on detailed clinical modelling (DCM) and clinical information models being led by Dr William Goossen of The Netherlands is being put forward to JIC as a Preliminary Joint Work Item (PJWI). Dr Goossen advised JWG that the ISO/NWIP ballot would commence in Jun 09 and would include an outline draft of the proposed DCM quality standards. ISO, HL7, CEN, CDISC are planning to participate. There was a lot of discussion of this project at JWG, including exploration of issues surrounding: project team structure; the related establishment of a DCM repository; and relationship to 13606/harmonisation. The DCM project is the subject of further reporting in section 7 below.
- **Entity Name Harmonisation.** Proposed as a PJWI, this proposed project follows-on from earlier work attempting to reconcile the functional viewpoint in the harmonised data types standard with the information and process viewpoints in the subjects of care and provider identification standards. The aim is to avoid rewriting either of the established standards but, rather, produce an implementation guide specifying how abstract data types should be mapped in identity management applications.

Required action: project lead, Heather Grain (TC215/WG3) to furnish JIC/JWG template for the item.

Follow-up: IT-014 and Standards Australia to liaise with NEHTA on needs for progression of this item.

The following potential joint projects, for which JIC/JWG joint project templates will need to be produced if they are to proceed, were also noted.

- **CDSS Guidelines:** A set of principles and desirable features of clinical decision support systems.
- **Alert Information in health records:** covering concepts, information model, and visual presentation of alert information - see section 12.9 below for more details of this item put forward by ISO/TC215/WG3 to build on work of the UK CfH programme and proposed IT-014 activities in Australia.
- **HL7 EHR-S Functional Model:** a revised version 1.1 of the HL7 EHR-S FM has been developed by the HL7 EHR WG as an HL7/ISO joint project and is headed for final ISO/FDIS and HL7 normative ballot. Closer cooperation between SDOs is sought as this cornerstone HL7 specification is further revised over the next two years. Progression of the EHR-S FM as a full international standard was a significant topic of discussion for WG1 and WG8 in Edinburgh - and is more fully reported in section 16.3 below.
- **Units of Measure (UoM):** This is currently an issue that has elicited strong debate within ISO/TC215 and which many have suggested needs to be a joint work item because of a need for harmonisation because of potential disconnections between:
 - TC215/WG6's work in defining units of measures standards for pharmacovigilance;
 - WG3's work on methodologies for maintaining units of measure;
 - Overlapping interests of IHTSDO, HL7, CDISC; and

- Widespread acceptance and use of UCUM (Unified Code for Units of Measure) - produced, maintained and openly distributed by Regenstrief Institute.

Within ISO/TC215, WG3 and WG6 have jointly committed to resolve UoM issues and report back to JWG on proposed joint work item status, alignments, interests of ISO/TC215 WG3 and WG6, IHTSDO, HL7 and CDISC.

Bev Knight (Canada) reminded the JWG of resource and policy issues surrounding any proposed standardisation of UoM as terminology.

- **Medical Device Terms**

Problems have been identified in the representation of specific device concept information in relationship to tests and procedures - including ongoing use of outdated SNOMED RT references to body sites at which tests were done. It is proposed to universally move to SNOMED CT (“SCT”) for device interface specifications. There are intellectual property licensing and ongoing maintenance issues to be considered in moving to SCT and UCUM [See section 15.4 below for WG7 consideration of these issues].

Standardization of medical device terms has been informally raised as a possible joint work item for JIC but, at this stage, there no specific JIC proposal has been put forward and some of the key participating organisations (including IEEE and Continua Alliance) are not JIC members. JWG will continue to monitor progress and facilitate harmonisation between existing SDO projects but, at present, JWG considered that this was more a matter for TC215/WG7, IEEE and IHTSDO, rather than becoming a JIC-approved work item.

Procedures and processes for Joint Task Group work

The procedures and processes developed for the conduct of Joint Task Group activities have been developed by JWG/JIC, approved by JIC members, and continue to be refined in the light of experience, with further changes to emphasise the following.

- Increased use of the Document and Glossary Registries to review SDO work program inventories (already entered) for overlaps, gaps, duplication
- Coordinated joint ballot schedules to a matching end date (noting the need for differing start dates to accommodate different balloting periods) with each organisation using its own individual comment templates - but with all comments being considered and reconciled in joint task group sessions
- Use of a standard template for proposing all New Joint Work Items (NJWIs) - covering the points set out in
- Attachment 2 below.
- Basic drafting policies for joint standards publications, including common approaches to citation of other standards and document titles. ISO/TC215 is leading development of these policies as they face the most rigid publication requirements (though ISO Directives) and these are similar to those to be addressed by CEN/TC251. Other JIC members s have more flexibility to adapt.

Managing and coordinating the revision and update of published joint standards remains a major challenge, particularly where an SDO seeks to elevate an established document (such as HL7 EHR-S FM, HL7v3 CDA or EN 13606) to a full international standard (which can take some years) at the same time as continuing to enhance the original document to address stakeholder demands and implementation experience. The result can be a series of competing and incompatible normative versions from different SDOs at the same time. The alternative of halting or significantly delaying

further review and development is also unrealistic. The JWG continues to consider how joint processes can be better used to overcome these potential problems.

Other harmonisation issues

The following are among topics canvassed with the JWG under other business:

- At the JWG, Mark Shafarman raised the business process requirement to be able to register and manage HL7v3 templates.. It was agreed that this needs to be progressed through strong liaison with the DCM standards and repository activities being led by Dr William Goossen at both HL7 and at ISO. Key aspects include registry and repository functions, the ability to track and manage submission, access and display, maintenance and currency of information and semantic indexing.

The business requirements for such a repository are being developed (as joint work) under the leadership of the HL7 Templates WG - He invited interested parties to contribute to this work by signing up to the Template WG email list and participating in regular teleconference calls.

Work in The Netherlands on translation between HL7v3 templates and *openEHR* archetypes and the desirability of any repository/registry to handle archetypes, templates and any other definitive form of clinical model was noted.

Other contributions to the discussion included suggestions that:

- The registry of data elements maintained by the National Library of Medicine (US) based on ISO 11179 provides a useful model (Dickinson)
 - It is essential that registries be created, shared and bound to ontologies in ways that facilitate multilingual usage (Chute)
 - A registry needs to be dynamic - supporting standards development in parallel with their implementation - not lagging or leading (Sauermann)
- **Formation of the SCO** (SDO Charter Organization) in the USA was noted. This group was convened for an initial meeting in Scottsdale, Arizona by NCPDP and includes HL7, NCPDP and ASC X.12 as full members and DICOM, CDISC, Office of the National Coordinator, RxNorm and others as observers.

Formation of the group was driven by a move toward full-service clinics staffed by physicians and nurses in retail pharmacy chains (e.g. Walgreens) - and a need to store and exchange a much wider range of clinical content. The aim is to build on existing standards based on rigorous information models and not reinvent the wheel by developing their own incompatible specifications. The US Government has signalled that it will back the group.

Upcoming meetings and other JIC/JWG communication

The next two JWG face-to-face meetings are scheduled for:

- Atlanta, Georgia, USA - Q4 on Sunday, 20 Sep 2009 at HL7 Plenary and Working Group Meetings
- Duke University, Durham, North Carolina, USA - Saturday, 17 October 17, 2009. There will also be a morning session on Monday, 19 October for joint work item leads and JWG convenors to review and develop "work items"

A short update session was also to be held for HL7-ers on 10 May/Q4 at the HL7 meeting in Kyoto (but this would not be a fully constituted JWG meeting with secretariat support).

The TC215 plenary was reminded by the JWG convener that JI/JWG/JIC Materials are posted on the open website maintained by the JWG Secretariat at Standards Australia: www.global-e-health-standards.org

Implications for Australia

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

Required action: Maintenance of the JIC/JWG project inventory is carried out by the JWG Secretariat – hosted by Standards Australia. It is important that resources be allocated to this function.

Publication of joint work items. At previous JWG meetings it had been agreed that, prior to submission to the JIC, JWG Secretariat [Standards Australia] would load details of each joint project proposal to the JI/JIC/JWG website at: <http://www.global-e-health-standards.org/>.

Required action: This process has yet to be initiated (and other some updates to the JI/JIC/JWG website have yet to occur) – requires action by Standards Australia.

4. International health informatics glossary and document register

An on-line glossary and document registry for health informatics is being developed as a harmonized activity between CEN, ISO and HL7, with Heather Grain of Australia leading the design, editorial curation and management of the Glossary and Canada providing the online tools (SKMT) and web-site. The aim is to capture and resolve differences between the various defined terms used globally in health informatics standards.

The health informatics document register has been integrated into the project. This has been achieved by extending the tool to keep metadata on health informatics standards documents and projects.

SKMT is an open web based tool for health informatics glossary and standards document register and is now populated with 112 documents, more than 1700 terms and 1900 definitions. The user guide is to be completed shortly.

Project leads, Heather Grain and Dr Andrew Grant (Université de Sherbrooke, Canada) led several presentations and discussions of SKMT functionality and application at the Edinburgh meeting - including at the JWG, the opening plenary and a well-attended joint session. Demonstrations highlighted the different components and the ability of the tool to effectively support a variety of roles: - administrator, developer, reader, editor and a variety of search

The meeting accepted the tool with great enthusiasm and many of the working groups reported that they found it useful and used it actively during their work at this meeting. Discussion during the opening plenary focussed on the potential benefits of wider adoption of the new tool for documents and terms glossary, document metadata and links - and potentially involving ten or more SDOs. Work to date has already identified a need to harmonise definitions (with some terms having 5 or more different definitions). There continues to be a need to capture information from existing standards, as well as using the tool with all new standards.

JIC will use the glossary and document registry to review SDO work program inventories (entered) for overlaps, gaps and duplication. The JIC will develop a standardised approach to naming conventions that has been informed by the glossary initiative. Heather Grain confirmed the process that will be trialled in handling the first 25 conflicted definitions.

A procedure has been established within ISO/TC215 to manage ongoing activity in the glossary:

- All new work items are to be recorded by the relevant project lead for the work item
- All convenors, vice-convenors and project leads will be given write access to the tool.

WG3 continues to have carriage of the glossary and document register work within TC215 and is forming a broader Task Group to address registry population, marketing, maintenance, and resolution of conflicting terms and definitions across standards - with the hope that all five SDOs represented on the JIC will participate. Others with relevant expertise are also sought.

The glossary and document register work originated with acceptance of a new work item proposal for development of *ISO/TS 28379* as a technical specification in August 2006. The question has been raised as to whether something will be published. This remains uncertain as the focus is currently on how to capture the information and use it dynamically in progressing the development of other standards. A hard-copy version of the glossary is likely to be out of date by the time it is published. This will need to be discussed further and, possibly, the nature of the standards work redefined.

Australia: We should consider whether we wish to include Australian health informatics standards in this tool and how we propose to use and inform others of the availability of the tool

A copy of user guide is available from Standards Australia and the web site is at http://www.cred.ca/skmt_glossary. Registration is open and free.

We need to consider the work involved in ongoing resolution of duplications and gap identification activities related to this work item. It is unlikely that these activities will proceed at an acceptable time frame if some form of committed support is not provided.

HL7 involvement. HL7 engagement has increased significantly with more active participation and contribution on the glossary work.

Australia needs to support this change by supporting activities of HL7 WGs to determine the process for HL7 to incorporate their extensive glossary and document registration beyond the V2 glossary which is the only document currently provided in the glossary.

5. European Mandate M/403 on e-Health Standards

EC mandate M/403 issued from EC Enterprise & Industry (DG ENTR) on 6 March 2007 and invited the three peak European Standards Organisations (ESO's) concerned with ICT standards - CEN, CENELEC and ETSI - to work together to meet needs for interoperability standards to support eHealth within the EU.

Mandate M/403 is driven by recognition that eHealth interoperability affects cross-border mobility of EU citizens, quality and safety of care and the competitiveness of potential European eHealth industries. Standards for interoperability of health information systems and services are needed in an environment where the responsibility for health care delivery and funding remains firmly with Member States.

Phase 1 of the work has involved analysis, research and planning, identifying existing standards and standardization activities needed to achieve eHealth interoperability, with a view to agreeing the way forward with DGEI and EU Member States.

The findings from Phase 1 have been accepted by all the participants and published as the eHealth-INTEROP report, which can be downloaded from the project website, maintained by NEN, the Dutch national standards body - secretariat to both the M/403 task force and CEN/TC251 at: <http://www.ehealth-interop.nen.nl/>.

The current forward direction is captured in the (2-page) Prague Declaration "*eHealth for Individuals, Society and Economy*" issued on 20 February 2009 as an output of the EU i2010 eHealth 2009 Conference for adoption by EU Member States. This declaration notes that several initiatives fostering the adoption of standards are making progress but agreement on a consistent set of EU-level harmonized standards is lacking.

It encourages support for M/403 Phase 2 (Execution), originally scheduled to run from mid-2008 until 2010. This phase aims for agreement on the details of implementable standards, guidelines and other documents guidelines, methods etc needed to achieve eHealth interoperability, while ensuring consistency of content and context.

Work under Mandate M/403 is funded as an EC initiative and seeks to provide interoperable EHRs across all member nations by 2012 - with a focus on standards for interoperability of patient and health practitioner identifiers, patient EHR summaries and emergency datasets - which raises acknowledged needs in areas of ontological/semantic standards and the safety, security and privacy of health information.

As part of the process, and encouraged by DG ENTR, the three ESOs have engaged with HL7, IHE, IHTSDO and others. The role of individual SDOs is likely to reduce in Phase 2 but it is expected they will be called on to assist in delivering the required outcomes with JIC/JWG seen as a potential point of coordination.

From informal discussion of progress with some of the leaders and other material presented by Melvyn Reynolds (UK), Jeremy Thorp (UK), Stephen Kay (UK) and Kees Molenaar (NL), it was revealed that:

- The Phase 1 project team have been invited to put together a proposal for Phase 2 which is intended to start as soon as possible
- On-going negotiation is taking place among the ESOs on how to deliver the recommendations of the report and how to divide up the work.

- The technical content and overall methodology which a strong emphasis on IHE is pretty stable. However, getting a delivery model that suits all three ESOs, as well as the stakeholders and EC officials, is proving more challenging.
- The EC has committed some money for the Phase 2 work - but needs an agreed direction in order to draw down the funds.
- The M/403 process is running approximately 4 to 6 months behind schedule.
- Standards processes and products need to be aligned - focussing on satisfying stakeholders' real requirements - with a standards life cycle addressing a continuum from use case, to development and implementation.
- The development of standards for e-health in Europe will therefore be supported by an agreed process for assembling, analysing, consolidating and prioritising use cases from local/national programs, clinical bodies, industry etc.
- The process then asks whether there are existing technical standards available to support all or parts of each use case - using the standards as they are or with modification and identifying any gaps. Only where necessary, standards can be proposed for development to address the gaps.
- Profile development and maintenance is a key element in Phase 2 - an entity or consortium will be accredited to take business use cases, break them down into technical use cases, for which specific base standards will be selected and profiled - with critical success factors being:
 - maximising potential re-use of the resulting profiles,
 - credibility of the accredited entities among stakeholders, and
 - use of timely, open and transparent processes
- Accreditation of IHE-Europe in partnership with ETSI, Continua (assuming its capability is proven in time) and possibly others is being considered.
- Profile quality assurance - a process for independent quality assurance, test plans and tools for profiles, coordinating among the various contributors and users. It is seen as important that this activity be linked with existing national testing efforts in some European countries, and with international arrangements.
- Best practice forum - a formal structure for publishing, communicating and sharing experiences and best practices in the deployment of eHealth projects.

For 2009 and 2010 it is proposed to run this form through the existing EHTEL and CALLIOPE arrangements, with permanent body to follow later.
- As a general principle, the approach is to adopt existing standards wherever possible, then adapt and only invent as a last resort
- Standards are not developed as priority work without implementation strategies
- The current standards development cycle is considered too slow. Mechanisms, such as direct funding and use of experts, are being considered to speed up the standards development process.
- Governance structures are still under review. One option from the INTEROP report is an EEICC (European eHealth Interoperability Coordination Committee) to empower and oversee the five core operational activities: use cases, base standards, profile portfolio development, profile quality assurance and best

practice forum. The existing M/403 structure could be used as a pilot. There is concern that the complexity of separate governance may outweigh the benefits.

- Other EU eHealth interoperability projects, such as epSOS and Calliope will be valuable sources of use cases and will influence the way in which standards for this area can be developed, based on existing or emerging working solutions
- The European impact and requirements for international standardisation activities are expected to increase significantly.

Australia: In conjunction with DOHA, NEHTA, jurisdictions, clinical users and health consumers, the Australian health informatics community should seriously study these processes and consider how similar approaches and collaborations with the EU initiatives could be used to inform Australian eHealth developments and needs.

6. Traditional Medicine (TM) Task Force

The Ad Hoc group on Traditional Medicine (TM) was instigated to investigate mechanisms for incorporating the needs of the TM community into e-health standards. There is a clear need to represent TM concepts accurately and safely to support healthcare delivery, research and planning - encompassing support for:

- Integration of knowledge and processes of traditional medicine to build consistent and harmonised approaches to computerisation.
- Interoperability of traditional medicine concepts
- Interoperability of traditional medicine concepts between traditional medicine and Western medicine.

The work will address needs for representation of TM concepts, interoperability of TM information and supporting the integration of TM knowledge.

Like other specialised branches of medicine, TM has already been involved in some TC215 activity. There is a growing range of requirements for standards to support TM and a need to provide a mechanism to bring together domain experts to coordinate the standards development activities of TM within the TC and to ensure coordination and liaison with work of the working groups and liaison organisations. There are benefits in providing support and guidance to the proposed TM Taskforce through WG3, which already addresses most of similar issues to those raised for TM standardisation.

TC215 has approved forming a Taskforce on Traditional Medicine - reporting to WG3, which is convened by an Australian having experience with health informatics in China (Heather Grain). The Task Force is responsible for:

- Identification of standards requirements for Traditional Medicine
- Development of work item proposals for Traditional Medicine
- Recommendation of working groups relevant to undertake these proposals
- Review of New Work Item Proposals of the TC to identify where the requirements of Traditional Medicine should be incorporated.

China, Japan and Korea have all offered to provide the secretariat for the TM Task Force.

As per normal ISO practice, the status of the TM Task Force and its activities will be reviewed in 2 years (and its term may be further renewed at that time - or it may become one or more separate working groups).

Australia: Through the previous Ad Hoc Group on TM, Australian resources have contributed as independent advisors in bringing TM interests together, framing proposed work activities and progressing the formation of the TM Task Force, which is unlikely to have reached a conclusion without these contributions. Although her responsibilities to the former Ad Hoc Group on TM are now complete, the Chair of WG3 will continue to provide oversight of the TM Task Force but not as its direct leader.

It should be realised that there may be a need to assist further in this Task Force.

Australia should also consider how to engage the TM community within Australia in this activity.

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

7. Detailed clinical models (DCM)

The Detailed Clinical Modelling initiative seeks to bridge the gap between clinicians and health IT - by collecting and modelling clinical information requirements once and then re-using the models to express the same information in different technologies (e.g. HL7 and *openEHR*) and to define different outputs – messages, documents and decision support tools. Proposed standards work in this field is also increasingly concerned with the processes for collecting and managing DCMs.

Dr William Goossen (Netherlands) is leading the DCM initiative which has separate but related components within ISO/CEN and within HL7.

The background to ISO DCM activities, the nature of the initiative and its status were reported at some length in section 6.12 of the report of the October 2008 ISO/TC215 meeting in Istanbul [[link to report](#)] and are only summarised briefly here.

The project has now progressed to point where an ISO/TC 215 New Work Item Proposal (NWIP) for development of an international standard on *Quality requirements and methodologies for detailed clinical models* is out to ballot with TC215 members with a response due mid-July 2009. This document seeks to establish quality criteria addressing all four subject areas:-

1. Clinical content specification - clinician involvement and endorsement
2. DCM meta-information and content
3. DCM information modelling (and transformation)
4. DCM repository services

In parallel with ISO/CEN work on these quality requirements and methodologies, HL7 is looking to actually start populating a repository of lower-level clinical data models - in the first instance represented by transformable UML models to comply with the emerging quality requirements set by the proposed standard.

In addition, under the leadership of Mark Shafarman, the HL7 Templates WG have starting a project (in strong liaison with DCM) aimed at documenting business requirements and specifications for:

- A DCM registry where basic metadata can be stored for DCMs from different paradigms – including *openEHR* – allowing indexing and searching to find relevant DCMs and manage compositional relationships and versioning of DCM data held in various repositories.
- A DCM repository - at least capable of storing HL7v3 templates - but preferably *openEHR* archetypes as well.

The proposed ISO/CEN standard and the related Shafarman activities in defining registry/ repository requirements were discussed at some length in the JWG and in a well-attended joint session of WGs 1, 3, 7 and 8, which included consideration of:

- A presentation by Dr Goossen on the development, structure and purpose of the proposed NWIP and draft standard, highlighting the need for re-usability of completed work as well as the importance of clinician engagement and meeting clinician requirements. It was noted that DCMs can be represented in different formats, e.g. with the *openEHR* archetype editor.
- Composition of the proposed project team, which has separate subgroups to address each of the four main components of the standard and to integrate the work with other SDO activities. Those sought by Dr Goossen included:
 - **Organisational liaisons:** Julie Richards (TC215/WG1)(CA); Stephen Kay (CEN/TC251)(UK); Mark Shafarnan (HL7 Templates)(US); Dave Iberson Hurst (CDISC)(UK); IHTSDO representative (tbd)
 - **Clinical team:** Derek Hoy (Scottish NHS, UK) - as leader; Evelyn Hovenga (AU); Heather Leslie (AU)(*openEHR*), Nick Hardiker (UK); HL7 CIC nominee (tbd)
 - **Content team:** Anneke Goossen (NL); Pat van Dyke (HL7 EHR)(US); Stan Huff & Tom Oniki (IMHC)(US)
 - **Modelling team:** Kai Heitmann (DE) - as leader; Jobst Landgrebe (CDISC)(US); Patrick Loyd (CHI)(CA); Jan Talmon (NL); Ewout Kramer (NL); Yan Heras & Joey Coyle (IMHC) (US); ADL/archetype expert (tbd); UML/XMI expert (tbd)
 - **Repository team:** Sebastian Garde (*openEHR*)(DE); Beatriz Leao (BR); Jane Curry (HL7)(CA)
 - **Editorial team:** Dipak Kalra (UK); William Goossen (NL)
- The fundamental requirement underpinning the work from a clinical perspective is *“irrespective of technical format (eg: openEHR archetype, HL7v3 template and/or RMIM, clinical data definition, 13606 archetype, XML representation or UML) the medical equivalence must be maintained and usable.”*
- Proposed transformations (perhaps UML to *openEHR* archetypes, R-MIM?) have been tested and are working.
- The need for engagement between WG7 (Devices) and DCM was noted (see notes at section 15.5 below).
- The HL7 DCM repository project has already been approved and is underway. It based on capturing UML models for basic care (such as activities of daily living ADLS.). It needs to integrate with the work on HL7 tooling and it will be a challenge to have the HL7 repository operational by year-end.
- Mapping to terminologies such as Snomed CT and INCP was also in progress.

- By way of contrast to the HL7 component, the aim of the ISO project is a standard specifying quality criteria - with a draft to be complete by year-end
- In response to queries about relationships to existing projects (CKM), it was reiterated that the DCM work item will include requirements for repositories. The existence of example projects has been noted - the standard will be developed in conjunction with these projects. A repository may be created as a result.
- Clinical safety issues in relation to DCM have not been considered yet. The intention is for DCM to represent best practices. It was suggested that real use evidence is required to ensure clinical safety.
- From parallel work on quality criteria for archetypes it was suggested that requirements for a trustworthy DCM be included in the draft - recognising the importance and difficulties of getting clinician engagement in pilot testing.

The project is seeking real-world examples prepared with input from real clinical experts, and having tangible outcomes.

It was proposed that modellers, clinicians, and payers all need to be engaged in pilot testing.

- The importance of the relationship with the HL7 project currently specifying registry/ repository requirements was noted. Experts interested in participating in that project should contact the HL7 Templates WG through Mark Shafarman.
- Swedish DCM work suggests that one should start with generic models to assure context and traceability then move to lower level models. This finding was questioned. Other DCM work uses a bottom-up approach, which is the approach currently being addressed in the proposed standard.
- Dr Goossen advised that, in the proposed DCM development approach, details are specified initially with a subsequent review to ensure the DCM fits required contexts. The initial model is important to investigate re-use across contexts.
- An attempt at making a template for nursing-specific knowledge had revealed some difficulty handling subjective assessment data. Local quality and safety criteria may dictate changes for each country, but the basic framework for each DCM should remain.
- Incorporation of genomic research findings in clinical models has not yet been explored - contributions would be welcome.
- Using implementation success as a metric was suggested when determining the model quality (but this might lead to the wrong conclusion).
- On a related issue, some models are too complex to implement and it was recommended that simplicity and elegance be a goal for models to be used in a chaotic and complex world.
- Key clinical modelling challenges were highlighted: 1) clinicians need to be able to declare and check, in ways that they understand, how concepts are rendered in DCM with safety being extremely important; 2) downstream technology implementations rely on tested translations from a DCM - but need to be practical, adaptive and responsive to changing clinical needs; 3) in general, it is difficult to assure quality by comparing a technology implementation back to the stated initial requirement(s) from which it is derived.
- Dr Goossen invited comments on the draft documents, including examples, device details, etc.

- The importance of this work also being registered as a JIC/JWG joint project was also noted.

Re-use is the driver. The cost of EHR and eHealth messaging projects is huge with specification and transformation of clinical material being up to 80% of project costs. Coupled with growing needs for exchange of patient data for lifetime continuity of care records and secondary data use, standardised capture, storage, transformation and re-use of DCMs aims to provide a cost-effective basis for semantic interoperability.

Implications for Australia: Involvement by clinicians in this project is important possibly through Standards Australia and NEHTA. An established framework for engaging clinicians and guiding the process is essential if Australia is to participate or review the clinical content definitions.

While Australians have strongly supported the DCM concept, there is growing concern at the specific approach now being pushed. IT-014 needs to consult widely in voting on the NWIP proposal. It is also considered that a full international standard may be premature.

8. Use of UCUM in international standards

In relation to units of measure, the UCUM¹ specifications developed, maintained and distributed by Regenstrief Institute are widely regarded as representing best practice as language for expressing physical quantities (eg in laboratories and for climate research etc) but they do not have the standing of being normative international standards in the same sense as ISO standards.

UCUM is based on ISO 2955 and widely accepted, but is strictly open source and cannot be licensed for incorporation, publication and sale as part of another standard. Its codes are referenced in many other standards and mapped to other term sets. Consideration is being given to the question of how to make UCUM ISO-recognised (but not require payment for copies of it).

WG6 (Pharmacy and Medication Business) has been working on a different Units of Measure standard for pharmacovigilance, which was not based on UCUM and which is being reconsidered in light of discussions with WG3, JWG and at JIC.

In WG 7, the ISO 11703.x (device communication interface) series of standards do not presently reference UCUM but IHE profiles using these standards do. HL7 and DICOM also both mandate use of UCUM.

There is a growing desire to build on the open source UCUM code and conversions maintained by Regenstrief Institute as the global standard for UOM but there remain concerns about the governance and how to manage the respective intellectual property rights issues.

To address IPR issues, WG 7 are currently considering ISO standards making references to UCUM rather than bringing it into ISO documents, so people are not paying for something that is otherwise available as an open source product.

A “wrapper” approach was discussed at WG7 in Edinburgh - having an ISO standard for the architecture/structure, with instantiation by listing the details as a separate document or database. WG7 is considering raising an NWIP for this.

¹ UCUM – Unified Code for Units of Measure.

Plans for longer-term maintenance and governance of UCUM are other issues needing to be properly addressed at the institutional, rather than the standards-development, level. Maintenance presently depends on 2 people that perform this function at the Regenstrief Institute.

WG 3 has been considering methodologies for infrastructure, registration and maintenance of UOM code sets in with a view to aligning interests and activities, taking into account those of HL7, Regenstrief Institute/UCUM, CDISC, IHTSDO and others.

The JIC/JWG is now tracking and discussed work on UOM arising from WG3, WG 6 and WG7 activities and, within ISO/TC215, WG3 and WG6 have jointly committed to resolve UoM issues and report back to JWG on proposed joint work item status, alignments, interests of ISO/TC215 WG3 and WG6, IHTSDO, HL7 and CDISC.

In Edinburgh, a subsequent joint session with WG6 (Pharmacy and Medication Business) centred on the use of UCUM units of measurement for the description of medicinal products. WG6 are unsure whether the Issues below are covered in the current review of UCUM:

- mapping to existing units of measure that might be used now
- Translation into non-English languages
- Synonyms and translations of synonyms for use in different countries

A work item was considered at the previous meeting with the intent of not developing a terminology but ensuring the bits of the terminology required for regulation in pharmaceuticals are accurately covered.

This may take the work into the maintenance of terminologies. WG6 will be defining the requirements and structures to maintain the standard, but not the terminology. This work will be further progressed and brought forward at the next meeting. Issues that relate to terminology maintenance will be an addendum to the current work item on guidelines for terminology maintenance.

During discussions of UCUM issues in joint session of WG3, WG7 [and also in JWG], concerns were raised that some of the countries (particularly in Europe) have variations on some measures and that there is a need to harmonise and map their existing representations with UCUM.

Melvin Reynolds agreed to provide WG3 with details of the process for mapping European units – based upon Alan Rector's requirements/ methodology and underlying information to support this item. This is simpler tooling than maps from SNOMED-CT.

Australia: this is of significance for safe use of medications through legacy systems to a standardised approach through UCUM - for consideration of an Australian position.

9. Provider Identification (DTS 27527) and Entity Name Harmonisation

Heather Grain (AU), WG3 Convener and project lead for the identification projects provided a status report to WG1, WG2 and WG8 on the development of *ISO/DTS 27527* and on the consequent Entity Name Harmonisation activity. Key points included:

- *DTS 27527* originally passed ballot in April 2008 with subsequent work being undertaken to address comments and integrate its seamlessly with *ISO/DIS 21090 harmonised data types* (which is close to final acceptance across ISO, HL7 and CEN)
- After intense work, it was found that a tightly integrated approach would destroy the value of both *DIS 21090* and/or *DTS 27527* and would prejudice stakeholder acceptability. The two documents essentially serve two quite different purposes and stakeholder groups but do need to be mapped to each other for consistency of implementation.
- It was decided to proceed to publication of *DTS 27527* in essentially its current form and *ISO/DIS 21090* would also be finalised without being significantly changed on account of *DTS 27527*.
- The *DTS 27527* project team will now develop an informative annex to be subsequently published as a technical corrigendum indicating how to realise *ISO/TS 27527* at the technical level.
- Complexity had proven the enemy - it has been agreed with the data types Project Lead that functionally the content is used one way, and technically it's used another way. In producing an implementation guide as an Annex, both audiences can be informed appropriately, and in an appropriate time-scale.
- The annex will be the subject of a separate NWIP raised by WG3.
- The Entity Name Harmonisation activity has also been flagged at JWG, as it involves HL7 and CEN components, as well as ISO/TC215.

Working Group and Meeting Reports

10. WG 1 – Data Structure

Meetings of WG1 were held over 2½ days, with a total aggregate attendance of some 75 delegates representing 16 countries plus IHE International, WHO and ISO/TC106 (Dentistry). Most of the WG1 sessions in Edinburgh were joint sessions with WG8 (EHR Business Requirements) and with the WG1 mirror committee from CEN, TC251/WG i (Information Models).

Richard Dixon Hughes and Andrew Caswell had principal responsibility for coverage of in the WG 1 meeting in Edinburgh and participated for much of the time, with Janette Gogler, Dr Vince McCauley, Prof Anthony Maeder and Heather Grain also contributing at key points. In addition to notes contributed by Australian delegates, draft minutes circulated by the WG1 and CEN/TC251/WG i secretariats have been of help in preparing this report.

Of the matters addressed by WG1 in Edinburgh, the following have been reported separately as major issues and are not considered further in this section of the report:

- **Quality requirements and methodology for detailed clinical models (DCM).** After extensive discussion at previous TC215 and HL7 meetings, the ISO component of the DCM work is now out to NWIP ballot seeking approval to start serious work on an international standard. The proposed standards affect the formation of clinical information models with Australian contributions expected.

Consideration of the DCM project is reported more fully in [section 7 above](#).

- **European eHealth Standards - Mandate M/403.** M/403 activities and impacts are summarised in [section 5 above](#).

The following are among the other more significant matters addressed by WG 1 in Edinburgh:

1. **Relationship with CEN.** While a close relationship between WG1 and TC251/WG i (information Models) is expected to continue, TC251/WG i has announced that it will need more time in alone in its own stream at future joint WG meetings in order to address pressures to meet stakeholder needs in relationship to the EU eHealth INTEROP program and Mandate M/403.
2. **Clinical Data Warehouse (CDW).** Agreement to renew ISO/TR 22221 on CDW for another 3 years and progress ballot the more detailed companion, ISO/DTS 29585, are noted in [section 10.1 below](#).
3. **Identity Management Frameworks (IMF).** Following on with matters reported from the Istanbul meeting and discussion of a presentation by Prof Bryan Manning (UK) on work of other SDOs and major programs on identity management, WG1 established an IMF project team to continue work and report back at the October TC215 meeting. For more information, see [section 10.2 below](#).

The many initiatives and activities underway around the world in the fields of identity and privacy management - including work by several JTC1 technical subcommittees was a significant issue to emerge from the report on the previous October 2008 TC215 meeting in Istanbul.

4. **ISO 12967 Health Informatics Service Architecture (HISA).** While final publication of the 3-part HISA standard is awaited - preparation of HISA Implementation Guidance has been proposed, as well as other measures needed to support implementation of eHealth service architectures [see section 10.3 below for more information].
5. **ISO/DIS 21667 – Health Indicators Conceptual Framework** [see section 10.4 below].
6. **ISO 13606– EHR Communication**, in particular, *Part 5: Interface Specification*. This was presented to a joint session of WG 1 and WG 8 and CEN/TC251/WG 1 as reported in section 10.5 below.
7. **NWIP to standardise a list of purposes for processing EHR data.** Dr Dipak Kalra (UK), project leader, addressed a joint meeting of WG1 and WG8 on the proposed work item on classification of purposes for use of data, which had been introduced at the October 2008 TC215 meeting in Istanbul and is being progressed by WG4. See section 13.3 below for more information.
8. **NWIP for a TR on EHR Migration.** Pekka Routsalainen (FI), addressed a joint meeting of WG1 and WG8 on this item which is being worked up by WG4 (see section 13.1 below for more information). WG4 is suggesting that the work involve collaboration between WG4, WG1, WG8 and their CEN mirror committees.
9. **CDISC BRIDG model as an ISO international standard.** In joint discussion with WG2 and CDISC, it was agreed that WG1 and WG2 would undertake this new work item as a joint project to turn an updated version of the existing CDISC BRIDG model for biomedical research into a full ISO standard (with the project also likely to be joint with HL7 under JIC/JWG rules (see section 11.7 below for more information).
10. Update on **DTS 27527 Provider Identification and Entity Name Harmonisation Task Group.** Heather Grain (AU), WG3 Convener and project lead for the identification projects provided a status report to WG1, WG2 and WG8 on the development of *ISO/DTS 27527* and on the consequent Entity Name Harmonisation activity. [See commentary in section 9 above].
11. **Progression of WG1 Projects on the TC215 Work program.** Relevant recent changes including progress with publication of parts of ISO 13606 (EHR communication) and HISA are reported in Section 19 below.

Experts from WG 1 also participated in discussions of the following topics in joint sessions hosted by WG 8. Refer to commentary in section 16 for more details.

12. **Integrated eHealth architecture (for the Global South).** Dr Beatriz Leao (Brazil) gave a presentation on health information needs in developing and emerging economies, with small group from WG8 being commissioned to draft a NWIP for a joint ISO/WHO Technical Report on *"eHealth enterprise architecture for emerging and developing countries"* [see section 16.1 below].

WHO Presentation. The lunchtime presentation by Christopher Bailey of the World Health Organization (WHO) also focussed on particular needs of D&E nations and is reported in section 17 below.

13. **International Health Informatics Glossary and Document Register** (derived from project: TS 28379 Common Glossary for ISO/TC215) - see section 4 above. Lead contacts are now sought to manage use by each WG.
14. **ISO DIS 18308:2004 Requirements for an EHR Reference Architecture**. Dr Dipak Kalra (UK) provided a summary of the history to date, the DIS ballot results, comments received and the main issues, which are all reported further in section 16.2 below. A second-round DIS ballot is anticipated to commence after August 2009.
15. **Definition, Scope and Context of Personal Health Records (PHR)**. Dipak Kalra (UK) provided an update on this PHR activity and proposed a significant revision to the original concept for the project. The NWIP ballot package incorporating the suggested changes has now been posted to the TC215 website - closing in August.
16. **International Requirements for the PHR; including D&E economies**. Gora Datta (US) presented on “*Use of EHR/PHR in D&E economies*”. After discussion, it was agreed that relevant aspects would be folded into an extension of the previous work item.
17. **ISO/TR 13054 Knowledge Management of Health Informatics Standards**.
18. **ISO/DIS 10781 HL7 EHR System Functional Model (EHR-S FM)** - as reported in section 16.3 below.
19. **Potential NWIP - Guide to the principles and desirable features of clinical decision support systems (CDSS)**. Refer to WG3 report at section 12.14 below and points/discussion arising from the presentation to WG8/WG1 in section 16.4 below.
20. **Potential NWIP - User interface requirements for the visual presentation of health data**. Refer to WG3 report at section 12.14 below and points/discussion arising from the presentation to WG8/WG1 in section 16.5 below.
21. **Choice of standards for eHealth information exchange**. Jan Talmon delivered a presentation summarising a white paper from activities in The Netherlands that provides insight into the choices to be made in selecting standards for electronic exchange of health record information documents.
22. **Standards Simplification Strategy**. Gary Dickinson (US) provided a brief summary to WG 1 and WG 8 of a Simplification Strategy Proposal that he had put to the Healthcare Information Technology Standards Panel (HITSP) Foundations Framework Committee. Feedback was welcomed.
23. **Dentistry input to the EHR**. Jim McClees (US) (TC106 liaison) outlined a proposed NWIP intended to facilitate inclusion of dental content in existing and future data standards for the storage, transit, and retrieval of EHR information - for consideration at the October TC215 meeting in Durham.

Working documents relating to WG 1 activities are posted on the TC 215/WG 1 secure portal, which is managed by Standards Council of Canada, which is responsible for the WG1 secretariat.

For general enquiries about WG1 activities and access to its working drafts (where required for approved standards development work), contact Andrew Caswell at Standards Australia (Andrew.caswell@standards.org.au).

Richard Dixon Hughes (richard@dh4.com.au), co-chair of the Australian IT-014-09 EHR Interoperability subcommittee and Australian Head of Delegation to ISO/TC215 is also well positioned to discuss WG1 and many other TC215 activities.

10.1 Clinical data warehouse (CDW) - ISO TR 22221 and DTS29585

The role of a CDW is to enable data analyses in support of effective policies and decision making, to improve quality of care, to improve health services organisations, as well as to influence learning and research, among others. A CDW may be implemented as either a physical or virtual repository.

The existing ISO technical report, *ISO TR 22221:2006- Good principles and practices*

for a clinical data warehouse (CDW) was published in 2006.

ISO/TR 22221 has the primary goal of underpinning a coherent approach to the diverse and multi-stakeholder perspectives of secondary use of data from various health system sources.

WG1 has been working on a companion technical specification since 2007: *ISO/TS 29585 Deployment of a Clinical Data Warehouse (CDW)*. It provides more detailed best practice implementation guidance in the areas of:

- CDW development and deployment,
- CDW data aggregation and data modelling
- CDW architecture and data analysis

More detailed background on *ISO/TS 29585* and a report of previous progress in its development may be found in section 7.5 of the report of the October 2008 ISO/TC215 meeting in Istanbul [[link to report](#)].

ISO/TR 22221. Under ISO guidelines, continued publication of any ISO technical report must be reviewed for relevance at least every three years. Following a request for comment posted to the WG1 website and strong support from Brazil, WG1 recommended that *TR 22221* be renewed for a further 3 years. This was accepted by TC215 in plenary.

ISO/TS 29585. Project leader, Dr Andrew Grant (Canada) gave WG1 an update on progress with the project to produce a more detailed technical specification. A final committee draft was “in circulation” within the TC215 community - seeking comments and input prior to its being submitted to TC215 secretariat for issue to members as a DTS ballot in June 2009. WG1 unanimously supported proceeding to ballot with the document, which was subsequently approved by the TC215 plenary.

Australia. There are many organisations in Australia with an interest in CDW and a potential interest in this standard - including AIHW, State and Commonwealth health authorities (NHIPC), AGPN, and peak advisory/health industry bodies. On receipt of the ballot, IT-014 should approach them for input.

10.2 Identity management frameworks

There are many initiatives and activities underway around the world in the field of identity and privacy management - including work by several JTC1 subcommittees.

The report of the Australian Delegation to the October 2008 TC215 meeting in Istanbul [[link to report](#)] included considerable coverage of these matters, in particular:

- Section 6.10 (**Collaboration on information privacy, confidentiality, access control and identity management**) - a 5-page review of many potentially different but overlapping standards activities being undertaken, commenced or proposed in the areas of information privacy, confidentiality, access control and identity management . The following is a key observation from that work:

“to avoid disharmony and confusion over a proliferation of “standards” there appears to be a need for those working in this area, or commencing work in it, to be more aware of other activity and collaborate much more actively – hopefully, being guided toward harmonisation by the JWG and the Joint Initiative for Health Informatics SDO.”

- Section 7.4 (**Identity management architectures and frameworks**) - based on a two-part presentation given by Prof Bryan Manning (UK) on broad cross-industry activities by JTC1 and others in standardizing architectures and frameworks for identity management (**IdM**) and their proposed application to manage information access and control in EU applications.

In Edinburgh, Prof Manning gave a follow-up presentation to WG1, which is the main activity to be reported on this occasion (see below).

- Section 7.3 (**CEN/TR on Patient identification and cross referencing of identities**). A presentation by Karima Bourquard (France) on work being carried out by a joint Task Force of CEN/TC 251 WG i (Data content) and WG iii (Security) to deliver a CEN Technical Report setting out a defined framework which EU states, health authorities and healthcare organisations may reference when establishing policy, procedures and regulation on patient identification practices and systems.

In Edinburgh, Ms Bourquard was scheduled to give a follow-up presentation and progress report but was not able to be present.

- Section 6.7 (**Patient and provider identification**). Addresses one of the several pieces of WG3 work led by Australia in the area of Patient and Provider Identification - specifically aimed at identifying harmonization activities for Patient and Provider Identification to ensure compatibility between the various activities being carried out in CEN, ISO and HL7 (including matching identification business requirements standards and harmonised datatypes).

This activity has now been absorbed within the **Entity Name Harmonisation** activity which will be put forward to JIC as a “Proposed Joint Work Item” under the JIC/JWG rules - and being managed by WG3 on behalf of TC215. [See JWG report in section 3.3 above].

The need to address these issues is unlikely to abate without significant changes in work practices and significant investments in collaborative activity at the level of peak activities such as EU eHealth INTEROP and new Obama Administration’s eHealth strategies in the USA. However, lower-level opportunities to link with leading cross-sectoral standards bodies with high credibility in the major power blocs can be adopted as an immediate strategy.

Report on Identity Management Frameworks (IMF)
Prof Bryan Manning (UK)

Continuing the themes from his earlier presentations in the Istanbul meeting, Prof Manning provided an update on related activity taking place in other forums, such as ISO/JTC1/SC25 *Interconnection of information technology equipment* and the ISO Technical Management Board (TMB) Privacy Task Force, which met in late 2008.

Key themes included: UK work on individual privacy control rights; and the EU looking to cross-sectoral solutions through the eGovShare model - aimed at cross-border interoperability - but working progressively, testing ideas of what is required before building into Pan-European specifications.

In concluding, he suggested that a method to bridge communication among the various groups working on this subject area is required and **suggested that no TC215 NWIP should be put forward until the JTC1 work is more mature.**

The following points arose in discussion:

- B Blobel (DE) advised that he is involved with EU agencies in identity management security services with a special focus on biometrics and that he would support a collaborative effort with other committees and organizations.
- Awareness of JTC1/SC27 *IT security techniques* related-work was recommended (noting that Richard Dixon Hughes (AU) is the TC215 liaison for JTC1 and that policy frameworks for using these IdM technologies are being developed. Monitoring these projects will be important).

It was agreed to seek volunteers from the WG to collaborate on an update for the October 2008 meeting in Durham, NC - considering the IdM-related activity of liaison committees, including JTC1, HL7 and the ISO TMB Privacy Task Force, as well as national and jurisdictional developments.

WG1 resolved to establish an “**IMF Project Team**” to continue work and report back at the October TC215 meeting.

Those volunteering to serve on the IMF Project Team include:- B Blobel (DE); P Routsalainen (FI); L Posthumus(NL); E Sawasky (CA) and D Mon (US).

10.3 Health Information Services Architecture (HISA)

The three-part EN12967 HISA standard was published by CEN in 2007 and is based on the reference model for open distributed processing (RM-ODP) as specified in ISO 10746.

Following a successful “fast-track” ballot, at its October 2008 meeting, TC215 approved publication of *ISO 12967 Health informatics - Service architecture* as a full ISO international standard. While public release of the document has yet to occur, this is expected soon. More detailed background on HISA and its application were previously provided in reports of the TC215 meetings:

- in Gothenburg, Sweden, May 2008 at Section 6.2 [[link to report](#)]
- in Istanbul, Turkey, October 2008 at Section 7.2 [[link to report](#)].

Dr Gunnar Klein (SE), one of the leaders of the HISA project has now proposed to WG1 that it support preparation of HISA Implementation Guidance explaining how to use the ISO 12967-series of HISA standards. The document would aims to relate the

HISA standard to a broader framework of eHealth and ICT standards and provide some less formal views and more instructive views on how to implement HISA in concert with related standards on EHR structure and specific messages.

The guidance document might also usefully describe implementation experiences with HISA-based architectures at sites like Uppsala County Council Health Service in Sweden and Copenhagen Hospital Corporation in Denmark.

A draft of the guidance document is available for review within WG1 and members of the WG were asked to consider it and to make contributions (by 29 May) to assist in its finalisation for circulation to a [Committee Draft] ballot in mid-Year.

A HISA website is also proposed to create a central location for HISA-related information. The URL will be included in the guidance document when it is published.

During further discussion:

- It was acknowledged that implementation experience is limited as documents are still in the ISO publication process.
- A question was raised regarding plans to develop content explaining how HISA fits in with the HL7 architecture. Dr Klein indicated that while this hasn't been undertaken to date, it would be beneficial. Mark Shafarman (HL7)(US) offered to assist with this.

10.4 ISO/TS 21667 – Health indicators conceptual framework

At the May 2008 Göteborg meeting of TC215, it was resolved that the existing technical specification *ISO/TS 21667:2004 Health indicators conceptual framework* should be revised and elevated to a full ISO international standard.

This standard establishes a common health indicators conceptual framework for the field of health informatics. It is intended to foster a common vocabulary and conceptual definitions to enable the appropriate dimensions and sub-dimensions required to describe the health population and performance of large-scale health care systems to be described. The conceptual framework has 5 dimensions of:

- Health system status;
- Determinants of health;
- Health system performance;
- Community and health system characteristics, and
- Equity

The Framework has been designed to be capable of being mapped to OECD performance framework, health data, and health care quality indicators.

Canada is leading the work with Indra Pulcins of the Canadian Institute for Health Information (CIHI), one of the original authors of the document, as the project lead. When the project went to NWIP ballot, Australia voted affirmative.

Other volunteer experts for the project include: Bob Owens (US) Patrick Whitacker (World Health Organization -WHO), Gunnar Klein (SE), Jeremy Thorp (UK), and Mark Fuller (CA).

At previous meetings, Brazil, France, Japan and Australia also indicated interest in participating and were subsequently requested to confirm nominated experts. However, Australia has had difficulty finding someone to be available to assist, despite discussions with AIHW and jurisdictional representatives.

In presenting progress to WG1 in Edinburgh, Indra Pulcins provided an overview of the revised draft, context for the framework, in scope and out of scope details, as well as an outline for future development. It was noted that wording in the draft has been updated from 'non-medical determinants' to simply 'determinants in health' as it has broader application. The continuing high correspondence with other international frameworks was recognized, including the OECD frameworks. During discussion:

- It was confirmed that the draft is being developed as an International Standard (despite still having many references to "Technical Specification").
- The different viewpoints of providers and purchasers were noted, acknowledged and recommended for inclusion in the dimensions.
- It was suggested that the draft be more 3 dimensional - but it was argued the additional perspectives can be mapped within the current document, which is meant to have flexibility in how the indicators are used. It was noted that experience using the document in Brazil suggested that details can be mapped under the current dimensions.
- Consideration of need, demand, &c was recommended, from the viewpoint of managing the health system. It was recommended that the document be structured differently to facilitate this
- The Convenor reminded members of the resolution passed to maintain the level of granularity – There was agreement on maintaining the level of granularity and a note that each country will have indicators and it's important to maintain flexibility for the needs of NMBs
- A concern was raised regarding balloting, as it was suggested that more work is required. The UK voted against proceeding to ballot,

A recommendation to commence the 5-month DIS ballot in July 09 (after the draft was circulated inside WG1 for comment) was agreed and subsequently approved by TC215 at its plenary session.

Implications for Australia. This document provides a basis for understanding variation in health and health care in context of the other variables and allows internationally comparable health data with a common vocabulary.

Monitoring, and where possible contributing to, the progress of this international work is on the IT-014-09 work program. There is considerable expertise in this country that can assist in review of this work and make sure that it can be applied in developing and island nations. When the DIS ballot arrives, an early attempt should be made to engage with appropriate experts through clinical academic, NGO and government circles.

10.5 ISO 13606 EHR communication

Status of ISO 13606 - Parts 1 to 4

The first three parts of ISO 13606 are now all published as ISO international standards. Apart from later amendment to incorporate harmonised data types and for ongoing maintenance of some reference code tables to continue aligning with HL7, these Parts

have reached stability. IT-014 can now consider their adoption for greater availability and potential use in the Australian environment.

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

More complete background on EN 13606 and ISO 13606 with progress, Australian positions and recent voting is documented and/or referenced in the following sections of the Australian Delegation on the October 2008 TC215 meeting in Istanbul [[link to report](#)]:

- Section 6.3 ISO 13606 – EHR communication Parts 1 to 3
- Section 6.4 ISO/TS 13606-4 EHR communication – Part 4 Security
- Section 6.5 ISO 13606-5 EHR communication – Part 5 Interface specification

As can be seen from the following table, which gives the current status of the 5 parts, this part of the work is substantially complete for now; however, there was also a commitment for an HL7v3 implementation guide to be produced for ISO 13606 (which is on hold for the present).

13606 Standard- Part:	Status in CEN	Status in ISO
1: EHR Reference Model	EN published in February 2007	ISO 13606-1 published 07 Feb 2008
2: Archetype Interchange Specification	EN published in July 2007	ISO 13606-2 published 25 Nov 2008
3: Reference Archetypes and Term Lists	EN published in February 2008	ISO 13606-3 published 14 Jan 2009
4: Security	EN published in March 2007	Final ISO/DTS 13606-4 draft approved and received for publishing May 2009
5: Interface Specification	Passed ENQ/DIS ballot, under Vienna Agreement (CEN lead). Comments considered - amended draft ready to release for FDIS ballot.	

Progress in finalising 13606 Part 5

In Edinburgh, Dipak Kalra, 13606 team leader provided an update on progress with the final Part 5 of ISO 13606 (Interface Specification) noting that it is being developed under the Vienna Agreement, with CEN leading the initiative.

In the DIS ballot of *ISO 13606-5 EHR Communication Part 5* almost half of the many DIS ballot comments received came from Australia. The analysis and proposed disposition of comments on Part 5 were reported in section 6.5 of the Australian Delegation on the October 2008 TC215 meeting in Istanbul - and need not be repeated.

Dr Kalra reminded the meeting of the outcomes of the DIS ballot for *13606-5* and the comments that had been received and initially discussed in Istanbul. He then reviewed the main changes made to the draft and highlighted responses to the issues raised in the disposition of comments. He indicated that agreement to proceed to FDIS ballot was now being sought. During discussion:

- It was noted that TC215 had passed a resolution in Istanbul allowing the draft to progress to FDIS ballot, whenever a draft acceptable to WG1 becomes available (it should also go to parallel CEN/FV ballot at the same time)

- Potential conflicts with HL7 Service Oriented Architecture (SOA) work were questioned. Where appropriate 13606-5 specifies payload that would be then be handled via SOA. Experts that had been consulted agreed that this is sound. The disposition now includes a note that collaboration with HL7 to address these issues will take place

A motion to accept the disposition and progress 13606-5 to FDIS ballot was approved by WG1.

Dr Dipak Kalra was thanked sincerely for all of his hard work and diligence on EN 13606 and ISO 13606 over the past few years.

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

Australian interests reviewed and submitted significant comments in the DIS ballot. There will be a need for follow up to approve the final FDIS ballot, if appropriate.

Australian representatives continue to press for earlier commitments to produce an HLv3 implementation guide for *ISO 13606* to be honoured to provide a harmonious path for coexistence of HL7v3 (including CDA) and 13606 technology and to avoid any negative sentiment reflecting on the FDIS vote for Part 5.

11. WG2 – Data Interchange

Meetings of WG 2 were held over 2½ days, with a total aggregate attendance of around 30 delegates representing 11 countries.

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

While no single delegate was assigned to WG 2 in Edinburgh, Dr Vince McCauley and Prof Anthony Maeder participated at key points - providing notes used to assist in the preparation of this report. Maintenance of coverage is made more difficult as WG2 operates as two independent breakout groups for much of the time, and tends not to be involved in many joint sessions.

The long-term Secretary of WG2, Dr Adrian Stokes, has announced his resignation to take effect immediately after the October ISO/TC215 meeting in Durham. Hence an election will be required at that meeting. In informal discussion there did not appear to be an obvious replacement candidate at this stage.

Working documents relating to WG 2 activities are posted on the TC 215 Sharepoint portal, which is managed by HIMMS as the TC 215 secretariat.

For queries about WG2, information about its activities, or access to working documents for use in approved standards development work contact Andrew Caswell at Standards Australia (Andrew.caswell@standards.org.au).

Richard Dixon Hughes (richard@dh4.com.au), co-chair of the Australian IT-014-09 EHR Interoperability subcommittee and Australian Head of Delegation to ISO/TC215 is also well positioned to discuss WG2 and many other TC215 activities.

11.1 WG2 Business Practices

The initial WG2 session at the Edinburgh meeting was devoted to a review of WG2's scope and business practices. It was noted that an increasingly large part of the workload consisted of updates to ISO standards and technical reports that originated from outside ISO - notably HL7 and IHE.

ISO did little work on these documents as they were maintained by the originating organization but existing agreements (with HL7 in particular) meant that the updates had to go through the full and lengthy ISO processes. The outcome of this was an increasing administrative workload for the working group and ISO standards that were 2-3 years behind the corresponding original Standard, in particular:

- *ISO/HL7 27932 Clinical Document Architecture – Version 2* has not yet been published by ISO - 3 years after its publication by HL7 (partly due to problems with incompatibility of formatting)
- *IS/HL7 27931:2009 Health Informatics - HL7 Version 2.5* was eventually published as a full ISO international standard on 17 Jun 2009 - whereas HL7 has published the subsequent v2.6 two years ago and v2.7 will be balloted in the near future.

- The publication of the HL7 RIM and in the near future (see later in this report) and the Common HL7/ISO datatypes would increase this workload considerably as well as associated delays under the current arrangements.

It was agreed that discussions would be held with the TC 215 secretariat as to how the existing agreements with HL7 and IHE in particular could be modified to speed up the adoption of their specifications as ISO standards documents - at least for maintenance releases and updates to those documents that are already published as ISO documents.

11.2 Status of WG2 Work Items

Section 19 (Progress of TC215 standards development) examines the status of key items progressing through the TC215 work program, with comments on possible problems and likely needs for Australian input - listing them under the following headings, according to their development/ballot stage. However, as the aim was to highlight matters of interest or concern, some inactive items or those being drafted in committee are not included on these lists.

- Section 19.1 Recently completed TC 215 work
- Section 19.2 Previously approved with publication pending
- Section 19.3 FDIS ballots upcoming and in progress
- Section 19.4 Upcoming ballots - draft standards documents
- Section 19.5 Upcoming ballots - new work items
- Section 19.6 Other recently completed ballots
- Section 19.7 Other upcoming work

The current status of all current and recently completed WG2 work items in relation to the overall work program is as follows (noting that hyperlinks in the above can be used to navigate to the relevant part of section 19 for further comments):

ISO 21090 Harmonised Datatypes for Information Interchange

- Lead: Grahame Grieve (HL7) - Australia
- To go to final HL7 normative and ISO/FDIS ballot in June ([section 19.3](#))
- Minor HL7 comments to be resolved at the HL7 meeting in Kyoto May10-15
- Updated document to be available late May - ready for final ballots

ISO/HL7 27931:2009 Health Informatics - HL7 Version 2.5.

- Finally published as full ISO international standard on 18 Jun 2009

ISO/HL7 27932 Clinical Document Architecture – Release 2

- Lead: Woody Beeler (HL7)
- FDIS ballot closed 10 Jun 2009 but results not yet posted.
- If passed, will be sent for publication (with minor edits)

HL7 Version 2.6

- Appears that NWIP and final document is in preparation [report to meeting that “NWIP passed” with “no significant comments” could not be validated - Editor.]

ISO/TS 27790 Document Registry Framework

- An extension to the IHE XDS specification based on IHE Korea work
- Provides a separation of a CDA document header from the body

- Several comments from DTS ballot were resolved in Edinburgh meeting
- Approved by TC215 for publication as an ISO technical specification
- Updated final text due at TC215 Secretariat by Jun 09

ISO 13128 Clinical Document Registry Federation

- Byoung-Kee Yi (KR) - proposed as an ISO technical report
- The goal is to produce a technical report that defines an extension to the IHE Document Registry in order to allow a federated registry model.
- The concern has always been that this needs to be done in concert with IHE, if it is not to be an isolated approach overtaken by mainstream IHE developments
- For more information on progress, refer to [section 11.3 below](#).

ISO/CD 10159 Web Access Resource Manifest (WARM)

- Lead: Nick Brown (UK) - proposed as an ISO international standard
- Public comment resolution was in progress - with Committee Draft (CD) being posted to website on 20 May 2009. Ballot on revised CD anticipated soon.

ISO/NP 12974 - Web access to DICOM persistent objects by means of Web services (WADO-WS)

- Lead: Nick Brown (UK) - proposed as an ISO international standard
- Extends *ISO 17432:2004* (WADO) to Web services by providing a Notification Service and a Query Service for retrieval of DICOM persistent objects (images)
- Being developed by a joint ISO/DICOM task group and in conjunction with updated IHE XDSi (Cross Enterprise Document Sharing for Imaging) profiles
- Refer to write-up in section 8.3 of Australian delegation report on October 2008 TC215 meeting in Istanbul for more project background [[link to report](#)].
- CD being prepared - with some technical issues outstanding.

ISO 25720 Genetic Sequence Variation Markup Language (GSVML)

- Approved by TC215 for publication as a full ISO international standard at October 2008 meeting in Istanbul
- WG2 were advised that revised drafts have been provided for publication - see follow-up comments in [section 11.4 below](#).

ISO 13449 - Clinical genomics – Pedigree topic

- Lead: Ed Hammond (HL7)
- This is an HL7 standard that is being moved to an ISO document
- NWIP ballot closed 18 May 2009 - the work item was approved
- Potential issues noted during discussion included:
 - Consent and security/privacy implications for family history data
 - Ethical considerations (e.g. insurance or employment discrimination)
 - Practicalities of managing, storing and using family history data
- Refer to write-up in section 8.3 of Australian delegation report on October 2008 TC215 meeting in Istanbul for more project background [[link to report](#)].

ISO/TR 28380 IHE global standards adoption (Parts 1, 2 and 3)

- Lead: Charles Parisot (IHE International)
- This work is aimed at IHE standards profiling processes and profiles being internationally recognised by being documented in approved ISO documents.

- For more information on the progress of these items, see [section 11.5 below](#).

ISO/TR 13131 Quality Criteria for Services and Systems in Telehealth

- Lead: The Netherlands (AR Bakker)
- NWIP ballot was completed since the Istanbul meeting and passed. Resolution of comments was completed during the Edinburgh meeting.
- For more information, refer to commentary in [section 11.6 below](#).
- **Note:** This work should not be confused with *ISO/TR 16056 Interoperability of telehealth systems and networks*, on which it builds.

ISO/TS 16058:2004 Health informatics - Interoperability of telelearning systems

- Publication confirmed as an ISO/TS following systematic review.

BRIDG domain analysis model for protocol-driven biomedical research

- Lead: D Ibersen-Hurst, CDISC (Clinical Data Interchange Standard Consortium)
- NWIP to be prepared - proposing a full international standard - to be managed jointly by WG1 and WG2
- The item will make the BRIDG data model used and maintained by CDISC for the biomedical research community into an ISO standard.
- For more information, refer to [section 11.7 below](#).

Next Meeting

The next meeting of ISO/TC 215/WG 2 is scheduled for:

19-20 Oct 2009	Duke University, Durham, North Carolina (USA)	TC 215 Working Group Meeting
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11.3 ISO 13128 - Health Informatics – Clinical Document Registry Federation

This work item put forward by Korea proposes a technical report that defines an extension to the IHE Document Registry in order to allow a federated registry model.

A draft proposal for this new work item was first presented by Byoung-Kee Yi (Korea) at the October 2008 TC215 meeting in Istanbul and was met with some scepticism as to whether this technical report was really needed. There was also concern about how well it might integrate with IHE strategic directions. On the other hand, there was considerable reluctance to pre-emptively refuse to support an item that is strongly sought by Korea, with considerable technical input and some other support.

The mini-plenary at the Istanbul Meeting approved that *ISO/NPR 13128* be released for an NWIP ballot which closed on 14 Feb 2009. The results and comments were discussed in Edinburgh, with the following being addressed and resolved:

- Queries either need to be limited to registry metadata or there needs to be agreement on what document content can be included.

Queries probably should be limited to metadata.

- Federation is based on shared Metadata which is replicated from regional registries to a “national” registry. There is lack of clarity around the sponsor’s use cases that this specification has been drafted to address.
- Issues exist with harmonization between the work on this proposed standards document and work being done within IHE International. Charles Parisot, IHE International spoke to:
 - IHE harmonization with the Registry Federation. Project
 - Three strands within IHE – see White paper on Cross community Information Exchange
http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_White_Paper_Cross_Community_2008-11-07.pdf
 - See also XCA (Cross Community Access) profile for trial implementation - Austria is currently doing a trial implementation of XCA.
8 US and 7 European vendors tested XCA at the most recent USA and European Connectathons
- Currently IHE are working on XCPD – Cross Community Patient Discovery which provides a cross-directory patient ID and location discovery facility
XCPD goes to public comment June 1 with planned release for trial implementation in August. The US national program will use XCPD. It includes a detailed and complete analysis of all use cases of patient ID assignment by multiple federated hierarchies and is implemented using HL7 V3 patient queries.
- The UK are planning to use a record locator service based on a similar federated XDS (Paul Woolman)

These comments were used to clarify the original scope and harmonise this NWIP with current IHE work. It was subsequently resolved by the committee that the project could now continue to preparation of a draft Technical Report.

11.4 ISO 25720 Genomic sequence variation markup language (GSVML)

Following a DIS ballot closing in Jun 08, *ISO 25720* was approved in Istanbul for publication as a full ISO international standard with the draft to be revised to address ballot comments. The revised draft was circulated to TC215/WG2 following an out of session meeting in Orlando in Jan 09. The base document was largely translated from Japanese - so the final version was given a further English language cleanup.

An update on the project’s status was given to WG2 in Edinburgh, with the following points being noted:

- Started in 2006 with annotation of SNPs concept, at NWIP other polymorphisms were considered for addition (dual etc) but thought to be too complex and not widespread enough in adoption;
- HL7 harmonisation was subsequently included.
- It is now being used in Japan and to exchange clinical and genetic information and with some universities internationally.
- It is hoped that it will help promote more accurate recording and use of family history and personalised medicine.

- It also can be used to underpin applications that use genetic markers for personal identification, and for identification and avoidance of genetically-linked allergic reactions

In Edinburgh, WG2 reported the document as being “in publication” but also noted that: *“as a result of the ISO process, the project, which originally centred on SNP, has been extended to include all DNA variations”.*

Given the extent of the changes, it is still possible that the publication proof may still require a final FDIS ballot.

11.5 ISO/TR 28380 IHE global standards adoption

International acceptance of IHE and its processes has been high on the agenda for many Australians involved in eHealth interoperability. Acceptance of IHE in Australia is highlighted by the formation of IHE Australia and its role in organising IHE activities in the Indo-Pacific region.

ISO/TR 28380 is a multi-part set of technical reports aimed at formally documenting IHE standards profiling processes and profiles in approved ISO documents - with a view to increasing their international recognition. The project is proceeding in phases, toward a situation where agreed and established IHE profiles are documented and approved through the ISO standards processes.

Project leader, Charles Parisot of IHE International, provided an update on progress to the Methodology sub-group within WG2. From the presentation and discussion, it was noted that:

Phase I

- **ISO/TR 28380-1 IHE Global Standards Adoption – Part 1: Process** was submitted to ISO Central Secretariat for publication but was rejected on the basis that it did not conform to the standard ISO template.

Charles Parisot indicated that he would reformat and resubmit the document by 14 July (Bastille Day) 2009. [As stated in WG2 minutes from Dr Adrian Stokes].

Note: Hopefully, this explanation overcomes the problems. Part 1 has been reported to TC215 as being “in publication” at every meeting since it first passed ballot in October 2007 but remains unpublished - with no change in status recorded by ISO-CS since 19 Jun 2008.

- **ISO/TR 28380-2 IHE Global Standards Adoption – Part 2: Integration and Content Profiles** was approved in Edinburgh for publication as an ISO technical report (with final text due at TC215 Secretariat by 15 May).

Note: Whilst this report is positive, the successful ballot for Part 2 closed in Sep 08 and TC215 passed an almost identical resolution in Istanbul regarding approving the publication of Part 2 - in that case, the **finalised** documentation was due to be received by the TC215 Secretariat by 31 October 2008.

Comments on ISO/TR 28380-2 from the recently completed ballot were resolved at the meeting.

- ISO/TR 28380-1 and ISO/TR 28380-2 both need to be transferred to the correct ISO template and before being submitted to ISO Secretariat for publishing. Charles Parisot is to complete this - hoping to do it by the end of May (but apparently committing to mid-July).

Phase II

[Phase II involves the detailed documentation of specific use cases and IHE integration profiles - which is characterised as Part 3 of *ISO/TR 28380*. The possible need for a repository, registration authority or maintenance organisation had been previously discussed in relation to Part 3. Commencement of part 3 also depends on completion of parts 1 and 2 to provide adequate context.]

- During the Edinburgh meeting, there was a brief discussion of what material needed to be included in the new work item proposal (NWIP) for *ISO/TR 28380 Part 3 on "Use cases and Integration profiles (Regional and National Health projects)"*.
- IHE made a commitment to Phase II with the NWIP for Part 3 to be prepared in time for the October 2008 meeting in Durham.
- It was agreed that the following use cases will be included:
 - (a) Sharing health summaries/and continuity of care documents
 - (b) Ordering and receiving laboratory results
 - (c) Sharing imaging information

Phase III

- This phase, which may be some time away, envisages further standardisation of IHE conformance testing for interoperability, testing and test tools.

11.6 Telehealth/Telemedicine

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

Further information on the background to this project may be found in the reports of the Australian delegation to the TC215 meetings in Istanbul (October 2008 - at section 6.15) [[link to report](#)] and Göteborg (May 2008 - a short piece at section 7.2) [[link to report](#)].

The **NWIP ballot for ISO 13131 Quality Criteria for Services and Systems for telehealth** closed in Feb 09 and **was approved** for development of an ISO technical specification (Germany was the only country to oppose the proposal). The NWIP ballot was accompanied by an updated translation of the Dutch telemedicine guidelines for use as the Committee Draft.

The results of the ballot and associated comments had been circulated shortly before the Edinburgh meeting

The Edinburgh meeting discussed the NWIP comments in detail arriving at an agreed disposition, with Prof Anthony Maeder noting the following.

Project formation and scope

- 5 ISO P-members needed to nominate experts as part of NWI. The Swedish expert nomination is still to be finalised and is needed.

- Applicability of legal aspects from jurisdictional domains needs to be acknowledged.
- Should the scope include all aspects of tele-services in health (eg billing, booking etc?) The meeting considered that these are generic business processes that happen to be used in a health context and so it would not be appropriate to require their inclusion. However concepts and terms developed for telehealth aspects may be useful in these other areas.
- Telemedicine and telehealth. These terms should appear in the new glossary - noting that *ISO/TR16016*, *ISO/TR16056* already define these terms.
- There is a strong German perception that the *ISO 11073*-series of point of care medical device communication standards (including *20601*) overlap on interoperability and device/message aspects, and *80001* overlap on risk management.

These are also under TC215/WG7 and IEC/TC62 JWG7 joint group (also with IEEE). Another member of the project team should be appointed to ensure this aspect is covered (could be Germany?).

- Title of the draft document deals with Telemedicine services, which have medical and engineering aspects, need to have doctors involved, perhaps by linking to other groups that include this group (eg ISFTEH). Some national standards bodies include doctors as part of their IT committees.

Netherlands is progressing national standard on this in tandem with ISO, with a committee of 30 people (including doctors) and this will be delivered into the ISO process for comments. Funding for editorial role on this is not yet committed.

- Should scope of work be Telehealth, or just Telemedicine? The Dutch standard will only cover Telemedicine and this is the same as in the present NWIP. Some reservations expressed on this but accepted that the discussion had been had and resolved at the Istanbul meeting. [NB the title is “Telehealth”].
- Significant discussions with Continua Alliance have been held on Telehealth. These discussions have identified that they are looking to do hardware standards in the area while ISO does process standards.

Potential liaisons required for the project

- Continua has applied to be a category D member (formal liaison) of ISO TC-215, engaging with WG7 and may also have an overlap with WG4. Continua’s role is certification of compliance against their (closed) standards.
- In terms of other liaisons, discussion between WG2 and WG7 chairs should be held, expecting to hold a joint meeting of the two WGs on this work.

DICOM may also become involved through the joint initiative as they have device interests. They are involved in teledentistry devices and teleradiology (with telereporting). It was noted that IHE would be appropriate here as well.

The proposed standard is mainly for health professional to health professional communications, whereas Continua Alliance is aiming at consumers and consumer devices (but there are some grey areas such as ECG).

- ITU may also need to be involved as they are currently dealing with telehealth matters.

11.7 BRIDG model for clinical trials and research

In a joint session of WG 1, WG 2 and WG 8, Rebecca Kush (USA)(CEO and President of CDISC) provided an introduction to CDISC (Clinical Data Interchange Standards Consortium Inc), its mission and its relationships with other SDOs. She had previously introduced CDISC at the TC215 meeting in Istanbul - but on this occasion, the focus was on the proposed NWIP for making the BRIDG (Biomedical Research Integrated Domain Group) model a joint international standard.

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

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

Dave Iberson-Hurst (CTO of CDISC - based in the UK) provided an overview of the BRIDG Model, including its scope, and highlighting that it bridges a gap between healthcare and clinical research.

The BRIDG Model is a Domain Analysis Model (DAM) that is developed through a collaborative effort of stakeholders from the Clinical Data Interchange Standards Consortium (CDISC), the HL7 Regulated Clinical Research Information Management (RCRIM) Workgroup, the National Cancer Institute (NCI) and the US Food and Drug Administration (FDA). The goal of the BRIDG Project is to produce a shared view of the dynamic and static semantics of a common domain of interest, specifically the domain of protocol driven research and its associated regulatory artefacts.

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

CDISC is now seeking to bring BRIDG to a global community, specifically through the JIC, to further improve its links to healthcare. They had submitted a draft NWIP for consideration by the meeting, which was then discussed at length with the following points being noted (with particular thanks to Dr Vince McCauley).

Background

- BRIDG is an information model for research protocols - therefore the primary scope of the BRIDG model is protocol driven research.
- Current BRIDG Components include:
 - Study Tabulation Model
 - Regulated product submission
 - Patient study calendar
 - Trial design model
 - Exchangeable laboratory hub
 - Clinical trial object models

- Proposed future BRIDG components indicate significant development and harmonisation activity lies ahead and include:
 - Adverse events
 - Player scope for person/and organisation,
 - Patient registry
 - Clinical trial registry
 - Protocol abstraction
- A description of the elements would be a very important artefact from the process. The CDISC website contains a mapping spreadsheet that reviews elements that are included in the BRIDG Model.
- The work is continually being progressed by the BRIDG project group. The teams are formed and re-formed as the project progresses and each component comes up for review - a list of past participants is included in documents.
- The BRIDG Model provides a two level data map between a clinician/triallist view and the HL7 Reference Information Model (RIM).
- It is proposed this work be balloted as a joint project through HL7, CDISC and ISO simultaneously with a first ballot around Jan. 2010.

Issues

- A number of concerns were raised about this proposal:
 - Although CDISC strongly promotes itself as an “international” standards body, the view from outside CDISC is that there is relatively little real international input to CDISC and its processes, which are attuned to domestic US industry requirements.
 - The need for more comprehensive, diverse and inclusive coverage of interests - especially internationally
 - The BRIDG Board (unincorporated) is making the submission to ISO and not CDISC itself.
 - There was significant potential for overlap with existing standards work especially in the proposed provider and patient registries
- The title of the NWIP was discussed at some length, including concern about the proprietary nature of the title (which needed to be balanced against the benefits of the linkages to acknowledged BRIDG work). The WG2 Convenor noted that the issue of how to standardize titles is still under review with TC215 and the JIC, and that the title may need to be standard according to JIC/JWG rules. If including BRIDG in the title helps provide clarity, it was accepted that this should be utilised. At the same time, consistency within the TC is required.

Other questions

- Why did the BRIDG project only focus on research trials (and related activities, such as post market and surveillance) and not clinical? Extending the work into areas with different domain models for clinical may increase the need to harmonise.

- Where can more information be found?
Information and the ability to provide comments are available via the website <http://www.bridgmodel.org/>. To listen what is going on, a webinar (1 hour) is recommended.
- How does it align with regulatory and legislative requirements?
The BRIDG project team hoped to obtain regulator input during the review process, when the BRIDG model is open for comment from the CDISC website and when it is reviewed under the ISO balloting process.
The BRIDG model was brought to ISO to ensure that national member bodies engage the appropriate organizations in the development process.
- How do the BRIDG data elements align with other standards?
This development drew heavily from CDISC, HL7 and the Cancer Biomedical Informatics Grid (caBIG®).

Agreement on progression of the NWIP

The scope of the proposal was edited for the NWIP, to better reflect the work item's intention.

The submission from CDISC (after lengthy discussion) was accepted and proposed as the basis for the proposed NWIP ballot with the working title: ***“The BRIDG domain Analysis Model for protocol-driven biomedical research”***.

The work item will be balloted by CDISC first (in September) and then go to ISO for ballot as NWIP.

12. WG 3 Semantic Content

WG3 had a large attendance (around 30 people from 12 countries) including representatives from Australia, Brazil, Canada, Denmark, Germany, France, Japan, Korea, The Netherlands, Sweden, UK, USA and one liaison representative. This working group is very active and strongly supported by countries introducing terminological systems.

The European CEN /TC 251 /WG ii Terminology working group again met jointly with WG3 for much of the Edinburgh meeting – continuing the support for joint work items and the much closer relationship between the European standards community and the ISO working group.

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

- Glossary of terms for health informatics [see report in [section 4 above](#)]
- Traditional Medicine Task Force [see report in [section 6 above](#)]
- The use of UCUM (Unified Codes for Units of Measure) in international standards, which was discussed in several forums, including a joint meeting between WG3 and WG6 [see report in [section 8 above](#)].

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

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

12.1 Mapping of Terminologies to Classifications - ISO/NP TR 12300

This work aims to provide guidance to governance organisations and decision makers to assist in understanding of the requirements and processes for mapping of terminologies to classifications. A summary of the proposed purpose and content of this technical report (ISO/NP TR 12300) was provided in section 9.6 of the report of the October 2008 ISO/TC215 meeting in Istanbul [[link to report](#)].

The structure of the document is to be reviewed as an informal joint activity between IHTSDO and TC215 in order to improve its general flow.

Australia is leading and has been contributing to this work item through NEHTA and Standards Australia IT14/2 and should continue to do so.

12.2 Categorical structures for symptoms, signs and patterns/syndromes in Traditional Medicine – Part 1

This first part will focus on categorical structures for use with traditional medicine in China, Japan, Korea and other parts of East Asia.

To date, this work has been developed jointly between Korea and France and will compare the defined categorical structures in biomedicine standards with the

requirements for traditional medicine and indicate the scope required for traditional East Asian medicine and the relationships to existing western medicine concepts. Though there is broad support for this work, the title and sensitivities of the Chinese community prove extremely difficult to progress.

The TC215 plenary meeting approved a resolution to circulate an outline of the proposed standard for NWIP ballot prior to the next TC215 meeting in October.

Australia: We have been active in resolving these issues, but it is anticipated that further effort will be required to assist this item progress. There have been contributions from Australian traditional medicine specialists into this work.

12.3 System of concepts to support continuity of care – ISO/EN13940 (ContSys)

EN 13940 comprises two parts:

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

At the May 2008 TC215 Meeting in Göteborg, consideration was given to whether and how the two parts of the European EN 13940 ContSys standard should be adopted within ISO - with most members being in agreement. Since Part 1 was published, it has been used to develop systemic requirements in several northern European countries. CEN/TC251 plans to work jointly with ISO/TC215 in developing Part 2; however, this has yet to progress significantly.

As described more fully in section 9.2 of the report of the October 2008 ISO/TC215 meeting in Istanbul [[link to report](#)], the ContSys standard seeks to provide a general structure supporting continuity of care concept representation.

Within ISO, the proposed adaptation of Part 1 was accepted as a new work item in November 2008, with the existing European version adopted as the initial Committee Draft (CD) - recognising that it has gaps and needs to become less Euro-centric, more international and applicable to a wider range of health service delivery modalities.

Comments from the NWIP ballot of Part 1 were discussed in Edinburgh. While TC215 members generally continue to support this work, comments revealed some difficulties and the relationship between Part1 and Part 2 is also not clear. CEN will take all the comments and prepare a new CD with the intent to attach details of part 2 to make the total scope clearer. An NWIP for Part 2 will now be prepared to complete the set - with a view to progressing and agreeing the approach and content at the next TC215 meeting in October.

12.4 A syntax to represent the content of medical classification systems

WG3 is preparing an NWIP to adopt an international standard to provide a consistent and reproducible electronic format for maintaining and distributing coding systems through XML - based on a recommendation from WHO. The Netherlands are

extending and further developing this work to reflect the comments received during discussion within WG3.

Australia: this work is of direct relevance to the NCCH who publish ICD-10-AM. The AIHW may also find this work relevant as may NEHTA. We have asked to be on the expert group – and this means that drafts may be provided to us for comment out of meeting and ballot cycles.

12.5 Clinical Knowledge Resources – Metadata (MetaKnow) - ISO/CD 13119

Commencing with the recently published *CEN/TS 15699:2009 Health informatics - Clinical knowledge resources – Metadata*, as a Committee Draft (CD), this item passed NWIP ballot in February targeting the joint development of a full international standard with CEN via the Vienna Agreement (with CEN lead).

The document will attempt to identify, based originally on the Dublin Core, a standard structure and method of describing clinical knowledge to support the presentation of knowledge in clinical information or decision support systems.

There was some concern that getting the standard may be possible, but getting agreement on how to implement this work may be more difficult. This was not seen as a solid reason to not progress the work as it is a first step in building agreement and understanding in this area that would support quality and safety of the representation of clinical knowledge in our systems. Relevant metadata includes

- Resource form
- Intended use
- Subject and scope
- Quality Control

A class model was presented.

Australia: This work offers the potential to support a national and consistent approach to the storage, access and representation of clinical information to support decision support. Australia provided a number of comments which were well received.

Organisations with a potential interest include: NEHTA, AIHW, NCCH, Queensland Health and, possibly, NHMRC,

12.6 Guidelines for terminology development organizations ISO/DTR 12309

Publication of this document as a technical report was approved by DTR ballot closing in March 2009. In Edinburgh, the TC215 plenary approved the draft being forwarded for publication, when updated to address comments submitted.

Following DTR ballot comments, TC215 also resolved to rename the *ISO/TR 12309* work item "... *Guidelines for terminology development organisations*" replacing the previously agreed title "... *Guidelines for international healthcare terminology standardisation*".

The project lead, Anne Casey (UK), reported to WG3 on progress, noting that Australia's comments are being addressed.

Results of the DTR ballot were discussed. Specific changes do not substantially change the document. This technical report is to cover all kinds of terminology, classification, vocabulary systems, any thing that can be classed colloquially as a healthcare terminology, therefore terminological system is not adequate if it doesn't cover all of these things.

Australia: this work supports quality practices in terminology governance and should be of interest to NEHTA, AIHW, State health authorities, NCCH and QIMR/CSIRO.

12.7 Product maintenance guidelines for terminology development organisations

The NWIP ballot on the proposed technical report: **ISO/NP TR 12975 Health informatics - Principles and guidelines for the maintenance of terminological systems** closed in Nov 2008 and passed without objection with the work being accepted and considered globally relevant.

The document is in the process of being updated based on comments received. WG3 is seeking WG6 (pharmacy/medications) expertise and collaboration on this item to ensure congruence on similar work occurring within that group. Their work will become an appendix to this document.

Scope of this work includes governance aspects of a maintenance organization that effects how they manage the terminology system. This work will provide guidelines for EHR terminology standards maintenance that covers governance and high level processes for terminology development organizations, including national, state and local governance requirements. Specific headings include:

- Submission
- Tracking
- Evaluation
- Completion
- Approval
- Harmonisation with terminology authority
- Publication

The governance principles include:

- Relevant editorial policies,
- Technology (aligned with common terminology services architecture) and including a robust database
- Being available at hours and times consistent with those who use the system
- Well documented content, structure, language translations authority and process
- Consistent versioning methodology, date/time and clear version numbering and the ability to highlight changes from previous versions
- Ability for users to be able to retrieve all the attributes of a term at a given date and time.
- Consideration for historic archiving
- Guidance/editorial policy on translation (which translators should follow)
- Processes for change requests including processes for open or hidden request details and the ability of the user community to be able to view the status of the requests

- Ability to support searches and meet data mining requirements, including the maintenance organization making available a standard search that identifies the changes made to a controlled term list during a specified period.

Australia: This work is being done in conjunction with some IHTSDO activities but is aimed more specifically at national/state/local governance requirements – work which is not being undertaken directly by IHTSDO. As we have a terminology governance organization emerging within NEHTA, and some similar activities in the jurisdictions this work is of considerable relevance to Australia. Active participation would be an advantage.

12.8 Principles and guidelines for the measurement of conformance in the implementation of terminological systems (ISO TR 12310)

A new work item proposal for commencement of this project was accepted just prior to the May 2008 TC215 meeting in Gothenburg. The work is to be led by Canada and will anticipate close liaison with HL7 and IHTSDO.

This work is currently on hold as it will be based on the product maintenance document (see section 12.7 above), which must be completed prior to beginning this work.

12.9 Proposal for ISO standard on alerts, including classifications of severity

WG3 has commenced preliminary work on *“Alert information in health records - concepts, information model and visual presentation”* preparing a draft for TC215 to circulate for ballot as a new work item after its next meeting in October.

This work covers requirements for clinical alerts including differentiation of the type of alert by icon. This work includes information model and definitions as well as symbols and icons. This is a nationwide application in Sweden. There was broad support within WG3 for progressing this work.

Australia: We need to comment on this as it relates to our existing standards and the NEHTA work in this area. There is also evidence shown in this work of the issue when converting from paper based records to electronic records.

Need to consider taking this early information and acting to assist those hospitals converting information as they are doing it now and should learn from this work.

12.10 OID Registers for e-health interoperability

OIDS are required within CDA and within messaging and for other eHealth applications. There is a strong will to achieve a centralized register of OIDS to harmonise and support those issuing OIDS for e-health interoperability. HL7 are already managing OIDS as do France Télécom, ISO (and bodies registered with ISO) and ITU-T. The work is based upon existing standards, but these have not proven to be sufficient for the needs of Germany, which resulted in HL7 referring the issue to TC215 to take up with ISO. To address these needs, two new work items have been submitted for ballot, closing on 10 June 2009:

- *ISO/NP 13581: Health informatics: Guidance for maintenance of object identifiers*
- *ISO/NP 13582: Health informatics: Communication model and XML interface specification for OID registries*

The work provides an XML construct to support harmonisation of information from disparate OID registers into a single register and demonstrates use cases where sharing and retrieval of OID lists is required.

Further development and the data model will be undertaken in conjunction with HL7 and France Télécom.

On recommendation of WG3, TC215 is seeking to carry out this activity in close liaison with relevant bodies responsible for the OID identifier standards and frameworks, with expert input and guidance being sought through:

- ISO/IEC JTC1/SC6 (Telecommunications and Information Exchange Between Systems)
- ITU-T SG17 (Telecommunication security), and
- ISO/TC 54 [this is incorrect - should probably be ISO/TC 184/SC5 - Architecture, communications and integration frameworks]

Australia: watching brief, this work may be of value in the harmonisation activity and therefore of interest to NEHTA, jurisdictions and the HL7 community in Australia

12.11 Categorial structures to support interoperability between health terminology standardisation

This work aims to harmonise the existing categorial structures and understand the methodology and relationships between them and the new models emerging with a view to underpinning other work detailed clinical models and terminology.

This approach of defining categorial structures is very strong in Europe and has now been adopted, with the help of the French, for us in traditional medicine representation.

Australia: this work is a useful introduction to the concepts required in clinical environments, supports the use of openEHR or HL7 concepts. The existing standards and current work items should be assessed by NEHTA to determine their applicability to their activities.

12.12 Joint activity with WG6 (Pharmacy and Medication)

WG 3 has been considering methodologies for infrastructure, registration and maintenance of UOM code sets in with a view to aligning interests and activities, taking into account those of HL7, Regenstrief Institute/UCUM, CDISC, IHTSDO and others.

The JIC/JWG is now tracking and discussed work on UOM arising from WG3, WG 6 and WG7 activities.

Within ISO/TC215, WG3 and WG6 have jointly committed to resolve UoM issues and report back to JWG on proposed joint work item status, alignments, interests of ISO/TC215 WG3 and WG6, IHTSDO, HL7 and CDISC.

12.13 Categorial structure for human anatomy within healthcare terminological systems

It is proposed to review the existing CEN standard *EN15521:2007 Health informatics - Categorial structure for terminologies of human anatomy* with a view toward updating it to produce a second generation categorial structure.

Limitations have been identified in the existing work on surgery and nursing terminology structure that relate to the anatomical binding to the structure. The scope of the proposed work is to:

- Internationalise the European standard on the categorial structure of human anatomy within healthcare terminology systems
- To support the binding of healthcare terminological systems to ontology by analysing (dissecting) terminologies in concept categories.
- To provide a common value set on an important healthcare field of knowledge for different terminological systems to ease their maintenance and interoperability.

The strategy for review of the existing categorial structure in this area is to continue to view it as a subset of the foundation of medical anatomy. The main stakeholders of terminological systems on Catanat (Catalogue of Anatomy) will be surveyed, these include (but are not limited to) WHO, FIC, ICD, ICHI, ICF, ICPS, ICN, IHTSDO and national classification centres that are developing surgical procedures. Finally a technical report on the results of this investigation will be developed to confirm either to adopt/adapt the European standard, to adopt another standard or to do nothing.

In plenary session, TC215 approved WG3's recommendation to circulate an NWIP for ballot on "*Health informatics – Categorial structure for human anatomy within healthcare terminological systems*" - targeting a Technical Report as joint work with CEN via the Vienna Agreement (with ISO lead).

Australia: The National Centre for Classification in Health will be one of the organisations surveyed. It would be to their advantage to review the existing standards on categorial structures.

12.14 Guidelines on user interface for health care and best practice in clinical decision support

These are work items brought forward by Australia, based upon our existing handbooks. This work generated enormous interest and support.

It is the wish of the ISO community that this be elevated to a proposal to the Joint Initiative Council. There are many countries who want to actively participate in this work e.g. UK will provide their documents (from a major NHS/Microsoft study) to add to our work and generate additional harmonised work items.

For the User Interface (UI) item, WG3 is preparing a draft for TC215 to circulate for ballot as a new work item after consideration at its October meeting. This topic was also discussed at a joint session of WG1 and WG8 - reported at [section 16.5 below](#).

In relation to the work on CDSS, TC215 approved WG3's recommendation to circulate an NWIP for ballot on "*Health informatics – Guidelines for the principles and desirable features of clinical decision support systems*" - targeting a Technical Report and inviting JIC to advise on the appropriate mechanism for progressing this as a joint work item.

This topic was also discussed at a joint session of WG1 and WG8 - reported at section 16.4 below.

Australia: The UI and the CDSS work items are originally our work and Australia will need to decide how we wish to take carriage of the work item.

This will no longer be the simpler international update of our work, but two major pieces of work of significant national and international impact. The interest generated and the preparedness of the community to provide significant research resources to support develop could also provide a significant opportunity for Australian learning. However it is also likely to need significant input in time / resources.

13. WG 4 Security, Safety and Privacy

Meetings of WG 4 were held over 2½ days, with most work being conducted in joint session with WG 4's European mirror committee, CEN/TC 251/WG iii. Attendance was good with over 30 experts in total attending the various task group meetings and 25 delegates from 11 countries participating in the formal WG4 meeting.

Unfortunately, there were insufficient Australian experts able to provide full coverage of WG 4 activity; however, Dr Vince McCauley and Janette Gogler participated for some of the WG4 sessions key points - providing notes used to assist in the preparation of this report.

The officer responsible for providing the WG4 secretariat services is changing from Alice Rideau (AFNOR) to Delphine Bouis (AFNOR).

Working documents relating to WG 4 activities are posted on the TC 215 secure portal, which is managed by HIMSS.

For general enquiries about WG4 activities and access to its working drafts (where required for approved standards development work), contact Andrew Caswell at Standards Australia (Andrew.caswell@standards.org.au).

Richard Dixon Hughes (richard@dh4.com.au), co-chair of the Australian IT-014-09 EHR Interoperability subcommittee and Australian Head of Delegation to ISO/TC215 is also well positioned to discuss WG4 and many other TC215 activities.

13.1 Status of WG4 Work Items

Section 19 (Progress of TC215 standards development) examines the status of key items progressing through the TC215 work program, with comments on possible problems and likely needs for Australian input - listing them under the following headings, according to their development/ballot stage. However, as the aim was to highlight matters of interest or concern, some inactive items or those being drafted in committee are not included on these lists.

- Section 19.1 Recently completed TC 215 work
- Section 19.2 Previously approved with publication pending
- Section 19.3 FDIS ballots upcoming and in progress
- Section 19.4 Upcoming ballots - draft standards documents
- Section 19.5 Upcoming ballots - new work items
- Section 19.6 Other recently completed ballots
- Section 19.7 Other upcoming work

The status of WG4 work items noted from reports back at the Edinburgh meeting is as follows (noting that the list does not necessarily address all current WG4 work items).

ISO TS/TR 21547 Secure archiving of electronic health records

- This project has involved the production of a document in two parts:
 - Part:1 Principles and requirements (an ISO technical specification)
 - Part:2 Guidelines (an ISO technical report)

- It is a long-standing work item - reported as having been completed with documents approved for final publication (in Istanbul). As noted in section 19.2 below, the documents do not appear to have been published yet and follow-up on the delay and the project's status is warranted.

ISO 27789 Health informatics – Audit Trails for Electronic Health Records

- Lead: Luuc Posthumus (NL)
- Changes from over 100 comments on first Committee Draft (CD) reviewed
- Revised document to be submitted by mid-June for circulation as a second Committee Draft

NWIP on: *Classification of data purposes for processing of personal health information*

- Lead: Dipak Kalra (UK)
- The proposal is for an ISO technical specification
- An NWIP ballot will be held to approve the project - with documents due May 09
- The work aims to facilitate EHR interoperability through uniform classifications of use to enable automated, distributed interpretation of privacy/consent policies
- The current Working Draft (WD) is still being discussed in some depth and is not yet ready for circulation as a first CD
- Section 13.3 below provides more information on the progress of this project

NWIP on: *Security and privacy requirements for compliance testing of EHR systems*

- Leads: Luis Gustavo Kiatake (BR), kiatake@evaltec.com.br, and Alessandra Pastorino (IT), blena1@interfree.it
- Consists of two parts: **Part 1: Foundation** and **Part 2: Protection profile for small-scale electronic patient record systems**
- Draft NWIP for both parts prepared - for ISO technical specifications
- Section 13.2 below provides more information on the presentation and progression of this project in WG4.

NWIP on: *Health informatics - Security aspects of EHR record migration*

- Lead: Pekka Ruotsalainen (FI)
- NWIP documents to be prepared - for an ISO technical report
- WG4 will collaborate with WG1, WG8 and relevant CEN mirror groups
- Liaisons to WG4 on this include: Bryan Manning (WG1); Marion Lyver (WG8); Dipak Kalra (TC251 /WG i); and Bernd Blobel (TC251 /WG iii).

Australian issue. The need for this item was questioned by Australia in the Australian delegation report on the Istanbul meeting, noting many potentially competing efforts due to overlaps of SDO activities in the area of information privacy, confidentiality, access control and identity management

When the NWIP ballot finally arrives, the Australian response will need careful consideration by IT-014 to ensure that it meets a net public benefit test and does not involve significant duplication and, potentially, discussion at JIC/JWG.

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

- Lead: Hideyuki Miyohara (JP)
- Original 2007 draft was translation of a Japanese national guideline to produce an ISO technical report in two parts:
 - Part 1: Requirements and Risk assessment
 - Part 2: Implementation of ISMS
- Understood to be in final stages of publication - following approval in Istanbul for one-month final review by NMBs and then publication.

ISO/TR 11636 Health Informatics Dynamic on Demand Virtual Private network for health information infrastructure

- Project leads: Hiroshi Shimada (JP) and Kouichi Kita (JP)
- This TR reviews security threats to health information and outlines a two-layer PKI-encrypted hardware-supported approach for remote authenticated access to patient information held in repositories at health care provider institutions
- Approved by TC215 for final publication as an ISO technical report - having been used to trial acceptance of a document by ballot in a plenary
- Final text due at TC215 Secretariat by 15 May 2009

ISO/TS 13606-4 – EHR Communication – Part 4: Security

- Project lead: Dipak Kalra (UK)
- Final ISO/DTS 13606-4 draft approved and received for publishing May 2009
- Section 10.5 above provides commentary covering progress and remaining issues with all 5-parts of the ISO 13606 EHR communication standards.

ISO/DIS 21091 Directory Services for security, communications and identification of professionals and patients

- Project lead: Lori Reed-Forquet (US)
- Current *ISO/TS 21091:2005* is in process of being considered for update to a full ISO international standard
- Five-month DIS ballot closed on 27 April 2009 - during the Edinburgh meeting - it was successful with 2 negative votes (Spain, UK)
- The comments will require some document revision. Comment resolution is planned for HL7 meetings in Kyoto and Atlanta and TC215 in Durham
- Major concerns appear to be technical with many stemming from need to align with other work in Internet security and privacy and from the original work being too based on HL7 and US-centric.
- Australia had been a strong supporter and intended user of the original technical specification (probably due to work by HeSA/Medicare)
- Australia voted in favour but did not comment in the recent DIS ballot.

Required action. There is a risk that this document may no longer reflect mainstream identity management and directory services environments - now that IT-014-04 is again active, it needs be closely scrutinised by them, in conjunction with NEHTA (and possibly Medicare Australia) - with a view to more active participation in the project.

ISO/DIS 22857:2004 Guidelines on data protection to facilitate trans-border flows of personal health information

- This existing standard is subject to periodic review and with a revision being circulated as a committee draft before the Istanbul
- Final comments and concerns in the revision of this existing standard were reported to have been resolved with the revised version ready to proceed to DIS ballot as previously approved in Istanbul.

Health Cards Task Force

- In Istanbul, it was agreed that WG 4 and CEN WG iii would subsume work on health cards following the retirement of ISO/TC 215 Working Group 5
- On-going health card standards functions were given to a new Health Cards Task Force with Jürgen Sembritzki (DE), a former WG 5 convener, as leader
- The principal task is systematic review of existing HC standards and finalising publication of remaining documents.
- The Task Force reports to TC215 through WG 4 with involvement of experts from WG 1, WG 8 and other WGs as required
- Work had stopped with the passing away of Jürgen Sembritzki earlier this year
- Ivan Emlin (RU) and Masauhoshi Yachida (JP) will now jointly lead the Health Cards Taskforce.

13.2 Security and privacy requirements for compliance testing of EHR systems

A New Work Item Proposal (NWIP) for a multi-part ISO technical specification in two-parts was put forward by Brazil on “*Security and Privacy requirements for compliance testing of EHR systems*”. The first two parts to be proposed are:

- *Part 1 - Foundation* [addressing general requirements and best practices]
- *Part 2 – Protection Profile for Primary Care systems*

It is intended to add further parts in future to deal with medium and large scale EHR systems.

The documents aim to cover conformance requirements and conformance testing principles and techniques - initially for security and privacy of small scale EHR systems (e.g. clinical information systems used by clinicians working in private clinics).

This project was sponsored by Brazil who were keen on pushing certification of EHR systems and their original proposal had sought to address “certification” rather than “conformance testing”.

As this document has the potential to form the basis of a new certification regime (thereby impacting markets and costs of supply and implementation), there was a long discussion of the role of conformance and conformance testing and the expression to be used in the title and for the scope of the work item.

The UK, US, France and others noted that the word “certification” in the title would almost guarantee a negative vote - so “compliance testing” emerged as the preferred term. The title of the proposed work item was amended accordingly.

Nevertheless, as pointed out by Richard Dixon Hughes (Australia) in the closing plenary, this change of wording may not be adequate to avoid a negative outcome. The content of the work must align with global policies on conformance and assurance and the relevant provisions of the ISO/IEC directives (notably: *Section 6.7 Aspects of conformity assessment*).

The quest for universally acceptable language used to describe small clinics also presented WG with a challenge.

The activity is to be carried out as a joint activity with CEN/TC251 under the Vienna agreement - with ISO lead. Two project leads have been nominated, one from Brazil and the other from Italy.

Suggested further action. Following on from the experience with ISO/TS 29321 and ISO/TR 29322, it would seem this should not proceed if there is no clear net public benefit. Getting feedback on the ISO/CASCO provisions, the views of the health software industry and regulators should be considered once the details are clearer.

13.3 Classification of data purposes for processing of personal health information

At the previous October 2008 TC215 meeting in Istanbul, Dr Dipak Kalra (UK) had given presentations to a combined meeting of WG 1, WG 4 and WG 8 on the topic of “Standardizing purposes for processing EHR data” - reported at section 6.9 of the Australian delegation report of the Istanbul [\[link to report\]](#).

The aim is to have a standardised, encoded set of high-level categories of potential purposes for which EHR information may be processed (where “processing” might entail any or all of: collecting, storing, accessing, analysing or communicating EHR information).

The underlying need for such a classification is to support privacy and consent regimes in relation to EHR information. Most regimes governing information privacy give the individual control over the various “uses” or “purposes” to which their information may be put. (e.g. they might consent to its use for delivery of health services to themselves and their family but not for secondary use in drug trials).

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

The proposed standard would enable the establishment of conformance regimes for cross-border delivery of health care services and the cross-border communication of electronic health records, whereby: a jurisdiction or country would conform to the standard if formally agreed purposes for which use of EHR information is permitted within that jurisdiction are categorised according to the defined framework and published.

In Edinburgh, a draft NWIP was discussed that would focus on providing a normative classification supported by appropriate definitions and informative examples, elaborating on the fit with *ISO/TS 22600*, *ISO/TS 13606-4* and other relevant standards.

On the basis of the discussion in WG4, Janette Gogler noted that:

1. Various classifications have now been defined to describe the categories of use for which data from EHR may be used or disclosed. These include (in relation to subject of care information):
 - Clinical care provision to an individual subject of care
 - Support of care activities within the provider organisation for an individual subject of care
 - Administration of care of an individual
 - Health service management & quality improvements
 - Health population management
 - Education
 - Research
 - Market studies
2. This document defines a vocabulary classification for the purpose for which personal health data within a health record are collected used and/or disclosed.
3. A jurisdiction or country conforms to this specification if every formally agreed purpose for which the use (collection, storage, access, analysis and communication) of personal health information is permitted within that jurisdiction is published in a form that is categorised according to the framework defined in this specification. Some discussion occurred on what defines a jurisdiction and if any further local legislation is required.

Implications for Australia: If this document becomes normative, then conformance may be considered relevant for NEHTA or any health service that seeks to share EHR information. In particular the secondary use of such data should be managed formally within such a framework and have legislative guidance.

Australia needs to monitor and be involved in this work at key points to ensure that it matches our experience and needs as identified by NEHTA and in previous work such as the *HealthConnect* trials.

Richard Dixon Hughes noted that the following points in relation to this proposal had been raised in Istanbul and may still be potential issues:

- Relationship to the OASIS standard *Cross-Enterprise Security and Privacy Authorization (XSPA) Profile of Security Assertion Markup Language (SAML) for Healthcare*, which was then in development
- The proposed NWIP should not conflict with the OASIS work, or be unable to interoperate with it.
- Influencing this OASIS standard, rather than creating the NWIP, may be a more beneficial endeavour [Has this been considered by the project team ?]

If this approach doesn't meet the needs, then an NWIP for developing a document that aligns with the OASIS work would be the alternative.

- While considering that there was still a role for an ISO normative document, Lori Reed-Fourquet (US) had agreed to coordinate consideration of these matters within WG 4 as a joint activity with OASIS [Did this happen ?]

Implications for Australia: When the NWIP documentation is received, early consultation with NEHTA should take place to ensure that the technical approach adopted aligns with mainstream technology and accords with emerging Australian regulatory provisions.

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

14. WG 6 Pharmacy and Medication Business

A full program of WG 6 Pharmacy and Medication Business meetings were convened over the available 2½ days with good attendance. 9 countries and 4 liaisons participated.

Bryn Lewis attended many of the WG 6 sessions on behalf of Australia and is thanked for his notes which form the basis for this section of the report.

WG6 has 8 active work items; of these, 6 are from a set of standards relating to the Identification of Medicinal Products (IDMP), which was a significant focus for WG6 at the Edinburgh meeting and are the principal focus of this section of the report.

The two other active work items addressed by WG6 in Edinburgh were:

ISO/TR10895 ... Business Requirements for the reporting of pharmacist services

- A document describing the work program for this item has been circulated.
- Assistance in relation to this document is required, as at present, there is insufficient input into the item.
- A suggested set of feedback headings was given: Title of service, who for, by whom (eg. pharmacist), service description, comments.

ISO 27953 ... Pharmacovigilance – Individual Case Safety Report (ICSR)

- It was decided at the previous meeting in Istanbul that the working draft for this joint ISO/HL7 standard should be developed as two parts:
 - *ISO/DIS 27953-1 ... ICSR – Part 1: The framework for adverse event reporting; and*
 - *ISO/DIS 27953-2 ... ICSR – Part 2: Human pharmaceutical reporting requirements for ICSR.*
- Informative sections were being finalised
- Arrangements for (shorter) parallel ballot in HL7 still being finalised.
- Released for 5-month DIS ballot at around the time of the Edinburgh meeting.

Units of measure

As summarised in [section 8 above](#), WG6 is actively engaged with WG3 and WG7 in attempting to resolve the many issues surrounding the specification and maintenance of units of measure (UoM) - and how to integrate effectively with the use of UCUM. These harmonisation issues are being tracked by the JWG and JIC.

Within ISO/TC215, WG3 and WG6 have jointly committed to resolve UoM issues and report back to JWG on proposed joint work item status, alignments, interests of ISO/TC215 WG3 and WG6, IHTSDO, HL7 and CDISC.

In Edinburgh, a joint session of WG3 and WG6 centred on the use of UCUM units of measurement for the description of medicinal products. WG6 are unsure whether the Issues below are covered in the current review of UCUM:

- mapping to existing units of measure that might be used now
- Translation into non-English languages
- Synonyms and translations of synonyms for use in different countries

IHTSDO presentation

A presentation by an IHTSDO representative was given. The IHTSDO is going to work more closely with WG6 (one of the proposed IDMP project leads is an IHTSDO representative). This is a significant development (although not flagged, particularly). The mapping between the Australian Medicines Terminology (AMT) and SNOMED is an example of how a SNOMED structure can be integrated within a drug data model. IDMP may adopt such an approach, although this is not certain.

WG6 office bearers

As Ian Shepherd's first term as Convener of WG6 expired at the Edinburgh meeting, notice of the need to make an appointment had been announced at the previous meeting in Istanbul (and Ian had advised his willingness to stand for a second term). At the TC215 closing plenary, the following appointments were confirmed:

- Mr. Ian Shepherd (UK) - Convenor, WG6
- Ms. LuAnn Whittenburg (US) Vice Convenor WG6

Further information

Major issues confronting WG6 were also reported in section 12 of the report of the Australian delegation to the October 2008 ISO/TC215 meeting in Istanbul [\[link to report\]](#) and most of the material contained there is still relevant.

For general enquiries about WG6 activities and access to its working drafts (where required for approved standards development work), contact Andrew Caswell at Standards Australia (Andrew.caswell@standards.org.au).

Bryn Lewis (brynlewis@intelsoft.com.au) would also be pleased to respond to any queries about the activities of WG6 in Edinburgh.

14.1 Overview of IDMP program and changes

By the time of the Edinburgh meeting, work on IDMP had not proceeded sufficiently rapidly and was in danger of attaining “red flag” status. This occurs when there is insufficient time for the completion of a work item within the timeframe allocated for it under ISO’s progression rules. IDMP had already been extended and there was therefore no further capacity for extension.

There was also some concern that some of the IDMP standards are potentially incompatible with, and not clearly differentiated from, other more general work on medicines terminology. As a result, some were renamed to make it clear that these ICH-inspired standards are for the purposes of regulatory reporting of adverse drug events.

In order to deal with these problem, it was resolved that the following 5 IDMP work items would be withdrawn and will (effectively) be re-introduced as new work items into the program. A ballot of NMBs will be needed to do this. The work items were also re-named to reflect their true scope better and minimise any confusion with other standards.

- *ISO NP/CD 11615 Health informatics – Identification of Medicinal Products - Data elements and structures to uniquely identify medicinal products (MPIDs) for the exchange of regulated medicinal product information*
- *ISO NP/CD 11616 Health informatics – Identification of Medicinal Products - Data elements and structures to uniquely identify and exchange pharmaceutical products*
- *ISO NP/CD 11238 Health Informatics – Identification of Medicinal Products – Data elements and structures to uniquely identify and describe substances and specified substances*
- *ISO NP/CD 11239 Health informatics - Identification of medicinal products - Data elements and structures to uniquely identify pharmaceutical dose forms, units of presentation and routes of administration*
- *ISO NP/CD 11240 Health informatics - Identification of medicinal products - Data elements and structures to uniquely identify Units of Measurement*

NWIP/CD ballots for each of the above were posted almost immediately after the Edinburgh meeting and close on 11 Aug 2009. They were accompanied by the existing documents as near-complete drafts, with the development work to be carried out jointly with CEN but with ISO lead.

The sixth work item in the previous IDMP set, which was also withdrawn and is being balloted for re-introduction, is:

- *ISO/NP 11595 Pharmacovigilance – Test names and units for reporting laboratory results.*

Notwithstanding its being for pharmacovigilance applications, this item is progressing as an integral part of a package with the IDMP standards nominated above; however, considerable concern had been raised at the previous TC215 meeting in Istanbul over the potential for this item (and *ISO 11240*) to fail to integrate with established work of other WGs and SDOs (including the open source LOINC and UCUM materials from Regenstrief Institute).

As part of resolving the issues surrounding UoM, *ISO 11595* is to be referred to ISO/TC 212 (Clinical laboratory testing and in vitro diagnostic test systems) and other

relevant SDOs (LOINC, IHTSDO) for consultation and advice on an appropriate way forward. It is not expected to undergo significant further development until there has been consultation on, and further consideration of, UoM issues as discussed in section 8 above.

IDMP implementation guidance

WG6 is looking to produce a document aimed at explaining what is required to implement the IDMP-series of standards:

“Health informatics – Requirements for the implementation of the standards for the identification of medicinal products for the exchange of regulated medicinal product information”

In relation to this proposal:

- TC215 accepted the WG6 recommendation that NWIP documentation for a technical report on this topic be prepared for circulation and ballot of NMBs
- WG6 has until August to prepare and submit the NWIP documentation
- The new work item must be effectively coordinated with:
 - ISO/TR 12975 ... Principles and guidelines for the maintenance of terminological systems, and
 - ISO/TR12309 ... Guidelines for international healthcare terminology standardization
- Some countries considered this proposal to be premature, given that key elements of the IDMP program are still up in the air.

Australia: Consideration of the ballot for this NWIP is not expected to be required until around September.

14.2 IDMP - Discussion of comments and options for progression

Consideration of comments

Some comments received on the IDMP as discussed in the WG6 meeting in Edinburgh included:

- There is varying level of maturity of the 6 IDMP documents.
- WHO considers that insufficiently developed documents may detract from the contribution of the more mature documents
- GS1 wanted the examples used to reflect actual GS1 labels, rather than virtual examples

WG6 undertook to incorporate an appropriate response to the comments within the documents (although this will happen only after CD ballot). This was acceptable to those raising the comments.

Options for progression

The suggested options for the progressing work on IDMP were as follows:

Option 1: Continue to pursue December 2008 ballot pool documents to CD stage with no changes.

- If ISO timelines are to be met, CD would need to be into ballot by May 4 2009, out of ballot 4 August 2009 - with DIS ballot ready end by August 09
- Would require a TC to meet in August (which is not possible)

This option was perceived as not being feasible

Option 2: Stop current WI and start new WI

- Draft/edit NWI proposals for 6 work items with CD drafts for NWI+CD ballot to recommence work program timetable based on progress to date.
- Do not edit documents to incorporate comments at this stage. Previous comments will be reconciled after CD ballot.
- Submit NWIP and CD ballot end of May/June, end ballot ~August
- Period for review and recon by Oct 20 – 2 months (including review, comment reconciliation and meeting and agreement of WG6)

This option was recommended and accepted by the WG and, subsequently, by the TC215 at the closing plenary

Option 3: As for option 2, but incorporate comments into documents

This option was not recommended - would require out-of-session agreement on CD ballot drafts - and potential delay

Option 4: Separate the work items and schedule them in some convenient fashion. Use options 1 to 3 across the 6 work items

Not considered feasible as the items hang together as a whole.

Option 2 was recommended by the editors. The advantage of this option was that it opens up the documents for broader comments earlier than otherwise.

Option 4 was seriously considered, but not accepted.

The 6 work items are standalone, however, they are interlinked. This creates a risk, as any particular potential CD ballot failure will cause them all to fail.

However, the 'separation' only alters the timeframe within which they are put forward. (ie all at the same time, or not). It will not alter their interdependence.

Project leads for each work item were identified, as were 5 NMBs to support the proposal of the new work items, which are organised along the same lines as the previous work.

Scope: There was discussion of a perception of scope change. The clarification of scope within the documents can be interpreted as alteration of the original scope (as originally proposed).

The scope definitions are going to be changed after CD ballot (as the documents cannot be changed before that). This will clarify some of the more problematic aspects of the scope definition.

14.3 Long-term maintenance of IDMP data sets

A part of the development of the IDMP is consideration of maintenance of the vocabulary. This requires a focus on what the business case for what the maintenance organisation may be and how it will operate. Discussion to date has identified the following issues for further consideration:

- What is to be maintained?
- Process to be supported
- Confidentiality of information (and legal risks associated with it)
- Access to content is to be free of charge
- Information to be versioned
- Public browsing
- Ability of stakeholder organisations to use the resources
- Translation and certification of translation
- Governance model, such that there is operational independence from the maintenance organisation itself.

Some assumptions which need to be tested:

- Maintenance organization is to be appointed/accredited by ISO/TC215
- Based on recommendation of WG6, as the outcome of a potential RFT.
- Can an ISO standard refer to a specific organization as the maintainer of the vocabulary? If it can, the timing of the tender/appointment of a maintenance organization affects the timing of the IDMP standard development.

Current activity is focused on development of a survey which may be released to potentially interested organizations. The survey will seek to:

- Get feedback on the quality of the requirements
- Elicit suggestions/recommendations on funding models
- Gauge level of interest

The survey is NOT the start of the procurement process - indeed, it is far from clear exactly what the procurement process will be.

14.4 Implications for Australia - IDMP

The IDMP is a significant standards development work item as it will underpin subsequent activities, such as adverse reaction reporting.

As its scope is primarily regulatory, IDMP may have implications for the TGA. Integration of the IDMP within the AMT would be a means of leveraging IDMP content within Australia. The newly established and hopefully ongoing involvement of IHTSDO in IDMP may facilitate this.

The immediate barriers appear to be questions around the maintenance organisation and resolving the comments received to date.

15. WG 7 Devices

Parallel meetings of WG 7 and the CEN/TC 251/WG iv mirror group were formally convened over approximately 2 days, with experts from WG 7 also participating in joint sessions with WG 1, 3 and 8 (on DCM), WG 4 (on risk management) and with WG 3 (on device terminology mapping). Other relevant CEN/TC 251 working groups were also represented in the various joint sessions.

WG 7 works closely with IEEE, ISO, IEC and HL7 committees that deal with medical device interfaces and is the primary vehicle by which established IEEE medical device interface standards are fast-tracked into ISO international standards. WG7 also enjoys considerable support from the Continua Alliance.

While no single delegate was assigned to WG 7 in Edinburgh, Prof Anthony Maeder, Dr Vince McCauley and Janette Gogler participated at key points - providing notes used to assist in the preparation of this report.

WG 7 addressed the following substantive matters at the Edinburgh Meeting:

1. **Risk management of health software.** A joint session of WG7, WG4 and WG2 considered how TC215 should progress work on appropriate measures to address safety of health software following ISO ballots for ISO/TS 29321 and ISO/TR 29322 which had both failed to gain the approval needed for these documents to continue. It was noted that future work in this area needs to be integrated with IEC work on medical devices.

See section 15.1 below for more detail on this activity.

2. **IEC 80001 - Application of risk management to IT networks incorporating medical devices.** The IEC 80001 standard, which addresses some elements of the failed work on risk management of health software, is being developed by IEC SC62A/JWG 7 - a joint working group of IEC/SC62A and TC 215.

Part 1 is aiming to be a high-level standard setting out process requirements (roles, responsibilities and activities). It passed its second committee draft ballot in February this year.

TC215 is now proposing a new work item for JWG 7 - to prepare the second part of IEC 80001 - giving guidance on the application of Part 1.

See section 15.2 below for more detail on JWG 7 and IEC 80001.

3. **11073-series of health device communication standards.** WG7 continued the development of the 11073-series (where appropriate, based on fast track promotion of existing IEEE standards to become full ISO standards). The current status of this work and issues noted by the Australian delegates are reported in section 15.3 below.
4. **Medical Devices, Clinical Terminology and UCUM.** Problems have been identified in the specification of specific concepts in device standards in relationship to representation of tests and procedures. WG7 is progressing update of the 11073-series to use SNOMED CT for the coding of tests and procedures. Units of Measure (UoM) is also a topic of broader concern to several TC 215 Working Groups. WG7 needs to ensure that it participates as part of TC215 discussions, along with WG3, WG6 and JW6, in relation the open

source UCUM code and conversions maintained by Regenstrief Institute. [See section 8 above for more detail on these issues.]

Some of the other matters addressed by WG7 in Edinburgh and current plans for upcoming meetings are recorded in section 15.6 below. WG7 meets 5 to 6 times per year at a range of locations; the calendar of proposed future meetings is listed in section 15.7 below.

15.1 Health software risk management

A joint meeting of WG 4 (Security), WG3 (Health Concept representation (Vocabulary)) and WG7 (Devices) was held to discuss the next steps to be taken following the failure of two ISO/TC215 ballots seeking approval for the following two proposed ISO documents on health software risk management:

- *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.*

During the ballot cycle, clinical device manufacturers had mounted an intense campaign against the potential imposition of further software risk management and conformance criteria, beyond that already forming part of the accepted Medical Devices conformance regime.

After considerable debate and consideration, Australia vote negatively in the ballot but also provided extensive comments. A much more detailed description of the proposals and related issues (including reasons for Australia's vote) are provided in section 6.8 of the report of the October 2008 ISO/TC215 meeting in Istanbul [[link to report](#)].

At the simultaneous ballot in among CEN members, the proposal for TS 29321 failed but TR 29322 (which is dependent on 29321) was passed! In reviewing this situation, the CEN/TC251 Secretariat proposed the following way forward, which was accepted:

- (a) halt publication of 29322.
- (b) Halt drafting work on both 29321 and 29322 as items in ISO and CEN.
- (c) Address further work as part of work on IEC 80001 in JWG7 of IEC/SC62A with ISO/TC215
- (d) ISO TC 215 to be project lead in liaison with ISO TC 210 (Quality Standards)

Even though ISO TC215 had been communicating with, and enjoyed strong cross-membership with many of the relevant ISO, IEC and IEEE committees, given the comments accompanying the failed ballots, this liaison was insufficient to avoid problems and it has been noted that further TC215 involvement needs to be within the context of participating in relevant IEC medical device safety committees - seeking to ensure that proposed extensions of the medical device safety regime to software address health software safety risks appropriately.

In reporting on discussion of these topics in the joint meeting of WG3, WG4 and WG7, Australian delegates noted that:

- A compromise originating from BSI IST/35 proposes that relevant aspects of *TS 29321* and *TR 29322* be progressed through revision and extension of the

IEC 80001 health IT networks risk management standard, and is understood to have been developed with industry support.

- The approach now being pursued by WG4 and WG7 in relation to health software risk management includes production of more specific guidelines within a proposed new TR 80001-2, which would provide guidance to augment *TS 80001-1*. (The nature and proposed development of *TR 80001-2* is reported as a separate work item in section 15.2 below - and not further repeated here).
- In moving to work with JWG7 on extensions to *IEC 80001*, the focus of ISO/TC215 activities in health software risk management will be more focussed on the end-user facilities and its processes - rather than original developers.
- Coordination between other WGs and WG7 is needed for a number of projects. Discussion at TC-215 level is taking place to see how this can be addressed and improved.
- A new European standards committee, CLC/TC62, has been constituted within CENELEC to address Software and Medical Devices (the SAMD group) with scope "To monitor work related to software in the healthcare domain ... to maximize consistency in approach to software standardization". CENELEC is the mirror organisation for IEC in Europe (in the same way that CEN is the European mirror organisation for ISO).

The main activity of CLC/TC62 to date was to write to the ISO/TMB last year seeking to have ISO withdraw the *TS 29321* and *TR 29322* ballots on behalf of the medical device manufacturing industry. It appears that there is no intention to develop standards and their only other activity has been two scoping teleconferences.

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

15.2 IEC 80001 - Risk management of IT networks

IEC/SC62A/JWG 7 Risk management of IT networks integrating medical devices ("JWG7") is a joint working group of:

- *IEC/TC62/SC62A Common aspects of electrical equipment used in medical practice*, and
- *ISO/TC215 Health Informatics (through WG7 Devices)*

This joint working group also has an active liaison with *ISO/TC210, Quality management and corresponding general aspects for medical devices*.

JWG7 was formed in 2006 and held its first meeting in San Diego in January 2007. Its principal role to date has been work on the development of the one standard:

IEC 80001-1 Application of risk management for IT networks incorporating medical devices

This standard has the stated purpose of:

“... [defining] the roles, responsibilities and activities that are necessary when Medical Devices are incorporated into an IT Network to address the key properties of the IT Network incorporating a Medical Device.”

[However, its stated purpose specifically excludes clinical decision making applications and any role in the specification of acceptable levels of risk].

This document is being developed as a full IEC international standard and, being a joint publication, requires ballot approval at each stage of development from both members of IEC/SC62A and members of ISO/TC215. IEC 80001-1 passed its second CD ballot in both TC215 and SC62A on 27 Feb 2009.

TC215/WG7 now wishes to press on with a new work item for JWG 7 of SC62A and TC215 - to prepare the second part of IEC 80001 as a technical report giving guidance on the application of Part 1. In recommending that TC215 approve the work, WG7 noted that:

- The need for additional guidance in the application of 80001-1 was always anticipated since its early development stages
- 80001-1 is a high-level process oriented standard
- 80001-1 guides health organisations in setting up risk management for use of ICT in health applications (devices, software, infrastructure).
- 80001-2 will be TR or HB on how to go about achieving 80001-1 (eg specific organisational measures to implement it.
- It aligns with the BSI IST/35 disposition of comments on the failed 29321 and 29322 ballots (as noted in section 15.1 above)
- JWG7 itself has approved moving forward on 80001-2 at recent Frankfurt meetings and is now seeking endorsement of its “owners” - TC215 and SC62A.

Discussions in WG7 noted that the proposed project would partly address matters that previously fell within the ambit of 29321 and 29322, given a proposed scope for 80001-2 that includes:

“ Provide deployment advice related to health IT security and include incident configuration management, staff competency, commercial applications and clinical workflow, use of in-house “bespoke” software, organizational structure and scaling to accommodate 80000-x processes”

Some of the other points noted by Australian delegates in reporting on discussion of these topics included:

- The audience for 80001-2 includes Hospitals, Primary Care, National/regional services, community care and mental health services as well as 80001-1 implementers, regulatory authorities and National Health Standards Boards.
- Personal health will be included but not from a regulatory viewpoint. The main focus will be clinicians and clinical care.
- 80001-2 should help address the risks where health organisations take over maintenance and modification of health software from the original supplier, which can compromise safety.
- SC62/JWG7 is driving 80001-1 toward completion, aiming for a final ballot in mid-2010.

- Potential breadth of scope, overlaps and fear of excessive codification of responsibilities (removing flexibility) remain issues for some user organisations and suppliers - particularly in the UK where the definitions of what might be considered a “health organisation” (anyone/thing providing any health care) and “health information from medical devices” (any device-based data accepted by a health organisation, even if patient originated).
- Specific guidance is reported to be in an advanced state of development on the application of *ISO 14971:2007 Application of risk management to medical devices* to software used in medical devices.
- The regulatory scene for clinical software applications is changing:
 - A separate European order is expected to issue (possibly by 2010) stating that anything used in medical treatment is a medical device (which may mean software has to be regulated according to *ISO 14971*, *IEC 80001-1* and/or *IEC 80002*).
 - In the past, health software has not received as much attention from FDA in the US in making standards/guidelines eg EMC, safety etc.

Stand alone software and information systems are now regarded as major safety-critical components. FDA has sought submissions on existing standards for recognition under their certification processes, and how these standards relate to other existing certification processes.
- Because of evolving changes in its regulatory scope to encompass clinical software applications, **FDA will now participate in TC215/WG7**

There is another closely-related document near to completion: *IEC TR 80002 Medical device software - Guidance on the application of ISO 14971 to medical device software* - being prepared by SC62A/JWG3 (a joint WG between SC62A and ISO 210) and with a different composition and liaisons to JWG7.

Subject to final ballot approval, *IEC 80002* is targeted for publication within weeks and its existence is understood to have been one of the reasons that device manufacturers were particularly opposed to the proposed *TS 29321*.

IEC 80002 covers risk management specifically for medical device developers and applies to the development process (and addresses devices comprising both hardware and software or just software-only products).

There was agreement by the joint meeting of WG7, WG4 and WG3 that this was an appropriate way forward and ISO delegates interested in working on the proposal for *IEC/TR 80001-2* were requested to contact SC62A/JWG7.

At its closing plenary session in Edinburgh, TC215 approved development of a new work item proposal “*TR 80001-2 Application of risk management for IT-networks incorporating medical devices – Guidance for health delivery organizations*” to be submitted for parallel ballot within TC215 and SC62A, with TC215 to take the lead on the work in SC62A/JWG7 and involve WG7 and WG4 from within TC215.

Nevertheless, there is still a need for this proposed new work on *80001-2* to mesh into and not duplicate the protections given by *IEC 80002-1* which deals with the application of *ISO 14971* in the context of medical device software risk management (under a mix of regulatory approaches to medical device software across the globe). It would seem that continued coordination and communication is required to ensure adequate engagement with all relevant interests.

Australia: At the time that the ballot is released, IT-014 will need to consult with MSIA, device manufacturers and medical systems engineering professionals to ensure that the proposed scope for 80001-2 is clear and acceptable (relative to 80001-1 and 80002) and that previous problems with the intrusiveness of the failed 29321 and 29322 ballots have not returned in a different guise.

15.3 Review and approval of device standards

Dr Vince McCauley noted growing interest in Health Informatics standards by health regulatory agencies and device manufacturers. This appeared to be driven by an increasing need for standards to support enterprise software in being able to control, switch and interact with clinical devices.

The status of WG7's current work on fast track approval of the IEEE 11073 series of device interface standards by TC 215 is as follows:

Standard	Status
ISO/NP 11073-10404 ... Personal health device communication - Device specialization - Part 10404: Pulse oximeter	Registered as a new ISO project 7 Jul 2009
ISO/IEEE 11073-10406 ... Personal health device communication – Device specialization – Part 10406: Basic Electrocardiograph (1 to 3-lead ECG)	WG7 preparing documents being for 3-month ISO NWIP ballot.
ISO/NP 11073-10407 ... Personal health device communication – Device specialization – Part 10407: Blood pressure monitor	Registered as a new ISO project 7 Jul 2009
ISO/IEEE NP 11073-10408 ... Personal health device communication – Device specialization – Part 10408 Thermometer	Documents submitted to ISO for 30-day ballot to approve going to fast track FDIS using existing IEEE document. For vote May/Jun 09.
ISO/IEEE 11073-10415 ... Point of care medical device communication - Device specialization – Part 10415 Weighing scale	Documents submitted to ISO for 30-day ballot to approve going to fast track FDIS using existing IEEE document.
ISO/NP 11073-10417 ... Personal health device communication - Device specialization - Part 10417: Glucose meter	Registered as a new ISO project 7 Jul 2009
ISO/IEEE 11073-10418 ... Personal health device communication – Device specialization – Part 10418: International normalized ratio (INR) monitor	WG7 finalising documents to submit for 3-month ISO NWIP ballot.
ISO/IEEE 11073-10419 ... Personal health device communication – Device specialization – Part 10419: Insulin pump	WG7 finalising documents to submit for 3-month ISO NWIP ballot.
ISO/IEEE 11073-10420 ... Personal health device communication – Device specialization – Part 10420: Body composition analyzer	WG7 finalising documents to submit for 3-month ISO NWIP ballot.
ISO/IEEE 11073-10421 ... Personal health device communication – Device specialization – Part 10421: Peak expiratory flow monitor (peak flow)	WG7 finalising documents to submit for 3-month ISO NWIP ballot.

Standard	Status
ISO/IEEE 11073-10441 ... Point of care medical device communication – Device specialization – Part 10441: Cardiovascular fitness and activity monitor	Status unclear - listed on 2008 program - missing from Edinburgh list.
ISO/IEEE 11073-10442 ... Point of care medical device communication – Device specialization – Part 10442 Strength Fitness Equipment	WG7 finalising documents to submit for 3-month ISO NWIP ballot.
ISO/IEEE CD 11073-10471 ... Point-of-care medical device communication - Part 10471: Device Specialization - Independent Living Activity Hub	Documents submitted to ISO for 30-day ballot to approve going to fast track FDIS using existing IEEE document.
ISO/IEEE 11073-10472 ... Point-of-care medical device communication - Part 10472: Device Specialization - Medication monitor	Submitted to TC215 secretariat for ISO 3-month NWIP ballot (with draft attached)
ISO/IEEE 11073-20601 ... Personal health device communication – Application Profile – Optimized Exchange Protocol	Documents submitted to ISO for 30-day ballot to approve going to fast track FDIS.
ISO 11073-91064:2009 ... Point-of-care medical device communication - Part 90101: Analytical instruments - Point-of-care test	Published 8 Jan 2008.
ISO 11073-91064:2009 ... Standard communication protocol - Part 91064: Computer-assisted electrocardiography (SCP-ECG)	Published 5 May 2009. Based on earlier European EN 1064:2007
ISO 11073-92301 ... Medical waveform format - Encoding rules - Part 92301: Electrocardiography	Anticipating NWIP ready to discuss at WG7 meeting October 09 in Durham
ISO 11073-92302 ... Medical waveform format - Encoding rules - Part 92302: Long term ECG	Anticipating NWIP ready to discuss at WG7 meeting October 09 in Durham
ISO 11073-92305 ... Medical waveform format - Encoding rules - Part 92305: Reporting with HL7 CDA	Anticipating NWIP ready to discuss at WG7 meeting October 09 in Durham
ISO 11073-92306 ... Medical waveform format - Encoding rules - Part 92306: Standard Communication Protocol ECG	Anticipating NWIP ready to discuss at WG7 meeting October 09 in Durham

In addition, WG7 completed and published 6 members of the 11073-series as ISO standards between 2004 and 2007.

Medical waveform format encoding rules (MFER)

As indicated in the above table, WG7 is preparing NWIP documentation for parts 92301, 92302, 92305 and 92306 for consideration presented at the next TC215 meeting in October. In some cases, it is understood that translation of existing documentation from Japanese is required. Dr Vince McCauley noted the following matters in WG7's discussion of MFER.

- NWIP documentation needs to be prepared for the 11073-93xx series of MFER standards, aspects of which continue to cause controversy in the vendor community.
- These proposed standards will affect how a waveform is represented in a range of settings - for internal storage on recording device, as a message from the device, in a database or external storage device, for transmission to a scanner/analyser/display, or as an internal scanner format. (We need to cater

for a model where patient uses recorder and presents this data to another party, on a memory card).

- Using the proposed 11073-92302 standard for wave form encoding of 12 lead ECG, a 32MB memory device is able to hold 24hrs worth of data. Harmonising lead numbers and coded names has been attempted (used by several vendors) but there are still some inconsistencies with conventions used by others.
- Other parts of the standard address:
 - Waveform compression
 - SCP (standard communication protocol) format for transmission.
 - Data repository approach and functions for:
MFER data access, searching, case comparison, and
Web access (may be per hospital due to privacy requirements).
- MFER will include specifications for:
 - HL7v2.5 message exchange (part 2.1)
 - DICOM for data packaging (part 2.2)
 - 11073-92001 waveform transmission (part 2.3),
 - Some waveform compression (done via ISO as part 2.4)
 - Physiological report using CDA-R2 (new part 2.5 in ISO version),
 - SCP-ECG format translation for storage (new part 2.6 in ISO version)
- Parts 3.1 on Short term ECG; and 3.2 on Long term ECG are also needed.
- The international situation and competitive positioning of the work - should OpenECG/SCG also be a contender?
- *ISO/TS 11073-92001:2007 Medical waveform format - Encoding rules*, the initial MFER specification, was first released as a TS for discussion and implementation - with a view to being converted to a full international standard. A similar approach may be appropriate for at least some of the proposed new MFER material.

15.4 Medical devices and clinical terminology

As discussed at some length in the JWG meeting which took place in the lead-in to the Edinburgh meeting, problems have been identified in the representation of specific device concept information in relationship to tests and procedures - including ongoing use of outdated SNOMED RT references to body sites at which tests were done. To ensure accurate meaning is retained when information from devices is incorporated into medical records, it is now proposed that SNOMED CT ("SCT") be universally used to provide a definitive reference to the source term. This would allow developers to use device concepts without translation.

In the US, FDA rules suggest not doing translations - rather incorporating both terms - an original and any mapped term at its source and keeping both through to the destination to avoid possibility of error.

WG7 is one of the groups working with WG2 in considering how to standardize sharing of coded content - recognising the IPR, cost-impact and on-going maintenance issues

that arise when referencing licensed terminologies and code sets such as SCT and UCUM in normative standards documents.

The next generation of ISO/IEEE 11073 device standards are already being updated to use SCT and that, at the same time, improvements to SCT needed for this purpose are being fed back to IHTSDO. Continua Alliance is also developing 11073 - 92305 for encoding device outputs using HL7 CDA with concepts coded in SCT.

Standardization of medical device terms has been informally raised as a possible joint work item for JIC but, at this stage, there no specific JIC proposal has been put forward and some of the key participating organisations (including IEEE and Continua Alliance) are not JIC members. JWG will continue to monitor progress and facilitate harmonisation between existing SDO projects but, at present, JWG considered that this was more a matter for IEEE and IHTSDO, rather than a JIC-approved work item.

Dr Vince McCauley reported back that the following were among the points raised during WG7 discussion of these matters

- The representation of anatomical locations and other concepts is specified in 11073-10101 using outdated information structures and terminology sets.
- There is a need to embed some additional medical devices-related concepts in the relevant SNOMED-CT, if it is to provide the required terminology coverage - it is understood that the IHTSDO Anaesthesia is seeking to address this issue.
- The information models and terminology sets used with medical devices need to address four areas of identified needs:
 - clinical information for transmission and inclusion in the EHR;
 - Real-time data communication and device control;
 - Regulatory aspects (such as FDA translation rules); and
 - Auto identification.
- When the 11073 project started, there was no appropriate terminology, so much of it was custom-designed. So cross-referencing and mapping is needed between traditional 11073 conceptual structures and SNOMED-CT.
- There is an issue about IP rights as IHTSDO is reported to be wanting to levy a charge where 11073 refers to SNOMED CT concepts that have been adopted from existing 11073 sources (and which were previously referenced without cost in the earlier IEEE versions of the standard).
- A central database for all the 11073 content is needed, which is under development.
- On-going liaison on devices terminology is needed, using IHTSDO as central point using the IOTA Protégé tool to provide consistency and respond urgently (rather than via national coding centres), with eventual integration of OWL tooling to allow maps. This will set a precedent for aspects of 11073 that may be used with other standards.
- UCUM is widely used for specifying units of measure in IHE specifications and HL7 standards but not presently in the 11073-series. There appear to be intellectual property issues with its use in ISO, CEN and IEEE standards.

15.5 Detailed clinical models and device data

Janette Gogler reported on a WG7 presentation and discussion led by Ms Anneka Goossen (results4care@cs.com) addressing the relationship between the detailed clinical models project and data used in the context of medical and other devices used in healthcare settings.

The representation of device data as archetypes was considered at previous TC215 meetings in Brisbane and Istanbul; however, this needs to be brought forward into the joint ISO/HL7 Detailed Clinical Models (DCM) activities being led by Dr William Goossen, which aims to bridge the gap between clinicians and health IT as reported in section 7 above. The aim is to develop a core representation of information in various contexts signed off by relevant clinical professional groups that can then be implemented using different technologies such as HL7 v3 templates or *openEHR/13606* Archetypes.

The 11073 device standards have a defined common data model, which needs to be reflected in archetypes, HL7 clusters and other clinical models in order to link clinical devices such as BP machines and pulse oximeters into the electronic health record - taking into account the specific variables that may be needed to provide context and/or control of various clinical devices.

WG7 considered that the proposed DCM approaches correspond well with their current medical device semantic architecture development activities related to the 11073-series of interface standards. WG7 agreed to participate with WG1 on DCM work related to devices.

A new work proposal is to be drafted for next meeting specifically to review the relationship between medical device and the DCM so that detailed information is captured on specific devices.

Implications for Australia: Australia will participate in the drafting of the project proposal. Possible representatives will be Dr Heather Leslie, Vince McCauley and Janette Gogler.

The work will be of interest to NEHTA; States that are implementing clinical systems, the medical software and device industries and biomedical engineers.

15.6 Other matters addressed by WG7

1. **WG7 Secretariat.** Ms Patty Krantz of Medtronic (USA) has agreed to take on the WG7 Secretariat, replacing Melvin Reynolds (UK) who is withdrawing due a change in responsibilities and UK NHS funding priorities for standards work.
2. **Change in WG7 scope.** WG7 considered that its scope did not match the work items that it was handling - particularly in the area of personal health “wellness” devices. The a recommendation to amend the WG7 scope to the following was proposed and accepted by the TC215 plenary:

Standardization in the application of Information and Communications Technologies (ICT) to health device informatics and device interoperability in support of medicine, health care, and wellness.

3. Prof Anthony Maeder particularly noted that additional activities in which WG7 is collaborating with other WGs include:
 - Development of ISO 13131 on telemedicine quality (with WG2). As there is a limited amount of device-specific content, WG7's role is more one of providing expert input - and being kept informed of developments
 - Development of a general NWIP for structure and referencing UCUM (potential joint project with WGs 3, 6 and JWG)
 - Mapping between ISO/IEEE 11073 and SNOMED CT concepts and terms (potential joint project through JWG)
4. **Global Harmonization Task Force (GHTF) Liaison.** On 23 April, GHTF Study Group SG 2 sought representation on WG7 to work on the development of HL7 tagging of medical devices vigilance reports and the establishment of an MOU on adverse event reporting for medical devices.

WG7 welcomed the proposed MoU between GHTF and ISO TC215 regarding the development of standards for medical device adverse event reporting and, also, GHTF/SG2 representation in this work. [GHTF is a peak international collaboration of medical device manufacturers and regulators].

15.7 Upcoming meetings

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

Date	Location	Participants
05-08 May 2009	Gaithersburg, Maryland, USA	Joint HL7 DEV WG, IEEE 11073 & IHE PCD
10-12 Jun 2009	Brussels, Belgium	IEC+ISO JWG 7
15+ Sep 2009	USA (location TBD)	TC215 WG 7
20-25 Sep 2009	HL7 Plenary+WGM Atlanta, Georgia USA	Joint:HL7 DEV WG + IEEE 11073 + ISO/TC215 WG 7
18-21 Oct 2009	TC 215 Durham, North Carolina, USA	TC215 WG meetings - WG7
17-21 Jan 2010	HL7 WGM Phoenix, Arizona, USA	Joint:HL7 DEV WG + IEEE 11073 + ISO/TC215 WG 7
10-14 May 2010	Rio de Janeiro, Brazil	ISO/TC215 Plenary and WGMs - WG7
16-21 May 2010	Rio de Janeiro, Brazil	Joint:HL7 DEV WG + IEEE 11073 + ISO/TC215 WG 7

16. WG 8 Business Requirements for Electronic Health Records

Meetings of WG 8 were formally convened over 2½ days, with a majority of the sessions being joint with WG 1 and CEN/TC251/WG i. A total of around 60 experts from 16 different countries participated plus liaison representatives of WHO and TC106.

Andrew Caswell (WG 8 Secretariat) and Richard Dixon Hughes (as Australian subject matter expert) attended most WG 8 sessions and others from the Australian delegation also attended some WG8 sessions, including many joint sessions with WG 1.

Of the matters addressed by WG8 in Edinburgh, the following have been reported separately as major issues and are not considered further in this section of the report:

- **Quality requirements and methodology for detailed clinical models (DCM).** After extensive discussion at previous TC215 and HL7 meetings, the ISO component of the DCM work is now out to NWIP ballot seeking approval to start serious work on an international standard. The proposed standards affect the formation of clinical information models with Australian contributions expected.

Consideration of the DCM project is reported more fully in section 7 above.

- **European eHealth Standards - Mandate M/403.** M/403 activities and impacts are summarised in section 5 above.

The following are among the other more significant matters addressed by WG 8 in Edinburgh:

1. **Integrated eHealth architecture (for the Global South).** Dr Beatriz Leao (Brazil) gave a presentation on health information needs in developing and emerging economies highlighting strategies from the Bellagio eHealth forum conducted by Rockefeller Foundation and proposing an ISO technical report identifying the eHealth roadmap and standards needed to support health care delivery in developing and emerging nations [see section 16.1 below].

A small group from WG8 to be Led by Dr Leao was commissioned to draft an NWIP for a technical report on "*eHealth enterprise architecture for emerging and developing countries*". The ballot is expected to take place in Aug/Sep 2009.

Australian concerns: While strongly supporting the need for appropriate work to facilitate effective use of eHealth in the D&E world, we raised two concerns:

- This work should focus on systemic eHealth functional requirements, rather than being about prescribing a specific "architecture" (i.e. single prescribed set of standards, components and approaches).
- Early and detailed consideration must be given to negotiating intellectual property rights, if planning to produce an ISO technical report with a view to it then being freely available across the D&E world.

WHO Presentation. The lunchtime presentation by Christopher Bailey of the World Health Organization (WHO) also focussed on particular needs of D&E nations and is reported in section 17 below.

2. **International Health Informatics Glossary and Document Register** (derived from project: TS 28379 Common Glossary for ISO/TC215)

At a WG8/WG1 joint session, Heather Grain, WG3 Convenor, gave an overview of the ISO/TC215 Health Informatics Glossary and Document Register project,

the SKMT tools used to implement it, progress to date and its use with other TC215 projects - followed by discussion. Progress in implementing the glossary and project register is reported in section 4 above and is not repeated here

While development of the glossary is a WG3 work item, the use of the associated tools in TC215 project work needs to be embraced by all WGs and is proposed for TC215's partner SDOs in the JIC.

Heather Grain requested that WGs identify which of their members should have publisher access to the tool and that members register on the site and check their document details to ensure correctness. The resource is active and registration is now open to all (with read access) from the Glossary website: www.cred.ca/SKMT_Glossary/default.aspx

3. **ISO DIS 18308:2004 Requirements for an EHR Reference Architecture**

Dr Dipak Kalra (UK) provided a summary of the history to date, the DIS ballot results, comments received and the main issues, which are all reported further in section 16.2 below.

Following revision to improve the document's approach to requirements for conformity and to provide an informative annex on 18308's relationship to the HL7 EHR-S Functional Model, the revised draft will be submitted to a second-round DIS ballot, anticipated to commence after August 2009.

Australia: Given our previous work and active interest in 18308, IT-014 will need to plan for review and comment on the revised draft for the next DIS ballot.

4. **Definition, Scope and Context of Personal Health Records (PHR)**

TC215 Resolution 58 from Istanbul 2008 approved the preparation and circulation of an NWIP for a technical report on "*Personal Health Records: Definition, Scope and Context*" to include classifications and use cases and leveraging the HL7 PHR-S FM DSTU and other existing work.

Dipak Kalra (UK) provided an update on this PHR activity and proposed WG8 endorse a revision to the original concept for the project - under the revised title: "*Personal Health Records: Definition, scope, context and global variations of use*". This would parallel the existing ISO/TR 20514:2005 *Electronic Health Record: Definition, scope and context in relation to PHRs*. Dr Kalra pointed out that the current definitions require a personal health record to be "personal" but there is nothing in the definition that requires it be "electronic". Some might be paper-based.

In agreeing that this work should now be progressed, WG8 supported producing the document in two parts under a single project; while warning that the topic should not be approached at a too general level - if it is to be useful.

An NWIP ballot package incorporating the suggested changes was posted to the TC215 website - closing in August.

Australia: As this is an emerging area with many different perspectives, we need to review this NWIP carefully to ensure that the proposed work will allow and elaborate usefully on approaches likely in Australia and integrates well with the previous work led by Australia: *ISO/TR 20514:2005 EHR Definition, Scope and Context*. Prime responsibility for review and comment is IT-014-09 but NEHTA, DOHA< HISA, MSIA and many others have interests in the outcomes.

5. **International Requirements for the PHR; including D&E economies**

International needs for the Personal Health Record (PHR) and its potential to contribute positively to individual healthcare for people in developing and

emerging economies is being increasingly explored. At the October 2008 TC215 meeting in Istanbul, Gora Datta (US) presented on “*Use of EHR/PHR in D&E economies*” - as summarised in section 14.3 of the Australian Delegation report [[link to report](#)].

He gave an updated version of the same presentation at the Edinburgh meeting, providing a contextual overview of EHR/PHRs globally, as well as an outline of challenges and resources available in D&E economies. This was then considered in the context of Dr Leao’s “Global South” proposals, the WHO lunchtime presentation and Dr Kalra’s comments on the global impact of PHR.

On the basis of this discussion at WG8, it was agreed that this item will be incorporated in the NWIP being compiled by Dipak Kalra in relation to the *Definition, scope and context of PHRs* (see point 5 above) for a single new project proposal.

6. **ISO/TR 13054 Knowledge Management of Health Informatics Standards**

This work item, which passed NWIP ballot on 21 November 2008, aims at an ISO technical report reviewing the field of eHealth standards classification and making recommendations as a step toward determining a methodology, metadata and required tools for classifying and maintaining catalogues of health informatics standards. Key elements of the project and the potential different approaches were summarised in section 6.16 of the report of the Australian Delegation to the October 2008 TC215 meeting in Istanbul [[link to report](#)].

The item was presented and discussed at some length in joint session of WG 1, WG 8 and CEN/TC 251/ WG i led by Dr Andrew Grant (CA), Project Lead.

During discussion, the various alternative means of addressing the requirement were again canvassed and its potential importance for identifying “gaps” in standards coverage was noted. WG8’s role as the “owner” of this project was questioned, given that the project potentially affects many other WGs and SDOs and is closely associated with work being managed elsewhere.

WG8 resolved to request ISO TC215 to review the appropriateness of the proposed work item and its allocation to WG8 and seek advice on how the potential knowledge created might be managed and shared openly with all involved - given IPR restrictions on an ISO technical report.

Australia: National/regional eHealth programs (as well as SDOs) are intended to be the major recipients - input from NEHTA, DoHA and jurisdictions about the most effective approach to classification and use (and the avoidance of inappropriate outcomes) should be sought and welcomed by IT-014.

7. **ISO/DIS 10781 HL7 EHR System Functional Model (EHR-S FM)**

For background information on the nature, use and development of the EHR-S FM and fuller reporting of the issues arising at the Edinburgh meeting see [section 16.3 below](#).

Gary Dickinson (US), EHR-S Project Lead for ISO and liaison to HL7 EHR WG, which is responsible for this item, noted the work item's history, progress and gave an overview of the results of recent the joint HL7/ISO/CEN DIS re-ballot.

The draft was approved by HL7 and, in ISO/CEN, also passed 19/20 in favour with a negative vote from the UK. There were many comments, some of them critical, from 6 countries. Discussion in Edinburgh focussed on major issues that had arisen and arrangements for further work - with a full disposition of comments to take place, commencing at the HL7 meeting in Kyoto, Japan two weeks later.

The areas of most serious concern arising in the DIS re-ballot related to the standard's suitability for conformance testing and how it relates to its functional profiles and to other standards.

Ongoing alignment of the ISO and HL7 versions remains a challenge. The current ISO version aligns with a specially-developed Release 1.1 (R1.1) of the HL7 document. R1.1 enhances and corrects some features of the first HL7 normative version but omits many of the major changes proposed for the planned second release (R2).

The present aim is to have the EHR-S circulated for ISO FDIS ballot in sufficient time for results to be available for final publication to be considered and, if appropriate, approved at the HL7 Plenary in September and the ISO meeting in October. (Note: the ISO Central Secretariat shuts down for most of August).

Action: Australia should continue its strong support through the current ballot FDIS and HL7 cycles to ensure that the R1.1 document gains full acceptance.

We also need to continue to be involved with work on the major R2 version of the EHR-S FM with a view to ensuring that Australian and other international perspectives are adequately dealt with and that this integrates well with parallel work in HL7 on the PHR-S FM, now at DSTU stage.

Groups to whom this may be of interest: HL7 Australia, IHE, MSIA, NEHTA and any jurisdictions or organisations seeking to specify or implement clinical information systems.

8. **Potential NWIP - Guide to the principles and desirable features of clinical decision support systems (CDSS)**

As reported in section 12.14 above, WG3 is proposing that TC215 consider an NWIP for a technical report identifying processes, key principles, content elements and necessary domains for clinical decision support system (CDSS) development and maintenance.

Heather Grain (AU), Convener of WG3, addressed a joint meeting of WG1 and WG8 on the proposed work item - requesting advice on whether to pursue the NWIP for a TR or whether more information is required.

Key points and discussion arising from the presentation to WG8/WG1 are reported in section 16.4 below 16.5 below.

9. **Potential NWIP - User interface requirements for the visual presentation of health data**

As reported in section 12.14 above, WG3 is proposing that TC215 consider an NWIP for a standard addressing consistent and meaningful **visual presentation of health data** (such as clinical alerts). identifying processes, key principles, content elements and necessary domains for decision support system (DSS) development and maintenance.

Heather Grain (AU), Convener of WG3, addressed a joint meeting of WG1 and WG8 on the proposed work item with key points and discussion being reported in section 16.5 below.

10. **Choice of standards for eHealth information exchange**

Jan Talmon (NL) provided background details on a white paper that provides insight into the choices to be made in selecting standards for electronic exchange of health record information documents.

It includes points raised in The Netherlands from discussions on how to effectively utilize HL7 and ISO/EN 13606. The white paper is focussed on an analysis of what is needed for EHR data communication, as well as the structure of the document.

It was noted that a similar review was completed in Sweden.

No NWIP is being requested at this time. For further information, members were advised to contact Jan Talmon directly.

WG8 encourages similar exchange of national experiences related to requirements and standards for exchange of EHR information.

11. **Standards Simplification Strategy**

Gary Dickinson (US) provided a brief summary to WG 1 and WG 8 of a Simplification Strategy Proposal that he had put to the Healthcare Information Technology Standards Panel (HITSP) Foundations Framework Committee (managed by ANSI for the US Government Office of the National Coordinator).

The Simplification Strategy Proposal includes objectives, principles, and consideration for the selection and classification of use cases based on identification of related actions in the EHR information lifecycle. The documents will be made available to the WGs for further information and Gary Dickinson would welcome comments.

12. **Dentistry input to the EHR**

Jim McClees (US) (TC106 liaison) provided a brief summary of a proposed NWIP intended to facilitate inclusion of dental content in existing and future data standards for the storage, transit, and retrieval of EHR information. He expects it to be ready for consideration at the October TC215 meeting in Durham.

Existing documents from ISO/TC106 Dentistry may be sourced in the development of this NWIP, for example: the ISO 1942 Dental Vocabulary, which includes descriptors for oral morphology, cranial facial data sets and the tooth numbering system.

The proposed activity will inform standards work involving information structures, data and protocols in the dentistry domain, particularly those uniquely used for dental procedures and associated tracing of materials.

The timelines for the NWIP were questioned. As the ISO/TC106 meets just before the Durham Meeting, there will be no opportunity for advance review; however, a timeslot for TC215 input to the proposal will be requested.

13. **NWIP to standardise a list of *purposes for processing EHR data*.** Dr Dipak Kalra (UK), project leader, addressed a joint session of WG1 and WG8 on the proposed work item on classification of purposes for use of data, which had been introduced at the October 2008 TC215 meeting in Istanbul and is being progressed by WG4. See [section 13.3 above](#) for more information.

14. **NWIP for a TR on *EHR Migration*.** Pekka Routsalainen (FI), addressed a joint meeting of WG1 and WG8 on this item which is being worked up by WG4 (see [section 13.1 above](#) for more information). WG4 is suggesting that the work involve collaboration between WG4, WG1, WG8 and their CEN mirror committees.

Those volunteering in response to a WG4 request for liaisons to assist in developing this item were:- Bryan Manning (WG1); Marion Lyver (WG8); Dipak Kalra (TC251 /WG i); and Bernd Blobel (TC251 /WG iii).

15. **CDISC BRIDG Model** as an ISO international standard. In joint discussion with WG2 and CDISC, WG1 and WG8 expressed interest in being involved with this item which is to be balloted for progression within ISO and will also be considered as a joint project under JIC/JWG rules (see section 11.7 above for more information).
16. **TS 27527 Provider Identification and Entity Name Harmonisation Task Group.** Heather Grain (AU), WG3 Convener and project lead for the subject of care and provider identification projects provided a status report to WG1, WG2 and WG8 on the development of *ISO/DTS 27527* and on the consequent Entity Name Harmonisation activity. [See commentary in [section 9 above](#)].
17. **Progression of WG8 Projects on the TC215 Work program.** Relevant recent changes are summarised in [Section 19 below](#).

Experts from WG 8 also participated in discussions of the following work items in joint sessions hosted by WG 1.

18. **Clinical Data Warehouse (CDW).** ISO/TR 22221 to be renewed for another 3 years and ISO/DTS 29585 will be balloted. [See [section 10.1 above](#)].
19. **Identity Management Frameworks (IMF).** Following a presentation by Prof Bryan Manning (UK), WG1 established a project team to review cross-sectoral standards for IMF, to report back at the October TC215 meeting. [See [section 10.2 above](#)].
20. **ISO 12967 Health Informatics Service Architecture (HISA).** This 3-part standard is in final publication. New work to prepare Implementation Guidance has been proposed. [See [section 10.3 above](#) for more information].
21. **ISO/DIS 21667 – Health Indicators Conceptual Framework** [see [section 10.4 above](#)].
22. **ISO 13606 EHR Communication**, in particular, Part 5: Interface Specification, as reported in [section 10.5 above](#).

Working documents relating to WG8 activities are posted on the main TC 215 secure portal, which is managed by HIMSS, the TC 215 secretariat.

For queries about WG8, information about its activities, or access to draft documents produced by WG8 for use in approved standards development work contact Andrew Caswell at Standards Australia (andrew.caswell@standards.org.au).

16.1 Integrated eHealth architecture (for the Global South)

Dr Beatriz Leao (Brazil) gave a presentation on the health context in which nations with developing and emerging (D&E) economies operate - and an overview of the business requirements. She also encouraged all to participate to the lunchtime session with Chris Bailey of WHO (as reported in [section 17 below](#)).

She then provided background information on existing initiatives to improve the use of information in delivering health services, with some key points being:

- Problems flowing from nations reliant on vertical aid programs (“Silos”)
 - Each provides tools for reporting with each program - collecting information based on its own conventions, definitions and statistics.
 - Statistics cannot be aggregated through vertical programs are often unreliable - it is easy to count each case three times over
 - Better information needed to identify requirements, respond to gaps
- Most D&E nations lack personnel, infrastructure and standards needed to support national Health Informatics programs able to support service delivery
- Most countries don’t have a death certificate - and cannot even track cause of death. Where records exist, they are usually on paper and hard to access.
- They do not understand the complexity of conceiving, selecting, developing, deploying and maintaining national eHealth infrastructure
- The Rockefeller Foundation (RF) eHealth Bellagio series - a call to action! Identify priority information needs, strategies and potential resources/partners
- Fundamentals include - saying “no” to silos, ensuring mobility of service delivery and information collection, focussing on the individual and community (not type of disease and identification - who was attended to by whom and where
- Successful strategies address sparse infrastructure for support of health care and make intelligent use of alternative resources at the point of client interaction (e.g. via mobile phones).
- Urgently need an architectural framework & ‘maturity model’ as reference points for conceiving eHealth systems, planning implementations, deciding to build-or-buy, selecting acquisitions and evaluating education and training needs &c
- RF-sponsored project - Open Enterprise eHealth Architectural Framework and Strategy Development for the Global South
 - Aim:** To develop and publish the specifications of a robust, scalable and interoperable open architectural framework to allow for the construction and deployment of integrated eHealth systems for the GS (initially Africa)
- The Health Metrics Network (HMN) - is currently a most important resource for D&E nations (see: <http://www.who.int/healthmetrics/en/>)
- Potential components: - TOGAF, SKMT, CRIS (UNAIDS), PHDSC, SDMX-HD
- The Brazilian experience was presented and it was noted that other nations could leverage the knowledge gained from this (and similar) experience.

Dr Leao recommended that TC215 should develop a roadmap for ISO on what standards to use. A NWIP for a TR on business requirements for such a roadmap in the form of an “eHealth enterprise architecture” was proposed. During broad-ranging discussion of these proposals:

- The accessibility of standards to D&E countries was considered and the potential assistance of ISO DEVCO (the ISO policy committee on meeting needs of developing nations), - plus WHO Africa, the US. Public Health Standards Consortium, and the US. Federal Health Architecture
- A number of other open source and accessible resources were raised, including the Canadian *Infoway* Blueprint (which is standards based); the National Health Information Network (NHIN) in the US; Open Health Tooling; HL7 online training.
- It was suggested that implementation guidance is required to provide added value to standards access.

The joint WG1/WG8 meeting debated the means but generally favoured going ahead with an NWIP to produce a TR providing a roadmap for use in the D&E world, to be developed by **WG8** in conjunction with the Rockefeller Foundation - with Dr Leao as the Project Lead. Other points included

- The WHO mapping guide for HL7 developers is a useful example
- There was agreement that while a roadmap is needed, it needs to be augmented by success stories, illustrating where and how the recommended standards are being used and re-used.
- The assumption that ISO is the right host for such an activity was queried. The ISO business model does not support outputs being freely available (although ISO makes some allowances for D&E economies). What is the value of developing a TR if it will then not be made freely available cheaply for D&Es? The need for early dialogue with ISO etc on any approach based on international standards was noted - with alternatives being considered.
- Implementation guides for HL7 standards are important.
- In developing an eHealth architecture, infrastructural components and capabilities, such as registries, must be considered and addressed.
- Richard Dixon Hughes commented on need for the group to consider negotiating with ISO over IP and distribution rights before committing to an ISO Technical Report.

WHO Presentation. The lunchtime presentation by Christopher Bailey of the World Health Organization (WHO) also focussed on particular needs of D&E nations and is reported in section 17 below.

Australian concerns

While strongly supporting the need for appropriate work to facilitate effective use of eHealth in the D&E world, we raised two concerns:

- This work should focus on systemic eHealth functional requirements, rather than being about prescribing a specific “architecture” (i.e. single prescribed set of standards, components and approaches).
- Early and detailed consideration must be given to negotiating intellectual property rights, if planning to produce an ISO technical report with a view to it then being freely available across the D&E world.

WHO sponsorship was considered as one strategy for funding an open document - but it would not be appropriate to assume that an ISO TC’s resources and name could be used this way without prior agreement with ISO.

This will clearly benefit from more intelligent debate as there was also debate in the closing plenary on the nature and scope of the work and how to avoid pointless waste and make it most effective for its intended recipients in D&E economies

Outcomes

A small group from WG8 to be Led by Dr Leao was commissioned to draft a proposal for an NWIP ballot of ***"eHealth enterprise architecture for emerging and developing countries"*** for approval as a new work item targeting as a joint ISO/WHO Technical Report. It is expected that the ballot will take place in Aug/Sep 2009.

WG8 and WG1 resolved to request TC215 to urge the members of the Joint Initiative Council (JIC) to address their respective SDOs to ask for full collaboration to make the products of their SDOs available for developing and emerging countries in way that makes widespread dissemination in these countries feasible while developing new markets for SDO products. (This was moved by Brazil seconded by Australia and accepted unanimously by TC215 - without any abstentions)

Implications for Australia

If the appropriate persons are prepared to be involved, Australia could contribute to considerations about effective approaches for use in D&E economies, given some of the ICT initiatives piloted and actively used in this country to support indigenous health and primary care.

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

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

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

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

Background

Following systematic review and extensive revision of *ISO/TS 18308:2004 Requirements for an EHR architecture*, at its Göteborg meeting in May 2008, ISO /TC 215 approved a revised draft being circulated for a DIS ballot as the first step in upgrading this technical specification (TS) to a full ISO international standard.

The revised DIS (with further changes requested in Göteborg) was completed in August 2008, was discussed at the October 2008 TC215 meeting (see section 14.1 of the Australian Delegation report on the Istanbul meeting [\[link to report\]](#)).

It was finally released for DIS ballot in November, closing on 22 April 2009, just prior to the Edinburgh TC 215 meeting.

Australia (primarily through Dr Peter Schloeffel and Dr Sam Heard) played a leading role in development of the original ISO/TS document, which has also been adopted and published locally in Australia as *AS ISO 18308*.

Australia was also one of the main contributors of comments in the recent DIS ballot.

Edinburgh update

In Edinburgh, Dr Dipak Kalra (UK) provided a summary of the history to date, the results of the recent DIS ballot, comments received and the main issues, noting that:

- In the ISO DIS ballot 16 NMBs were in favour; 2 (Canada, UK) against - with 9 abstentions.

A total of 30 pages of comments were received from 8 countries. Out of 115 individual comments, 36 were from Canada, 33 from France, 19 from Australia, 14 from UK, 7 from Malaysia, 4 from Sweden and 1 each from Ireland and Norway. Some comments were simple and others quite complex.

- While Australia had voted positively, many of the comments indicated concerns that might cause us to vote negatively at the next stage, if not addressed. This message was accepted and, with active participation in discussion, we understood that most our comments and all the more important ones are likely to be addressed.
- There were discussions about the title and positioning of the document and the need to avoid introducing another definition of EHR - and the need for this to integrate with the HL7 EHR-S FM (about t become a full ISO standard).
- Dr Kalra observed that all comments looked to be good suggestions and there seemed to be no conflicts. The negative votes from Canada and UK were for good reasons, were well supported with comments and could be adequately addressed.
- The focus of the document would be shifted from “Requirements for an EHR” back to “Requirements for an EHR Architecture” (in line with Australia’s views).
- The main challenge in completing the work relates to conformance - this was the primary reason for two negative ballot responses. It was proposed that the Project Team review conformance statements and address the separation of 'shoulds/shalls' in the draft, in preparation for a second DIS ballot.
- There was debate over the business requirements (chapter 4) and whether they should be normative or informative. It was considered that they are aspirational and are difficult to test - noting that there are also many different ways of addressing them. In the US, certification is likely to be only based on the HL7 functional model.
- It was suggested that the document should be put into the new ISO template.

Following revision to improve the document’s approach to requirements for conformity and provision of an informative annex on 18308’s relationship to the HL7 EHR-S Functional Model, the revised draft will be submitted to a second-round DIS ballot, anticipated to commence after August 2009.

Implications for Australia

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

In due course, consideration will also needs to be given to locally adopting the revised ISO 18308, once it finally becomes a full ISO international standard – thereby ensuring that it is widely available at a reasonable cost to potential users in Australia.

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

Background

The HL7 EHR System Functional Model (EHR-S FM) standard identifies functions that may be required in an EHR system (in this context, “EHR system” refers to a clinical information application used in a health facility or practice). The model is applied by producing more detailed “profiles” identifying which particular functions and attributes “SHALL”, “SHOULD” or “MAY” be present in an EHR system claiming to meet the needs of a particular user domain and/or jurisdictional realm.

The EHR-S FM was first published as an HL7 DSTU in July 2004 and became a full ANSI/HL7 standard in February 2008. Australia contributed much of the early international input but in recent years the standard has tended to increasingly reflect US needs as it is now widely used in the United States, driven by the activities of the Certification Commission for Health IT (CCHIT) which has sponsored the creation of a series of US-realm profiles now used to certify various types of systems for use by providers. Further information on these aspects can be found in reports of Australian delegations to HL7 Working Group meetings ([e.g. Vancouver 2008 - see section 18](#)).

Release 1, the approved ANSI/HL7 version of the EHR-S FM was originally submitted to ISO/TC 215 for acceptance as an ISO International Standard; however, HL7 is also in the process of developing an extensively updated Release 2 (R2). The ISO process also threw up required changes that were not part of the original US standard.

At HL7 and ISO meetings in Sep/Oct 2008, a compromise position was reached under which a proposed Release 1.1 containing key changes is being put out through JWG/JIC processes for parallel ballot in both HL7 and ISO.

The joint ballots corresponding to the ISO/DIS stage closed in April 2009, with significant support for proceeding to adoption; however, over 40 participants submitted some 290 comments to reconcile. A final draft is now being prepared for final ISO/FDIS and HL7 ballot.

Edinburgh update

The outcome and comments arising from the two-month ISO/DIS 10781 DIS re-ballot (which closed on 19 Apr - a few days before the Edinburgh meeting) were discussed in a joint session of WG 1, WG 8 and CEN/TC 251/ WG i. A full disposition had not been possible; however, major comments were reviewed in Edinburgh and full reconciliation was commenced at the HL7 meeting in Kyoto, Japan two weeks later.

The ballot was passed with 19/20 in favour and one negative vote from the UK (subsequently withdrawn). There were comments, some critical, from 6 countries - the main areas of concern were its applicability for conformance testing and the relationship of this document to functional profiles, derived from it and to other standards.

For some of the ISO countries (notably the UK and Norway) there is concern that the normative content of the EHR-S FM standard cannot be directly applied to assess conformance of an EHR system without considering the requirements of the relevant functional profile. It has been argued that the normative requirements are therefore not normative; however, the standard has been widely and successfully applied through the use of profiles, in accordance with the requirements of Chapter 2 of the standard

(Conformance Clause), which was drafted on the advice of NIST, the relevant US conformance accreditation authority.

Following discussion, some of it quite robust, and a commitment by HL7 to review the conformance provisions in the subsequent major R2 release, the UK agreed to withdraw its negative ballot. Nevertheless, an Australian proposal that it proceed directly to publication as a full international standard (on the 100% of votes in favour rule) was not accepted, given the extent of the proposed changes following the second DIS ballot and the involvement of CEN through the Vienna Agreement. The final draft (as revised in the disposition of comments) must therefore be submitted for final ISO/FDIS and CEN/FV ballot.

Other points noted during discussion included:

- An informative annex will be developed (and included) to explain the ISO 18308 and ISO 10781 relationship.
- There was agreement on the decision to indicate that conformance issues will be dealt with in R2 in the disposition of comments for DIS 10781 R1.1.
- It was suggested that a conformance clause be added that is similar to the HL7 RIM conformance clause: conformance isn't to the standard but to products derived from it, i.e. the profiles. [But it was pointed out that Chapter 2 of the standard already addresses this].
- It was agreed that EHR S FM R1.1 would progress to FDIS ballot.
- Don Mon from HL7 advised that R2 is targeted for balloting by the end of the year.

Plan for finalisation

The formal ballot reconciliation and disposition process is being managed by the HL7 EHR WG on behalf of ISO, CEN and HL7. This process commenced two weeks after the Edinburgh TC215 meeting, when HL7 EHR WG met in Kyoto (see separate report on Kyoto meeting) and continued through an accelerated series of teleconferences (2 to 3 teleconferences each week) with the goal of completing reconciliation by 5 June and having an updated draft ready to submit for parallel ISO/FDIS and ANSI/HL7 normative ballot in June. [It is understood that this was achieved].

The aim is to have the EHR-S to FDIS ballot in ISO in time for finalisation at the HL7 Plenary in September and the ISO meeting in October (noting that the ISO Central Secretariat shuts down for most of August). It is believed that there will also be a parallel “normative” vote in HL7.

Implications for Australia

Australia needs to continue its strong support in order to ensure full acceptance in the final ISO FDIS vote and also in HL7.

We also need to continue to be involved with work on the major R2 version of the EHR-S FM with a view to ensuring that Australian and other international perspectives are adequately considered, that there is a single global standards framework for EHR systems functionality and that HL7 adequately honours its commitment to address conformance issues in R2 (which may mean partitioning the standard).

Integration of “EHR” and “PHR” information and perspectives is predicted to become increasingly important to support proposed new models of health care - including here

in Australia. It is therefore important that we work to secure integration of HL7 development of the EHR-S FM, PHR-S FM (now at DSTU stage) with work at ISO/CEN on EHR Architecture (through ISO 18308), EHR Communication (through ISO 13606) and services architecture (HISA, SOA).

Groups to whom this may be of interest: HL7 Australia, IHE, MSIA, NEHTA and any jurisdictions or organisations seeking to specify or implement clinical information systems.

16.4 Discussion of NWIP for CDSS guide

As reported in section 12.14 above, WG3 is proposing that TC215 consider an NWIP *“Guide to the principles and desirable features of clinical decision support systems”*. This probably be a technical report and would be aimed at identifying processes, key principles, content elements and necessary domains for clinical decision support system (CDSS) development and maintenance.

Heather Grain (AU), Convener of WG3, addressed a joint meeting of WG1 and WG8 on the proposed work item requesting advice on whether to pursue the NWIP for a TR or whether more information is required. She also noted that another WG3 NWIP on “alerts” is being proposed that would complement this effort. During discussion:

- A question was raised regarding diminishing returns on the Australian document's findings for CDSS. It was confirmed that in some areas diminishing returns were found.

It was suggested that including findings on diminishing returns in the draft would be very helpful in determining where to allocate resources for best returns.

- It was confirmed that an NWIP is ready; WG3 will lead the work and engage with WGs 1, 6 and 8; the initial goal is development of a TR which may become the basis of a full IS after it has been implemented and if it proves useful.

Support for this approach was noted.

- A question was raised about the research done on patient safety and how one decides what is essential versus what is a nice to have. In response, Heather Grain said that it is addressed to a degree but welcomes more input on this.
- It was noted that the work item is linked to academic work in Australia but, while it has a strong academic base, it is not written as an academic paper.
- It was suggested that a review of different CDSS types and how they conform would be useful. It is not part of the initial draft - and it would be a challenge to resource such an activity and keep the results up to date in a publication.
- It was agreed that the NWIP Form 4 would be circulated for informal comment by WG1 and WG8 (and others?) before being circulated for NMB ballot.

16.5 Discussion of NWIP for visual presentation of health information

As reported in section 12.14 above, WG3 is proposing that TC215 consider an NWIP for a technical report addressing consistent and meaningful visual presentation of health data (such as clinical alerts). Heather Grain (AU), Convener of WG3, presented the proposed work item to a joint meeting of WG1 and WG8 and led discussion, with the following being noted.

- This proposed NWIP originated from Australia (with similar background to the CDSS proposal)
- Several existing visual information standards were considered and the draft includes information presentation principles for the health care domain.
- It also identifies issues from a clinical environment and focuses on the representation of clinical information on the computer screen.
- The extensive work done in this area by the UK would be considered as part of the work. The document will benefit from wide international review and input.
- This proposal deals specifically with clinical safety issues, and thus differs from documents that focus on good user interface design. As the intended audience is more focussed in clinical application than IT and ergonomic issues, the activity has the potential to facilitate knowledge transfer and learning.
- It was suggested that proposed guidelines should be tested for usability and to ensure they work before being recommended. Heather Grain indicated her hope that the UK (and others) could contribute much such evidence.
- Agreement that cultural differences need to be considered and addressed.
- Reviewing and incorporating input from any similar national initiatives would be beneficial, both to the development of the draft and for domestic work in those countries.
- A question was raised regarding the NWIP scope's consideration of source/receiver interference. While this was part of the initial discussions, more content is needed in this area and input would be welcome.
- It was agreed that the NWIP Form 4 would be circulated for informal comment by WG1 and WG8 (and others?) before being circulated for NMB ballot.

17. WHO Presentation

Christopher Bailey, Health Care Informatics, WHO, presented to a well-attended lunchtime session on: *“Public Health Informatics Business Requirements”* with a strong focus on WHO experience in Africa. He highlighted a range of issues and factors including:

- Most health information is on paper and there are problems everywhere with the adequacy of ICT infrastructure. Improving the infrastructure and minimising the digital divide is a global priority - but is taking time. It is important to be flexible and use whatever infrastructure is available.
- WHO has a wide range of activities in Africa (e.g. use of handhelds, collaborative learning). Some specifics of issues include:
 - Work in Africa with 3 million patients on anti-retroviral drugs, trying to improve the public health situation (and providing a model for other public health approaches).
 - Moving from doing to learning culture.
- Question assumptions made about eHealth in Africa and be flexible. In Kenya for example, POTS is the lowest common denominator - therefore approaches need to be designed around simple communications.
- There are two main key opportunities: the local expertise and the use of open source and open standards. He suggests that there an interoperable monitoring infrastructure for health should be created.

- Localization (incl capacity) is a critical factor. . Paper based systems lead to many transcriptions (needs write once read many approaches).

In Tanzania for example: hospitals must fill in a library card with patient information, send it to HQ in Dar-es-Salaam, where it is then keyed into government records (50% error rate in gender field).

In Malawi: remoteness of patients from hospitals (long trip, long wait for admission/consultation). Introduction of a touch screen computer (like restaurant) reduced wait time to a few minutes, and they were then able to build a referral system on top.

- Building clinical quality circles is another technique. Uses patient summary forms of last 3 encounters, made up by nurses the day before the consultation, saved clinician time to achieve triple throughput rate.
- Handhelds/mobiles being adopted for out of hospital care: another example of a needs-driven rather than solution-driven approach.
- Another Kenya example: unrest during election, at HIV clinics patients receiving drugs dropped to 5% of normal level, so teams were sent into IDP (internal refugee) camps to continue treating patients based on electronic records. Ubuntu: your pain is mine, my wealth is yours, your salvation is mine.
- Listen to create trust. Collaborative learning rather than imposed solutions. Patient data interoperability is absolutely needed because patients are very much dealt with in separate systems (verticals) driven by sources of funds eg general health, HIV, TB...

- The key opportunities stem from enabling from local expertise through open source and standards: bringing in fixed solutions developed elsewhere doesn't work.
- Workforce pressures make information capture, transfer and integrity poor (eg can't run central EHRs with only a few people).
- Identification of patients is challenging, use of ISO standards is desirable.
- Standardise indicators for reporting, clinical guidelines for diagnosis/treatment. Roles/issues for standards include:
 - Top 10 indicators for GFATM reporting (Global) – 4 items not from patient records.
 - GFATM and PEPFAR offer grants.
 - Both individual and population data are needed, so build an interoperable environment to support the dual use of data and avoid multiple counting
 - Business cases for standards: eg standard access DTS 21667; ROADS = registry of open access data standards; SDX = data standard; OASIS = Open access.
- Need to deal with anonymous mobile population dynamics, moving from verticals to primary care.
- Infrastructure and service delivery model assumptions must be questioned. Particularly the need to make money by providing services, not by selling products.
- Complexity of managing health finance vs complexity of health care delivery: the latter is much more relevant in Africa.
- Question: What examples of successful open standards are in use in Africa? Open MRS eg trialled in western Kenya, has over 1M patients across Africa, adopted by 12 companies.
- There was general support for the NWIP on eHealth systems for developing (underserved) countries (Beatrice Leao's proposal).

18. Other Matters

18.1 ISO/IEC JTC1 Liaison

Richard Dixon Hughes (AU) TC215 liaison to ISO/IEC Joint Technical Committee 1 - (JTC1) the peak international standards committee across the ICT sector gave a presentation at the closing plenary on JTC1's history, activity and potential for interaction with TC215. The presentation was actually prepared by Dr Adrian Stokes (UK), JTC1 liaison to TC215 (with some input from Mr Dixon Hughes); however, Dr Stokes had had to depart the Edinburgh meeting before the time for the presentation arose. The presentation was well received, with the following impressions being noted by another Australian delegate.

- JTC1 has numerous specialist subcommittees
- Need to consult as considerable possibilities of TC215 undertaking work already done elsewhere - particularly in security, safety, sensor networks, digital content management, data protection, archiving, identity management
- In addition to health - there are some general "vertical" areas being attacked by ISO and IEC which intersect technology fields. These include Intelligent transport, global warming etc..
- Several groups seek interaction with ISO TC-215. Detailed report from Standards Australia.

During the course of the Edinburgh meeting, there were frequent opportunities for Mr Dixon Hughes to work with TC215 on more effective sharing and use of JTC1 capabilities.

18.2 TC 215 Business Planning Task Force

Further to discussion at the TC 215 Executive Council, a TC 215 Business Planning Task Force was established at the May 2008 TC215 meeting in to carry out a further review of TC 215 activities and organisational structure – with a view consolidation and rationalisation.

The Business Planning TF members are:

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

Progress was discussed in the Executive Council at Edinburgh and some changes to the TC215 scope had been made as a result of their progressive deliberations.

18.3 Suggestions for improvement

Dr Vince McCauley made the following observations on potential TC215 productivity improvements

- Approximately half of the time at the Edinburgh meeting was spent dealing with comments submitted as part of the ISO balloting process. Whilst some comment disposition occurs via email out of session, the comments must be agreed at the WG where all countries have the opportunity to take part. In addition comments which are more difficult to resolve, are discussed and disposed of at the WG meeting, especially those that result in changes to the underlying balloted document. Whilst all sessions are held in English, the hugely different language usage and greatly diverse political, cultural and medical communities represented at ISO, make the process of consensus challenging and time consuming.
- Unlike HL7, ISO has little funding to support regular teleconferences between working group meetings. Hence, the issues that would be dealt with by teleconference at HL7, in the period between working group meetings, has to be done face to face at ISO. This makes attendance at the meetings mandatory if a country is to have any involvement at all in ISO TC 215 work.
- ISO has strict and complex requirements for document production processes which are designed to provide fairness to all countries, large or small. In addition many documents are required to be published in French as well as English. This coupled with a less well developed support and secretariat infrastructure (web site, wikis, teleconferences), can result in significant elapses of time for production and publication of ISO TC 215 outputs.

Janette Gogler made the following observations on opportunities to engage much more strongly with the nursing profession in encouraging adoption :

- Many aspects of the standards meeting need to be disseminated to health jurisdictions for awareness and adoption; and to health professional bodies for input such as state nursing e-health committees.
- I believe there is excellent opportunity for further structured input from within nursing - nurses at the coal face of health organisations to participate in standards that affect nursing, and the clinical e-health environment.

18.4 New ISO document formats

The TC215 Secretariat advised all delegations and WG secretariats to use the new ISO document formats distributed on CD-ROM. Copies are available from Andrew Caswell at Standards Australia (Andrew.caswell@standards.org.au).

TC215 Work Program - Highlights for Australia

19. Progress of TC215 standards development

The following is a summary of overall progress compiled from the minutes of TC215 and its working groups (where available), the ISO-CS (Central Secretariat) website and from delegate reports of activity at the Edinburgh meeting.

Items on which Australian actions may be required are highlighted.

Particular attention needs to be given to items requiring ballots or other action in the period up to the next ISO/TC 215 meeting in Durham, North Carolina which will take place from 17 to 21 October 2009.

19.1 Recently completed TC 215 work

The following standards have been published since the previous (October 2008) ISO/TC215 meeting in Istanbul:

- *ISO/TS 21298:2008 Health Informatics - Functional and structural roles.* Published as an ISO technical specification on 17 Nov 2008.
- *ISO/TS 25237:2008 Health Informatics - Pseudonymization.* Published as an ISO technical specification on 24 Nov 2008.
- *ISO 13606-2:2008* <http://www.iso.org/iso/rss.xml?csnumber=50119&rss=detail> *Health Informatics - EHR communication -- Part 2: Archetype interchange specification.* Published as a full ISO international standard on 25 Nov 2008.
- *ISO 13606-3:2009 Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists.* Published as a full ISO international standard on 14 Jan 2009.

Note: Final publication of parts 2 and 3 of ISO 13606 clears the way to start work on the proposed IT-014-09 work item: An Australian guide to ISO 13606.

- *ISO/TS 22220:2009 Health Informatics - Identification of subjects of health care.* Published as an ISO technical specification on 11 Mar 2009.
- *ISO 11073-91064:2009 Health informatics - Standard communication protocol - Part 91064: Computer-assisted electrocardiography.* Published as a full ISO international standard on 5 May 2009.
- *ISO/TR 12773: 2009 Business requirements for health summary records*
 - *Part 1: Requirements.*
 - *Part 2: Environmental scan.*

Both parts were published as ISO technical reports on 4 Jun 2009.

Note: Although *ISO/TR 12773* was first approved for publication in May 2008, its final publication was delayed due to presentation and formatting problems. Having now been finalised, it can now be removed from IT-014-09 Work Program - but might be suitable for inclusion in IT-014 awareness programs.

- *ISO 27931:2009 Health Informatics - HL7 Version 2.5.* Published as a full ISO international standard on 17 Jun 2009 - eventually!!!

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

- *ISO/TR 12309 Health informatics – Guidelines for terminology development organisations;*
for publication as an ISO technical report (with final text due at TC215 Secretariat by 1 Aug 2009).

This TC215/WG3 work item was previously entitled: “*Health informatics – Guidelines for international healthcare terminology standardisation*”.

- *ISO/TR 11636 Health Informatics Dynamic on Demand Virtual Private network for health information infrastructure;*
for publication as an ISO technical report (with final text due at TC215 Secretariat by 15 May 2009).

Note: The ballot on this document was used by TC215 to trial a process of balloting acceptance of standards documents by vote in plenary session (rather than by correspondence); however, the trial raised many unforeseen practical difficulties (e.g. the need for proxies) which removed much of the anticipated benefit. It is expected that future Committee-level votes on acceptance of draft standards will continue the current practice of using online balloting to submit written ballots/comments in electronic form.

- *ISO/TS 27527 Provider identification;*
for publication as an ISO technical specification (with final text due at TC215 Secretariat by 15 May).

Follow-up Action: There were difficulties integrating this provider identification work with the *ISO/DIS 21090* harmonised data types. The project team under Heather Grain will proceed with development of an informative annex which will subsequently be published as a technical corrigendum indicating how *ISO/TS 27527* is to be realised at the technical level.

- *ISO/TS 27790 Document Registry Framework;*
for publication as an ISO technical specification (with final text due at TC215 Secretariat by 15 May). This document, based on IHE Korea work, relates to an extension to the IHE XDS specification

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

- *ISO TR 22221 Good Principles & Practices for a Clinical Data Warehouse.*
Continued publication as an ISO technical report confirmed - for next review no later than 2012.

19.2 Previously approved with publication pending

The following items approved for publication well prior to the Edinburgh meeting were still pending as at 30 Jun 2009.

- *ISO/TR 11633 Health informatics — Information security management for remote maintenance of medical devices and medical information systems - Parts 1 and 2*

TC215 approved the documents for publication in Istanbul subject to their being circulated to NMBs for a one-month final comment. WG4 report it as being “in publication” and ISO-CS records receipt of a proof in May 2009.

- *ISO 12967 Health informatics service architecture - Parts 1, 2 and 3.*
- still awaiting publication as full ISO international standards.

Action: Seek confirmation of *ISO 12967* publication status from TC215/WG1 and TC215 Secretariat (TC215 approved its publication in October 2008).

Note: Development of an implementation guide to *ISO 12967* was proposed and agreed in principle by TC215/WG1 and TC/251 WGi in Edinburgh. Comments on content and coverage are invited via CEN TC251 Central Secretariat at NEN.

- *ISO/TS 21547 Health informatics - Secure archiving of electronic health records -- Parts 1 and 2.*

These were balloted as a TS closing in Oct 08 but Istanbul minutes record approval for publication as full ISO international standards.

Status is unclear; WG4 reported it to be “in publication” but it does not appear to be on record as such with ISO-CS. The DTS ballot attracted some 12 pages of comments (predominantly from Canada).

Action: Seek confirmation of *ISO/TS 21547* publication status from TC215/WG4 and TC215 Secretariat and consider whether Australia needs to take a position on process/progress.

- *ISO/TS 22600-3 Health informatics - Privilege management and access control - Part 3: Implementations.* Approved in Istanbul for publication as an ISO technical specification to complete the series on privilege management and access control (PMAC).

ISO-CS had concerns about the format of the document which were resolved in Edinburgh and it was re-submitted for publication on 30 Apr 2009.

- *ISO 25720 Genomic Sequence Variation Markup Language (GSVML).*

Following a DIS ballot closing in Jun 08, *ISO 25720* was approved in Istanbul for publication as a full ISO international standard with the draft to be revised to address ballot comments. The revised draft was circulated to TC215/WG2 following an out of session meeting in Orlando in Jan 09. In Edinburgh, WG2 reported the document as being “in publication” but also noted that: “as a result of the ISO process, the project, which originally centred on SNP, has been extended to include all DNA variations”. Given the extent of the changes, it is possible that the publication proof may still require a final FDIS ballot.

- *ISO/TR 28380-2 IHE Global Standards Adoption – Part 2: Integration and Content Profiles* was approved in Edinburgh for publication as an ISO technical report (with final text due at TC215 Secretariat by 15 May).

Potential problem: International acceptance of IHE and its processes has been high on the agenda for many Australians involved in eHealth activities; however, despite having been “completed” and “approved for publication” there seems to have been little, if any, progress in finalising either of the two parts of *ISO/TR 28380* - which seeks to formally record the IHE processes.

Part 1 of *ISO/TR 28380* (“Process”) has been reported to TC215 as being “in publication” at every meeting since it passed ballot in October 2007 but remains unpublished - with no change in status recorded by ISO-CS since 19 Jun 2008.

The successful ballot for Part 2 closed in Sep 08 and TC215 passed almost identical resolutions in Istanbul and again in Edinburgh approving Part 2 for publication. In the first case, the finalised documentation was due to be received by the TC215 Secretariat by 31 October and by 15 May following Edinburgh.

Proposed action: Follow up progress with IHE, TC215/WG2 and TC215 Secretariat before Durham meeting and consider whether any Australian resources might be able to assist, if required.

19.3 FDIS ballots - upcoming and in progress

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

- *ISO FDIS 21090 Harmonised data types for information interchange*

Australia has been championing the cause of this standard - a flagship for harmonisation - with Grahame Grieve leading the work across HL7, ISO and CEN. Even though all countries voted positively in the DIS ballot, a final vote is now needed to accept revisions arising from technical comments. TC Secretariat was seeking revised documentation by end-May 09.

Action: Australia to continue strong support for finalisation and acceptance of this joint work as both full ISO international standard and its
- *ISO/HL7 FDIS 10781.2 EHR System Functional Model Release 1(EHR-S FM)*

This is another standard strongly supported by Australia, while recognising the importance of this standard to US stakeholders, because of its growing role in supporting US domestic eHealth policy. The version being balloted in both HL7 and ISO is a harmonised Release 1.1. As noted elsewhere, the UK and some others have expressed concern about how conformance can be expressed in terms of this standard and the derived profiles. These issues were discussed in Edinburgh - with significant revisions to be addressed in a subsequent Release 2.

Since Edinburgh, the HL7 EHR WG has pursued an aggressive schedule to deliver a revised document (incorporating reconciled comments), separate revisable figure files and a completed table of comments to the TC215 Secretariat by 15 Jun 2009 [this is understood to have been achieved].
- *ISO 13606-5 Electronic health record communication Part 5: Interface specification*

The October 2008 TC215 meeting in Istanbul approved that ISO 13606-5 could proceed to FDIS ballot following circulation of a revised draft incorporating comments arising in the DIS ballot (which also closed in Oct 08).

An updated draft and disposition of comments was circulated on 30 Mar and, given the level of comment received, was further reviewed in Edinburgh, with ISO/TC215/WG1 and CEN/TC251/WGi supporting the suitability of the revised draft for FDIS/FV ballot - which is now expected soon.

Australia will need to do a final review of each of these documents at FDIS ballot and submit any final comments through Standards Australia IT-014. Under ISO Directives, there is little opportunity for change at the final FDIS stage; however, it is also time to consider and, if appropriate, plan for their local adoption in Australia.

The following have progressed to the point of the FDIS ballot having been held but final status and approval for publication (where appropriate) have yet to be confirmed.

- *ISO/HL7 27932 Clinical Document Architecture, Release 2 [i.e. CDA]*

TC215 gave its approval at the Istanbul meeting in October 2008 for *ISO 27932* to proceed to FDIS ballot. A disposition of DIS comments was subsequently agreed and a final HTML version of the document was forwarded to the Secretariat. It was circulated in January 2009 for a 5-month “Fast Track” FDIS ballot, closing on 10 Jun 2009. The results had not been posted at the time of writing.

19.4 Upcoming ballots - draft standards documents

As a result of decisions at the Edinburgh meeting, each of the following documents is expected to be released for ballot as a Draft International Standard (DIS), Draft Technical Specification (DTS) or Draft Technical Report (DTR).

DIS is the “public enquiry” stage at which detailed acceptance review and specific comment by IT-014 and other relevant Australian interests is appropriate.

Active comment and input is also sought on DTR and DTS documentation, although technical reports and technical specifications can be published by ISO technical committees without having been through widespread “public enquiry”.

- *ISO DIS 21667 Health Indicators Conceptual Framework.*
A 5-month DIS ballot is expected to commence in Jul 09.
- *ISO DIS 18308 Requirements for an electronic health record architecture*
Changes from the previous DIS ballot are now to be incorporated for 2-month DIS re-ballot planned to commence in Aug 09.
Australian proposals for change were largely accepted.
- *ISO DTS 29585 Deployment of a Clinical Data Warehouse;*
Updated draft due at TC215 Secretariat by mid-Jun for ballot commencing in Jul 09.

At previous meetings, TC215 had approved that the following draft standards documents be circulated for DIS, DTS or DTR ballot but, at the time of writing, the ballots had not been completed.

- *ISO DIS 21549-8 Health informatics - Patient healthcard data - Part 8: Links;*
The DIS ballot opened on 30 Apr with Standards Australia requesting comments by 24 Aug 2009.
- *ISO DIS 22857:2004 Health informatics - Guidelines on data protection to facilitate trans-border flows of personal health information.*

In Edinburgh, TC215/WG4 reported that final comments and concerns in the revision of this existing standard have been resolved and the revised version is now ready to proceed to DIS ballot as previously approved in Istanbul.

- *ISO/HL7 DIS 27953-1 Health informatics – Pharmacovigilance – Individual case safety report [ICSR]*
 - *Part 1: The framework for adverse event reporting*
 - *Part 2: Human pharmaceutical reporting requirements for ICSR*

The DIS ballot for both parts of *ISO/HL7 DIS 27953-1* opened on 30 Apr with Standards Australia requesting comments by 24 Aug 2009.

Note: As with all current work on pharmacovigilance standards, balloting of this existing HL7 specification to full ISO status is controversial and requires some local effort to resolve the potential issues.

19.5 Upcoming and current ballots - new work items

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

- *The BRIDG domain Analysis Model for protocol-driven biomedical research*; proposed as a JIC joint project to become a full ISO international standard based on existing CDISC specifications developed with HL7 support. NWIP ballot expected Jun/Jul 09.

- *Health informatics – Categorical structures of symptoms, signs and patterns/syndromes in traditional medicine - Part 1*; proposed as an ISO technical specification.

Action: Heather Grain leading Task Force to produce draft documentation by 15 Jun 2009 for NWIP ballot expected Jul/Aug 09.

- *Health informatics – Guidelines for the principles and desirable features of clinical decision support systems*; proposed as an ISO technical report with draft documentation due by 15 May for NWIP ballot expected Jun/Jul 09.

Note: Whilst this item has been initiated by WG3, the importance of CDS to all TC215 WGs (and other health informatics SDOs) was noted and, if approved, JIC/JWG will need to consider progressing this work item via a separately convened joint Task Force. JIC/JWG and other TC215 WGs are to be invited to advise on the appropriate mechanism for pursuing the work item.

- *Health informatics – Categorical structure for human anatomy within healthcare terminological systems*; proposed as an ISO technical report (in conjunction with CEN via the Vienna Agreement with ISO lead) with draft documentation due by 15 Jun for NWIP ballot expected Jul/Aug 09.
- *Health informatics -- Classification of data purposes for processing of personal health information*; proposed as an ISO technical specification (in conjunction with CEN via the Vienna Agreement with ISO lead) with draft documentation due for NWIP ballot expected May/Jun 09.

Note: This WG4 activity is required to integrate with work already done through TC215/WG8 (EHR requirements), which will involve Australian WG8 Secretariat, IT-014-04 and IT-014-09 in preliminary support and review of this work item, which arose out of 13606 EHR security, privacy and access control issues.

- *Health informatics - Security and privacy requirements for compliance testing of EHR systems*
 - *Part 1: Foundation*;
 - *Part 2: Protection profile for small-scale electronic patient record systems*

Both parts proposed as ISO technical specifications (in conjunction with CEN via the Vienna Agreement with ISO lead) with draft documentation due by 11 May for NWIP ballot expected Jun 09. There was a question as to whether the proposed work fits within ISO directives in relation to compliance and management systems. **Action:** Richard Dixon Hughes to follow up and advise.

- *Health informatics -- Security aspects of EHR record migration*; proposed as an ISO technical report with draft documentation due mid-May for NWIP ballot expected Jun/Jul 09.
- *IEC TR 80001-2 Application of risk management for IT-networks incorporating medical devices – Guidance for health delivery organizations*. TC215 approved

registration of this as a preliminary work item. WG7 is to produce a proposal for a joint technical report for approval by both ISO TC215 and IEC SC62A. If approved, the TR will be jointly developed by ISO/TC215/WG7 and IEC SC62A, which are already working together on *IEC IS 80001-1 Application of risk management for IT networks incorporating medical devices*.

- *eHealth enterprise architecture for emerging and developing countries*; proposed as a joint ISO/WHO technical report with draft documentation due 30 Jun for NWIP ballot expected Aug/Sep 09.

Note: Australia expressed the view that the proposed work was more about eHealth functionality for developing countries, rather than about specific architecture and that the name should reflect this.

- *Personal Health Records: Definition, Scope and Context* – proposed by WG8 as an ISO Technical Report – including a classification of PHR approaches, use cases and leveraging the HL7 PHR-S FM. (See [section 16 above](#)).

This document appears to have been listed on the TC215 site for a ballot closing in August - but had not been circulated to IT-014. Standards Australia is following this up - as the topic and approach are of both interest and concern to potential Australian stakeholders - the standard goes some way to trying to answer questions about what are the critical characteristics of a PHR?

Each of the following standards projects on IDMP (Identification of Medicinal Products) have been actively underway for some years but have reached the point where they had to be withdrawn and revalidated by national member bodies if work is to continue. For more detail, refer to commentary in [section 14 above](#).

- *ISO NP/CD 11615 Health informatics – IDMP - data elements and structures to uniquely identify medicinal products (MPIDs) for the exchange of regulated medicinal product information*

Note: renamed to include: “ ... for the exchange of regulated medicinal product information”.

- *ISO NP/CD 11616 Health informatics – IDMP – Data elements and structures to uniquely identify and exchange pharmaceutical products (PhPIDs)*

Note: renamed from: “ ... - Structures and controlled vocabularies for pharmaceutical product identifiers (PhPIDs)”.

- *ISO NP/CD 11238 Health Informatics – IDMP – Data elements and structures to uniquely identify and describe substances and specified substances*

Note: renamed from: “ ... IDMP – Structures and controlled vocabularies for ingredients”.

- *ISO NP/CD 11239 Health informatics - IDMP - Data elements and structures to uniquely identify pharmaceutical dose forms, units of presentation and routes of administration*

Note: renamed from: “ ... IDMP – Structures and controlled vocabularies for pharmaceutical dose forms, units of presentation and routes of administration”

- *ISO NP/CD 11240, “Health informatics – IDMP – Data elements and structures to uniquely identify Units of Measurement*

Notes: (1) renamed from: “IDMP – Structures and Controlled Vocabularies for Units of Measurement”

(2) the potential for this item to clash with existing work of other TC215 TCs

and other SDOs (including the widely used UCUM conventions) was of considerable concern.

In addition, WG6 successfully proposed the following additional item:

- *Health informatics -- Classification of data purposes for processing of personal health information*; proposed as an ISO technical specification (in conjunction with CEN via the Vienna Agreement with ISO lead) with draft documentation due for NWIP ballot expected May/June 09.
- *Health informatics – Requirements for the implementation of the standards for the identification of medicinal products for the exchange of regulated medicinal product information*; proposed as an ISO technical report (to be coordinated with ISO/TR 12975 Principles and guidelines for the maintenance of terminological systems and ISO/TR 12309 Guidelines for international healthcare terminology standardization) with draft documentation due for NWIP ballot expected Aug 09

Balloting of the following major item as an NWIP was approved at the previous TC215 meeting in Istanbul but this had not been completed as at 30 Jun 2009.

- *Quality requirements and methodology for detailed clinical models* – proposed as an ISO international standard. Ballot documentation and a rough outline of the approach were circulated on 23 April, just prior to the Edinburgh meeting and were topics of some debate in WG1.

Standards Australia requested comments from IT-014 and its stakeholders by 17 Jun 2009 with the responses being reconciled for submission to ISO by mid-July. [Note: Australia's final position was to vote "NO" to an international standard but indicate a desire to proceed, but appropriately, foreshadowing acceptance of the work as a technical specification supported by a technical report].

Action: This is a significant piece of work of interest to many Australian stakeholders concerned to ensure that UML modelling approaches being promoted by HL7 interests do not exclude archetype-based models. On-going Australian input is seen as vital to ensuring that the work proceeds with adequate quality and balance.

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

19.6 Other recently completed ballots

Other significant ballots conducted since the Istanbul meeting in October 2008 have included

- *ISO/NP 13581: Health informatics: Guidance for maintenance of object identifiers (proposed as an ISO technical report), and*
ISO/NP 13582: Health informatics: Communication model and XML interface specification for OID registries (proposed as an ISO technical specification)
were issued on 10 Mar and closed in Jun 09 - with both being approved.

Note: The Edinburgh plenary recognised that TC215 needs to carry out this activity in close liaison with relevant bodies responsible for the OID identifier standards and frameworks. Guidance has therefore been sought on the process for liaison with ISO/IEC JTC1/SC6, ITU-T SG17 and ISO/TC 54² regarding these work items. Advice has been received that Prof. John Larmouth (UK-based convenor of ISO/IEC/JTC 1/SC 6/WG 9 and SG17/Q12 rapporteur) and Olivier Dubuisson (ASN.1 project leader) will provide liaison and expert guidance.

- *ISO/HL7 NWIP 13449 Clinical Genomics – Pedigree Topic.* NWIP ballot proposal based on an HL7 DSTU in the same field (including family history) and is proposed as a full ISO international standard. Ballot closed on 18 May 2009 with the proposal being approved.
- *ISO 13131 Quality Criteria for Services and Systems for telehealth.* NWIP ballot with Committee Draft for proposed ISO technical specification closed in Feb 09 and was approved (with one country opposed - Germany).

19.7 Other upcoming potential work

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

- *ISO/CD 10159 Web Access Resource Manifest (WARM)* - ballot of recently completed Committee Draft expected soon. Australia was previously critical of the work on grounds of potential security problems.
- *ISO CD 27789 Health informatics – Audit Trails for Electronic Health Records.* TC215 has accepted a recommendation from WG4 to circulate a second Committee Draft for NMB review, comment, input and approval. Target date for circulation is July 2009 - but it is likely to be later, if previous history of this item is *repeated*.
- **Continuing support to the Task Force on Traditional Medicine** (through Heather Grain as Convener TC215/WG3 and IT-014-02) and engagement of Australian experts in complementary medicine in the work of the Task Force in relation to:
 - 1 - Identification of standards requirements for Traditional Medicine
 - 2 - Development of work item proposals for Traditional Medicine
 - 3 - Review of NWIPs of the TC to identify where the requirements of Traditional Medicine should be incorporated.
- Participation in discussions related to use and registration of OIDs. This is an area of interest - particularly to HL7 Australia.
- *Health informatics - Alert information in health records - Concepts, information model and visual presentation.* TC215 gave approval in principle to work on this topic (with CEN/TC251 WG ii proposing to take a leading role); however, work is needed in the period up to the October TC215 meeting to ensure that the international work ties in with the approaches that were put forward by Australia and agreed with WG3 and WG8 - there are already differences in scope and detail between what WG ii proposed and what WG3 has presented.

² This appears incorrect. ISO 54 deals with "Essential Oils". It should probably have been ISO/TC 184/SC5 - Architecture, communications and integration frameworks.

In addition, there is also potential work for Standards Australia as the JWG secretariat in managing discussion of the item in JWG.

- Device standards. WG 7 has a continuing series of projects to adopt more of the *ISO 11073* series of standards being jointly developed with IEEE in relation to *Personal health device communication* as full ISO international standards. These all need to be considered - firstly for potential use of a “fast-track” to a 5-month FDIS ballot - and secondly as to *substance* in that final ballot.

19.8 Miscellaneous items for internal follow-up

The status of the following was unclear at the time of reporting. They are listed here to facilitate future follow-up by IT-014 and Australian delegations.

- Revision of *ISO 18104:2003 – Health informatics – Integration of a reference terminology model for nursing* [proposed as joint with CEN with ISO lead]
- *Business requirements for public health standards* – proposed by WG8 as an ISO Technical Report in Istanbul – identifying needs for adoption, adaptation or development of [information] standards in public health, with a focus on developing countries, WHO and leveraging existing work on EHRs and PHRs.

Attachments

Attachment 1 – Draft Minutes and Resolutions of Edinburgh ISO/TC215 Meeting



CEN TC 251 and ISO/TC 215 Health Informatics DRAFT Joint Closing Plenary Minutes Edinburgh Scotland - 30 April 2009 (0900-1700)

[Note - edited/modified in places for Australian delegation report]

- [1] Dr Kwak, Chair of TC 215 and Kees Molenaar, Chair of TC 251 opened the meeting by welcoming all of the delegates, experts and liaisons to the plenary meeting.
- [2] Dr. Kwak recognized Observing member Singapore for attending the meetings.
- [3] Dr. Kwak and Kees Molenaar recognized liaisons who participated in the meeting:
For ISO/TC 215 - CDISC, Continua, DICOME, IHE, IHTSDO, ICH, WHO
For CEN/TC 251 - Normeapne
- [4] The TC 215 secretary, Audrey Dickerson did the roll call of ISO/TC 215 Participating Member National Member Body Delegates attending the final plenary meeting.

Australia	Present	Korea	Present
Austria	Apologies for plenary but was at some WG sessions	Malaysia	Present
Belgium	Apologies	The Netherlands	Present
Brazil	Present	New Zealand	Apologies
Canada	Present	Norway	Present
China	Apologies	Russian Fed'n	Present
Czech Rep	Not present	Serbia	Apologies
Denmark	Not at plenary but was at some WG sessions	Slovakia	Apologies
Finland	Present	Spain	Present
France	Present	Sweden	Present
Germany	Present	Turkey	Apologies
Ireland	Present	United Kingdom	Present
Italy	Present	United States	Present
Japan	Present		

- [5] Bernd Blobel led the plenary in a moment of silence to recognize and honor the memory of former WG 5 Convenor, Jurgen Sembritski, who suddenly passed away earlier this year. Please see resolution #68.

- [6] The joint agenda was adopted by the plenary.
- [7] Resolutions from the Working Groups – WG conveners

NOTICE:

ISO/WG 4 Security, Safety and Privacy have agreed to test the [revised] proposal for “in-meeting” ballot resolutions at plenary meetings.

The proposal had been written and read to all NMB representatives and experts present in the Istanbul meeting. Request was for NMB’s to discuss with their Standards Institutes and be ready to vote this proposal into a resolution in Edinburgh in 2009, noting that the proposal would be voted upon during the Executive Council resolutions at the beginning of the Plenary day, 30 April 2009.

The following is the wording from resolution #2 Istanbul resolutions:

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

NOTE: Numbers without brackets are resolution numbers; numbers in square brackets represent agenda item numbers.

ISO/TC 215 Executive Council Resolutions (presented by Dr. Kwak)

- 1. Resolved that ISO/TC215 accepts the report and resolutions of the Executive Council.
- 2. Resolved that ISO/TC215 approves the Executive Council recommendation for ISO/TC 215 to exercise the ability to ballot one technical report, during the plenary meeting today following the rules outlined as noted on the closing plenary agenda.

Comments: Canada: Ballots and plenary resolutions should not be mixed. Please make this a one-time only ballot. US, agreed.

Note: Resolution #2 was revised to allow only one ballot - on the TR 11636 (*Dynamic on-demand virtual private network for health information infrastructure*)

*Motion: to revise resolution by UK/ Australia passed:
Affirmative 12; Abstain 1 (Germany); Against Nil.*

3. Resolved that ISO/TC215 approves the Executive Council recommendation for ISO/TC 215 to send suggested changes to the ISO/TC 215 scope out to the National Member Bodies for review and comment.
4. Resolved that ISO/TC215 approves the Executive Council recommendation for the ISO/TC 215 business plan to reflect the resource needs of the TC. Heads of national programs are requested to review what the needs are now.
5. Resolved that ISO/TC215 approves the Executive Council recommendation to form a task force to prepare for a Global Summit for 18 October 2009.
6. Resolved that ISO/TC215 approves the Executive Council recommendation for ISO/TC 215 to hold a mini-plenary for WG resolutions only in the afternoon of the TC JWG meetings. All other reports and plenary reports will remain for the Annual plenary
7. Resolved that ISO/TC215 approves the Executive Council recommendation for an ISO/TC 215 patient safety/quality task force to review the need for increased activities in health informatics for patient safety and quality. Delegates and NMB's who would like to participate please send your request to the TC secretary for participation. TC 215 will consult TC 251 on these issues.

*Note: The rest of the Executive Council resolutions were passed:
Affirmative 13; Abstain Nil; Against Nil.*

ISO/TC215 WG1 Data Structure (Grant Gillis)

[Note: Unless otherwise indicated, each WG reported in the form of a presentation containing resolutions which were reviewed with the plenary.]

Comments: US wanted to remind the TC that convenorship is not attached to a country rather there should be a specific motion for the convenorship.

*Motion to accept the WG 1 report and all resolutions by UK/ Australia passed:
Affirmative 16; Against Nil; Abstain 1 (Malaysia).*

8. Resolved that ISO/TC215 accepts the report of ISO/TC 215 WG 1.
9. Resolved that ISO/TC215 approves the WG 1 recommendation to approve the transition of WG 1 officer as follows: Julie Richards, Interim Convenor

Note: In consultation with the TC 215 Chair and Secretary, and the support of the Executive Council, Ms. Richards would serve until the end of the remaining term (May 2010) at which time an election for Convenor of WG 1 will be held for the next 3 (three) year term.
10. Resolved that ISO/TC215 approves the WG 1 recommendation that ISO TR 22221 *Good Principles & Practices for a Clinical Data Warehouse* be confirmed - for review no later than 2012.
11. Resolved that ISO/TC215 approves the WG1 recommendation that the ISO/TC215 Secretariat circulates the DTS ballot of ISO 29585 *Deployment of a Clinical Data Warehouse* for approval as a Technical Specification and that the document arrives at the TC Secretariat no later than June 15 2009, to be placed on the ISO/TC web site no later than June 29, 2009.

12. Resolved that ISO/TC215 approves the WG1 recommendation that the ISO/TC215/WG1 Secretariat circulates the draft DIS of ISO 21667 *Health Indicators Conceptual Framework* for a comment period closing on May 22, 2009, and that the resulting document arrives at the TC Secretariat no later than June 19, 2009 for circulation as DIS ballot.
13. Resolved that ISO/TC215 proceed with the publication of *ISO/DTS 27527 Provider identification* and that the project team under Heather Grain proceed with development of an informative annex which will subsequently be published as a technical corrigendum.

ISO/TC51 WGi Information Models (Stephen Kay)

In his report on CEN/TC251/WG1 Activities, Prof Kay confirmed the commitment of CEN/TC251 to using the SKMT glossary tool.

To view the report presentation for WGi Information Models, contact CEN/TC 251 secretary Shirin Golyardi shirin.golyardi@nen.nl.

ISO/TC215 WG2 Data Interchange Structure (Mike Glickman)

Note: Tom Marley was thanked for his assistance as the leader of the WG2 breakout group, methodology.

Comments: Canada: The TC needs to think about how research topics will be addressed going into the future and which TC is the appropriate home for these projects. Brazil: Asked about the telehealth projects – work continuing and an NWIP is forthcoming. Germany: also mentioned need for coordination with WG4 for some projects.

There was concern regarding the TC hearing [i.e. receiving] the WG reports during the Plenary session. Sweden: Expressed concerns about resolutions being available to all delegates at the time of the meetings. Urged – that resolutions be distributed as they are prepared.

Motion to approve report and all resolutions: Canada/ Germany passed: Affirmative 15; Abstain 2 (Italy and Spain); Against Nil.

14. Resolved that ISO/TC215 accepts the report of ISO/TC 215 WG 2.
15. Resolved that ISO/TC215 approves the WG 2 recommendation to request the Secretariat to forward document ISO/TR 28380-2, *"IHE Global Standards Adoption – Part 2: Integration and Content Profiles"* to the ISO Central Secretariat for publication and that the document arrives at the TC Secretariat no later than 15 May 2009.
16. Resolved that ISO/TC215 approves the joint WG 1 and WG 2 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of *"The BRIDG domain Analysis Model for protocol-driven biomedical research"* for approval as a new work item targeting an International Standard and that the Form 4 and a document arrives at the TC Secretariat no later than 30 April 2009 to be placed on the ISO/TC web site no later than 14 May 2009.
17. Resolved that ISO/TC215 approves the WG 2 recommendation for the ISO/TC215 Secretariat to forward to the ISO Central Secretariat ISO/DIS 21090 *"Harmonised data types for information interchange"* for circulation as FDIS ballot. The revised document,

separate revisable figures and a completed table of comments are to arrive at the TC Secretariat no later than 26 May 2009.

18. Resolved that ISO/TC215 approves the WG 2 recommendation to request the Secretariat to forward document ISO/TS 27790 “*Document Registry Framework*” to the ISO Central Secretariat for publication and that the document arrives at the TC Secretariat no later than 15 May 2009.

ISO/TC215 WG3 Semantic Content (Heather Grain)

19. Resolved that ISO/TC215 accepts the report of ISO/TC 215 WG 3.

*Motion to accept ISO/TC 215 WG 3 report by Australia/ Germany passed
Affirmative 15; Abstain 2 (Italy and Spain); Against Nil*

20. Resolved that ISO/TC215 approves the WG 3 recommendation that the ISO/TC 215 Secretariat circulates the NWIP ballot of “*Health informatics – Categorical structures of symptoms, signs and patterns/syndromes in traditional medicine - Part 1*” for approval as a new work item targeting a Technical Specification and that the Form 4 and a document arrives at the TC Secretariat no later than 15 June 2009 to be placed on the ISO/TC 215 balloting portal no later than 30 June 2009.

Comments: Canada – [This standard should be developed as a multi-part document] to incorporate other aboriginal medicines. This was supported by Brazil and Japan.

*Motion to approve the report and resolution 20 by Germany/ Brazil passed:
Affirmative 15; Abstain 2 (Italy and Spain); Against 1 (The Netherlands)*

21. Resolved that ISO/TC215 approves the WG 3 recommendation that the ISO/TC 215 Secretariat circulates the NWIP ballot of “*Health informatics – Guidelines for the principles and desirable features of clinical decision support systems*” for approval as a new work item targeting a Technical Report and that the Form 4 and a document arrives at the TC Secretariat no later than 15 May 2009 to be placed on the ISO/TC 215 balloting portal no later than 30 May 2009, and be it further resolved that all ISO/TC 215 WGs and the JIC be invited to participate and to advise on the appropriate mechanism to pursue the work item.

Comments: UK – question about resolution 21 – the work has merit, but not sure if there is the time to move forward. WG3 asked for advice from WG1/8 to move forward. WG3 happy to move forward.

*Motion to accept resolution 21 by Brazil/ Canada passed:
Affirmative 14; Abstain 3 (Italy, Spain and UK); Against Nil*

22. Resolved that ISO/TC215 approves the WG3 recommendation that the ISO/TC 215 Secretariat circulates the NWIP ballot of “*Health informatics – Categorical structure for human anatomy within healthcare terminological systems*” for approval as a new work item targeting a Technical Report via the Vienna Agreement with ISO lead and that the Form 4 and a document arrives at the TC Secretariat no later than 15 June 2009 to be placed on the ISO/TC 215 balloting portal no later than 30 June 2009.

*Motion to accept resolution 22: by Germany/ UK passed:
Affirmative 15; Abstain 2 (Italy and Spain); Against Nil*

23. Resolved that ISO/TC215 approves the WG 3 recommendation that, following DTR ballot comments, the work item ISO/TR 12309 “*Health informatics – Guidelines for*

international healthcare terminology standardisation” be renamed “Health informatics – Guidelines for terminology development organisations”.

*Motion to accept resolution 23 by Korea/ Germany passed:
Affirmative 15; Against Nil; Abstain 2 (Italy and Spain)*

24. Resolved that ISO/TC215 approves the WG3 recommendation to request the Secretariat to forward document ISO/TR 12309 “*Health informatics – Guidelines for terminology development organisations*” to the ISO Central Secretariat for publication and that the document arrives at the TC Secretariat no later than 1 August 2009.

*Motion to accept resolution 24 by Korea/ Germany passed:
Affirmative 15; Abstain 2 (Italy and Spain); Against Nil*

25. Resolved that ISO/TC215 approves the WG3 recommendation that, following NP ballot comments, the work item ISO/NP 12975 “*Health informatics – Principles and guidelines for the maintenance of terminological systems*” be renamed “*Health informatics – Guidelines for the maintenance of terminological systems*”.

*Motion to accept resolution 25 by Korea/ Canada passed:
Affirmative 14; Abstain 3 (Italy, The Netherlands and Spain); Against Nil*

26. Resolved that ISO/TC 215 provides guidance on the process for liaison with ISO/IEC JTC1/SC6, ITU-T SG17 and ISO/TC 54 regarding the following work items currently out for NP ballot, if the ballots are approved:

- ISO/NP 13581: *Health informatics: Guidance for maintenance of object identifiers*
- ISO/NP 13582: *Health informatics: Communication model and XML interface specification for OID registries*

*Motion to accept resolution 26 by Korea/ Japan passed:
Affirmative 15; Abstain 2 (Italy and Spain); Against Nil*

27. Resolved that ISO/TC215 approves the **CEN/TC251 WGii** recommendation that the work item *Health informatics - Alert information in health records - Concepts, information model and visual presentation* targeting a Technical Specification to be developed jointly with CEN/TC 251 under the Vienna agreement be registered at this stage as a preliminary work item subject to CEN agreement.

Comments: *TC215 Secretariat: the TC 215 plenary voted on this resolution with TC215 members voting who are not part of CEN (includes Australia, Brazil, Canada Japan, Korea and US). CEN requested to check the validity of the vote by non-CEN members.*

*Motion to accept resolution 27 by Finland/ Italy passed:
Affirmative 15; Abstain 1 (Spain); Against Nil*

28. Resolved that ISO/TC 215 creates and approves a Task Force on Traditional Medicine, reporting to WG 3, with China, Japan and Korea prepared to provide secretariat support to the Task Force and that the Task Force be responsible for:

- 1 - Identification of standards requirements for Traditional Medicine
- 2 - Development of work item proposals for Traditional Medicine
- 3 - Review of NWIPs of the TC to identify where the requirements of Traditional Medicine should be incorporated.

- 4 - TC 215 will review the status of the Health Informatics Traditional Medicine Task Force in 2 years.

Comments: ISO/TC 215 WG 3 provided report and suggested that work continue through a TF under the purview of WG3. China requested that a separate WG be formed. WG3 has considered this and thought that the TF would be able to lay the groundwork. Germany: recommended that no new work group should be formed but rather it should function under the current WG structure. Japan: suggested that if a Secretary is required that they are also prepared to support. Recommendation to approve as amended. Korea: also offered to provide a secretary for the taskforce.

*Motion to accept resolution 28 by Brazil/ Australia passed:
Affirmative 13; Abstain 4 (France, Italy, Netherlands and Spain); Against Nil*

CEN/TC251 WGii Terminology and Knowledge Representation (Francois Mennerat for Magnus Fogelburg)

To view the report presentation for WGii, contact CEN/TC 251 secretary Shirin Golyardi (shirin.golyardi@nen.nl).

ISO/TC215 WG4 Security, Safety and Privacy (Ross Fraser)

Notes:

- (1) *The secretary for WG 4 is changing from Alice Rideau (AFNOR) to Delphine Bouis (AFNOR)*
- (2) *Ivan Emlin (Russian Federation) and Masauhoshi Yachida (Japan) will lead the Health Cards Taskforce.*

29. Resolved that ISO/TC215 accepts the report of ISO/TC 215 WG 4.
30. Resolved that ISO/TC215 approves the WG 4 recommendation that the ISO/TC215 Secretariat circulates the revised CD of 27789 *Health informatics – Audit Trails for Electronic Health Records* as a second Committee Draft and a document arrives at the TC Secretariat no later than 19 June 2009 to be placed on the ISO/TC web site no later than 29 June 2009.

*Motion to accept resolutions 29 and 30 by Italy/ Malaysia passed:
Affirmative 15; Abstain Nil; Against Nil.*

31. Resolved that ISO/TC215 approves the WG 4 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of "*Health informatics -- Classification of data purposes for processing of personal health information*" for approval as a new work item targeting a Technical Specification via the Vienna Agreement with ISO lead, and that the Form 4 and a draft document arrives at the TC Secretariat no later than May 4 2009 to be placed on the ISO/TC web site no later than May 18 2009.

Comments: Netherlands: Question about WG4 resolution #31 – request that the standard focuses on integrating work already done through WG8 and on compliance issues. WG4 agreed.

*Motion to accept resolution 31 by Italy/ Malaysia passed:
Affirmative 17; Abstain Nil; Against Nil*

32. Resolved that ISO/TC215 approves the WG 4 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of "*Health informatics -- Security and privacy*

requirements for compliance testing of EHR systems -- Part 1: Foundation" for approval as a new work item targeting a Technical Specification via the Vienna Agreement with ISO lead, and that the Form 4 and a draft document arrives at the TC Secretariat no later than May 11 2009 to be placed on the ISO/TC web site no later than May 25 2009.

*Motion to accept resolution 32 by Germany/ Brazil passed:
Affirmative 17; Abstain Nil; Against Nil*

33. Resolved that ISO/TC215 approves the WG 4 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of "*Health informatics -- Security and privacy requirements for compliance testing of EHR systems -- Part 2: Protection profile for small-scale electronic patient record systems*" for approval as a new work item targeting a Technical Specification via the Vienna Agreement with ISO lead, and that the Form 4 and a draft document arrives at the TC Secretariat no later than May 11 2009 to be placed on the ISO/TC web site no later than May 25 2009.

Comments: *Australia: concerned about WG4 developing a conformance standard. WG4 Convenor: strictly developing standard on testing of conformance.*

*Motion to accept resolution 33 by Brazil/ Germany passed:
Affirmative 17; Abstain Nil; Against Nil*

34. Resolved that ISO/TC215 approves the WG 4 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of "*Health informatics -- Security aspects of EHR record migration*" for approval as a new work item targeting a Technical Report and that the Form 4 and a draft document arrives at the TC Secretariat no later than May 11 2009 to be placed on the ISO/TC web site no later than May 25 2009.

*Vote: Motion to accept resolution #34 by Italy/ Malaysia passed:
Affirmative 17; Abstain Nil; Against Nil*

35. Resolved that ISO/TC 215 approves the DTR Ballot for ISO 11636 "*Health Informatics Dynamic on Demand Virtual Private network for health information infrastructure.*"

Note: *ISO #11636 Documents can be found in Folder 3 on the official TC 215 site with the Edinburgh meeting documents and on the TC 215 Sharepoint site with Edinburgh meeting documents*

Comments: *Given during the Executive council resolution phase of the plenary voting.*

*Motion to accept Ballot resolution 35 by Italy/ Brazil passed:
Affirmative 10; Abstain 6 (Australia, France, Germany, Netherlands, UK and US);
Against 1 (Finland)*

CEN/TC251 WGiii Security-Safety-Quality (Colin Nolder)

To view the report presentation for WGiii, contact CEN/TC 251 secretary Shirin Golyardi shirin.golyardi@nen.nl.

ISO/TC215 WG6 Pharmacy and Medicines Business (Ian Shepherd)

36. Resolved that ISO/TC215 accepts the report of ISO/TC 215 WG 6.

37. Resolved that ISO/TC215 approves the WG 6 recommendation to approve the WG 6 officers as follows:

Mr. Ian Shepherd, Convenor,

Ms. LuAnn Whittenburg, Vice Convenor

*Motion to accept resolutions 36 and 37 by US/ UK passed:
Affirmative 13; Abstain 3 (Italy, Malaysia, Sweden); Against Nil*

38. Resolved that ISO/TC215 approves the WG 6 recommendation that the work item “Health informatics –prEN ISO 11615 Identification of Medicinal Products – Data Elements and Structures for the Exchange of Regulated Product Information for Drug Dictionaries (MPID)” be renamed “Health informatics – Identification of Medicinal Products - data elements and structures to uniquely identify medicinal products (MPIDs) for the exchange of regulated medicinal product information”

39. Resolved that ISO/TC215 approves the WG 6 recommendation that prEN ISO 11615, “Health informatics – Identification of Medicinal Products - data elements and structures to uniquely identify medicinal products (MPIDs) for the exchange of regulated medicinal product information” be withdrawn from the ISO/TC215 program of work.

40. Resolved that ISO/TC215 approves the WG 6 recommendation that the ISO/TC215 Secretariat circulates the NWIP/CD ballot of prEN ISO 11615, “Health informatics – Identification of Medicinal Products - data elements and structures to uniquely identify medicinal products (MPIDs) for the exchange of regulated medicinal product information” for approval as a new work item targeting IS via the Vienna Agreement with ISO lead and the Form 4 and a document arrives at the TC Secretariat no later than 1 May 2009 to be placed on the ISO/TC 215 balloting portal no later than 15 May 2009.

*Motion to accept resolutions 38, 39 and 40 by Spain/ Korea passed:
Affirmative 13; Abstain 2 (Italy, Sweden); Against Nil*

41. Resolved that ISO/TC215 approves the WG 6 recommendation that the work item “Health informatics –prEN ISO 11616 Identification of Medicinal Products – Structures and Controlled Vocabularies for Pharmaceutical Product Identifiers (PhPIDs)” be renamed “Health informatics – Identification of Medicinal Products - Data elements and structures to uniquely identify and exchange pharmaceutical products (PhPIDs)”

42. Resolved that ISO/TC215 approves the WG 6 recommendation that prEN ISO 11616, “Health informatics – Identification of Medicinal Products - Data elements and structures to uniquely identify and exchange pharmaceutical products (PhPIDs)” be withdrawn from the ISO/TC215 program of work.

43. Resolved that ISO/TC215 approves the WG 6 recommendation that the ISO/TC215 Secretariat circulates the NWIP/CD ballot of prEN ISO 11616, “Health informatics – Identification of Medicinal Products - Data elements and structures to uniquely identify and exchange pharmaceutical products (PhPIDs)” for approval as a new work item targeting IS via the Vienna Agreement with ISO lead and the Form 4 and a document arrives at the TC Secretariat no later than 1 May 2009 to be placed on the ISO/TC 215 balloting portal no later than 15 May 2009.

*Motion to accept resolutions 41, 42 and 43 by Germany/ Korea passed:
Affirmative 13; Abstain 2 (Malaysia, Norway); Against 2 (Italy, Sweden)*

44. Resolved that ISO/TC215 approves the WG 6 recommendation that the work item “Health informatics –prEN ISO 11238 Identification of medicinal Products – Structures and Controlled Vocabularies for Ingredients” be renamed “Health Informatics –

Identification of Medicinal Products – Data elements and structures to uniquely identify and describe substances and specified substances”

45. Resolved that ISO/TC215 approves the WG 6 recommendation that prEN ISO 11238, *“Health Informatics – Identification of Medicinal Products – Data elements and structures to uniquely identify and describe substances and specified substances”* be withdrawn from the ISO/TC215 program of work.
46. Resolved that ISO/TC215 approves the WG 6 recommendation that the ISO/TC215 Secretariat circulates the NWIP/CD ballot of prEN ISO 11238, *“Health Informatics – Identification of Medicinal Products – Data elements and structures to uniquely identify and describe substances and specified substances”* for approval as a new work item targeting IS via the Vienna Agreement with ISO lead and the Form 4 and a document arrives at the TC Secretariat no later than 1 May 2009 to be placed on the ISO/TC 215 balloting portal no later than 15 May 2009.

*Motion to accept resolutions 44, 45 and 46 by Korea/ Spain passed:
Affirmative 13; Abstain 2 (Malaysia, Norway); Against 2 (Italy, Sweden)*

47. Resolved that ISO/TC215 approves the WG 6 recommendation that the work item *“Health informatics –prEN ISO 11239 Identification of medicinal Products – Structures and Controlled Vocabularies for Pharmaceutical Dose Forms, Units of Presentation and Routes of Administration”* be renamed *“Health informatics - Identification of medicinal products - Data elements and structures to uniquely identify pharmaceutical dose forms, units of presentation and routes of administration”*
48. Resolved that ISO/TC215 approves the WG 6 recommendation that prEN ISO 11239, *“Health informatics – Identification of medicinal products – Data elements and structures to uniquely identify pharmaceutical dose forms, units of presentation and routes of administration”* be withdrawn from the ISO/TC215 program of work.
49. Resolved that ISO/TC215 approves the WG 6 recommendation that the ISO/TC215 Secretariat circulates the NWIP/CD ballot of prEN ISO 11239, *“Health informatics - Identification of medicinal products - Data elements and structures to uniquely identify pharmaceutical dose forms, units of presentation and routes of administration”* for approval as a new work item targeting IS via the Vienna Agreement with ISO lead and the Form 4 and a document arrives at the TC Secretariat no later than 1 May 2009 to be placed on the ISO/TC 215 balloting portal no later than 15 May 2009.

*Motion to accept resolutions 47, 48 and 49 by Germany/ Korea passed:
Affirmative 12; Abstain 2 (Malaysia, Norway); Against 1 (Italy)*

50. Resolved that ISO/TC215 approves the WG 6 recommendation that the work item *“Health informatics –prEN ISO 11240 Identification of medicinal Products – Structures and Controlled Vocabularies for Units of Measurement”* be renamed *“Health informatics – Identification of medicinal products – Data elements and structures to uniquely identify Units of Measurement”*
51. Resolved that ISO/TC215 approves the WG 6 recommendation that prEN ISO 11240, *“Health informatics – Identification of medicinal products – Data elements and structures to uniquely identify Units of Measurement”* be withdrawn from the ISO/TC215 program of work.
52. Resolved that ISO/TC215 approves the WG 6 recommendation that the ISO/TC215 Secretariat circulates the NWIP/CD ballot of prEN ISO 11240, *“Health informatics – Identification of medicinal products – Data elements and structures to uniquely identify Units of Measurement”* for approval as a new work item targeting IS via the Vienna

Agreement with ISO lead and the Form 4 and a document arrives at the TC Secretariat no later than 1 May 2009 to be placed on the ISO/TC 215 balloting portal no later than 15 May 2009.

Comments: *US commented that the issue of measure permeates many different aspects of many TCs and that it seems that this proposal should be revisited.*

*Motion to accept resolutions 50, 51 and 52 by Germany/ Korea passed:
Affirmative 10; Abstain 4 (Canada, Malaysia, Norway, US); Against 2 (Italy, Sweden)*

53. [as revised following comments]: Resolved that ISO/TC215 approves the WG 6 recommendation that the proposed scope and CD documents of prEN ISO 11595, “Health informatics — Pharmacovigilance – Data elements and structures for the reporting of laboratory results and clinical observations” be circulated to ISO/TC 212 and other relevant stakeholders (LOINC and IHTSDO) for consultation and advice on an appropriate way forward and be it further known that a report will be undertaken to TC 215 at the next meeting in October 2009.

Comments: *US believed the scope of the original draft resolution (which targeted a Technical Report) was too large and therefore did not support the continuation of this item. Canada concurred and added that more work needs to be done with TC212, while respecting the importance of this item but could not support it as written. UK: perhaps the scope of the document can be circulated to TC212 and other relevant stakeholders for information for the appropriate way to move forward.*

*Motion to remove item from the work program by Canada/ Spain passed:
Affirmative 15; Abstain 1 (Italy); Against Nil*

*Motion to accept resolution 53 as revised by US/ UK passed:
Affirmative 13; Abstain 4 (Italy, Korea, Malaysia, Russian Fedn); Against Nil*

54. Resolved that ISO/TC215 approves the WG 6 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot targeting a technical report ISO/DTR “Health informatics – Requirements for the implementation of the standards for the identification of medicinal products for the exchange of regulated medicinal product information for approval as a new work item coordinating with TR 12975 *HI: Principles and guidelines for the maintenance of terminological systems* and TR12309 *HI: Guidelines for international healthcare terminology standardization* and that the Form 4 and a document arrive at the TC Secretariat no later than 1 August 2009 to be placed on the ISO/TC 215 balloting portal no later than 15 August 2009.

Comments: *US: It is premature to develop an NWIP around this topic as information is still being gathered. It was proposed that this resolution be withdrawn. UK: perhaps the scope of the document can be a report.*

*Motion to accept resolution 54 targeting a Technical Report by Germany/ US passed:
Affirmative 14; Abstain 2 (Italy, Malaysia); Against Nil*

CEN/TC251 WGiv Technology for Interoperability (Melvin Reynolds)

Note: *WGiv has gone without a convenor and secretary for about a year. If this continues, CEN/TC251 will be forced to withdraw the WG. If a NMB is interested, contact Ms. Shirin Golyardi and/or Kees Molenaar. No official presentation.*

ISO/TC215 WG7 Devices (Todd Cooper)

55. Resolved that ISO/TC215 accepts the report of ISO/TC 215 WG7.

*Motion to accept resolution 55 by US/ Germany passed:
Affirmative 16; Against 2 (France, Malaysia); Abstain Nil*

56. Resolved that ISO/TC 215 approves the WG 7 recommendation that ISO/TC 215 accepts the following revised scope of this working group:

“Standardization in the application of Information and Communications Technologies (ICT) to health device informatics and device interoperability in support of medicine, health care, and wellness.”

*Motion to accept resolution 56 by Brazil/ Spain passed:
Affirmative 15; Abstain 1 (France); Against Nil*

57. Resolved that ISO/TC215 approves the WG7 recommendation to approve the WG7 Secretary as follows: Patty Krantz (US), Secretary

*Motion to accept resolution 57 by Sweden/ Korea passed:
Affirmative 16; Abstain 1 (France); Against Nil*

58. Resolved that ISO/TC215 approves the WG7 recommendation to present as a preliminary new work item for TR 80001-2, "Application of risk management for IT-networks incorporating medical devices – Guidance for health delivery organizations" targeting a Technical Report, to be jointly developed with IEC SC62A within the ISO TC215 / IEC SC62A JWG7, which is developing IEC IS 80001-1. The joint NWIP shall be balloted in parallel within ISO TC215 and IEC SC62A, and upon approval shall be added to the work programme of JWG7. It is proposed that TC215 take the lead for this work item and that in TC215 it be a joint activity between WG4 and WG7, with WG7 lead.

*Motion to accept resolution 58 by Spain/ Korea passed:
Affirmative 16; Abstain 1 (France); Against Nil*

ISO/TC215 WG8 EHR Business Requirements (Marion Lyver)

59. Resolved that ISO/TC215 accepts the report of ISO/TC 215 WG8

60. Resolved that ISO/TC215 approves the WG8 recommendation for the ISO/TC215 Secretariat to forward the ISO Central Secretariat ISO/HL7 10781.1 "EHR System Functional Model (EHR-S FM)" for circulation as an FDIS ballot. Revised document, separate revisable figure files and a completed table of comments to arrive at the TC Secretariat no later than June 15, 2009

*Motion to accept resolutions 59 and 60 by Brazil/ Australia passed:
Affirmative 16; Abstain Nil; Against Nil*

61. Resolved that ISO/TC 215 accepts the WG 8 recommendation for the ISO/TC215 Secretariat to forward to the ISO Central Secretariat ISO DIS 18308 "Requirements for an electronic health record architecture" as revised based on the DIS comments, and release for a two month DIS re-ballot and that a document arrives at the TC Secretariat no later than July 31, 2009.

*Motion to accept resolution 61 by Brazil/ Australia passed:
Affirmative 16; Abstain Nil; Against Nil*

62. Resolved that ISO/TC215 approves the WG 8 recommendation that the ISO/TC215 Secretariat circulates the NWIP ballot of "*eHealth enterprise architecture for emerging and developing countries*" for approval as a new work item targeting as a joint ISO/WHO Technical Report and that the Form 4 and a document arrives at the TC Secretariat no later than June 30, 2009 to be placed on the ISO/TC 215 balloting portal no later than July 21, 2009.

Comments: Australia considers that the subject matter is more about eHealth functionality for developing countries, rather than a specific architecture – may need to change the name to make more appropriate, however there are reasons for the naming.

Canada thinks that there are notable differences, especially in architecture capability and considers that there will be value in developing this TR.

Germany considers that the issue here is that the approach should allow systems to be scalable and more easily implementable.

The Netherlands agrees with the proposal but notes that this is very sensitive area.

Motion to accept resolution 63 by Italy/ UK passed:

Affirmative 16; Abstain Nil; Against Nil

63. Resolved that the ISO/TC 215 accept the WG8 and WG1 recommendation to urge the members of the Joint Initiative Council (JIC) to address their respective SDOs to ask for full collaboration to make the products of their SDOs available for developing and emerging countries in way that makes widespread dissemination in these countries feasible while developing new markets for SDO products.

Motion to accept resolution 63 by Brazil/ Australia passed:

Affirmative 16; Abstain Nil; Against Nil

64. Resolved that the ISO/TC 215 accepts the WG 8 recommendation that ISO TC 215 members be invited to participate in the drafting of ISO EHR-S FM Release 2 (R2).
65. Resolved that ISO/TC215 approves the WG 8 recommendation to ISO TC215 that the ISO/TC215 Secretariat forward to the JIC a request for EHR-S FM to become a JIC project.
66. Resolved that the ISO/TC 215 accepts the WG 8 recommendation to extend its appreciation to the ISO TC 215 Secretariat for its assistance and representations to ISO/CS in expediting the re-ballot of ISO DIS 18308.
67. Resolved that ISO/TC215 approves the WG 8 recommendation to ISO TC215 to review the *DTR 13054 "Knowledge Management of Health Information Standards"* appropriateness for WG 8 given that this work item is not specific to the business requirements for EHRs and because it has relevance to all WGs and all SDOs.

And be it further resolved that WG 8 recommends ISO/TC 215 investigate the appropriate mechanism to share the potential knowledge resulting from the use of 13504 and clarify the ownership and need for openness of this knowledge.

Motion to accept resolutions 64 to 67 by Brazil/ Australia passed:

Affirmative 16; Abstain Nil; Against Nil

[8] Reports

a. TC 215 Chair's Report (Dr Kwak)

Dr. Kwak thanked Grant Gillis for his service as convenor of work group 1 and wished him success in future endeavors. For the presentation, please see attached presentation.

b. Report from the CEN/TC 251 management Team
– Kees Molenaar/Melvin Reynolds

EU Mandate on e-Health

There is no EU regulation dictating the design of health systems across Europe as this is within the jurisdiction of each Member State. Interoperability of health systems is increasingly becoming an issue once the population becomes mobile. This issue is being addressed by multilateral cooperation at Ministerial level and a number of EC initiatives. The EC thought that the standards developed were not doing the job and, through mandate M/403, requesting CEN to conduct an assessment on standards and their development to support greater interoperability of health systems. Most of the work for the mandate resides in CEN/TC251 - with the other European Standards Organisations - CENELEC and ETSI having lesser roles. Following assessment of current standards, the future may involve development of new standards based on use cases from Member States - but only where needed as a last resort. A presentation is available. Those involved with EU Member States should request stakeholders to participate.

CEN/TC251 Business Plan

CEN/TC251 is reviewing its scope, noting that there is a some overlap with TC215, they are happy to share their thoughts/discussions with TC215. The current structure of TC251 and how to most efficiently conduct its work is also under active review. Prioritization of activities will also be addressed.

c. **Harmonization work JIC/JWG reports Ed Hammond/Don Newsham**

JIC Report

The on-going work of the JIC was reported, which included: further refinement of its processes (including synchronized balloting for the JIC projects); consideration of expanding the JIC to include additional organizations and a discussion on possible new work projects. In addition, there is now a template to bring other groups into the JIC and a template for work to be considered in the JIC. It was also reported that there will be a Leadership change in the JIC – with the term of chair for one year. Differences between the JIC and JWG were also addressed.

JWG Report

The on-going work of the JWG was reported, which included the review of the JWG's work program and a review of proposed work items. It was also decided that the convenors of the JWG will meet to help monitor on-going work as needed and that meetings of the JWG will occur mainly at ISO, CEN, HL7 meetings.

d. **Secretary's Report - Audrey Dickerson**

The Secretary's presentation is available in the meeting documents.

e. Report from JTC1 to TC 215 - Richard Dixon Hughes for Adrian Stokes

Dr Stokes had to leave on an early flight. As JTC1 liaison to TC215, Richard Dixon Hughes gave Dr Stokes' presentation, which discussed the history and structure of JTC1, liaisons, and issues for JTC. The JTC is also reviewing its business plan, considering streamlining the Directives and will be electing a new chair. The presentation is available in the post-meeting papers for further details.

[It was noted that Colin Nolder would represent TC216 at an upcoming meeting of JTC1/WG6 IT Governance when it meets in London in May 2009. The subject of a formal liaison between the two committees would require consideration of a submission, once JTC1/WG6 is established and operational.]

[9] Date/place of next ISO/TC 215 plenary:

This will take place in Rio de Janeiro, Brazil on 10 to 14 May 2010 (in the week before the May 2010 HL7 meeting). A presentation and video highlighting the meeting venue (Windsor Barra Hotel & Congressos) are available.

[10] Date of next ISO/TC 215 Joint WGM and Global Health IT Summit V

Ed Hammond gave a presentation on the upcoming joint WGM meeting being held from 18-21 October 2009, Durham, North Carolina, USA. The venue is Duke University and the meeting will include the 5th Global Health IT Summit (GHITS V) - focussed on reviewing progress in meeting the needs of national programs (which were addressed at the first GHITS in 2005)

[12] Dates/venues for ISO/TC 215 meetings in 2020/2011:

2010 Plenary	Brazil, 10-14 May 2010
2010 Joint WGM	The Netherlands, combined with CEN/TC251, 10-13 October 2011
2011	Finland and possibly China

[13] Concluding Resolutions [missing from original draft minutes from TC215 secretariat]

68. Resolved that ISO/TC 215 extends condolences to DIN on the passing of Mr. Jurgen Sembritski, former convenor of ISO/TC 215/ WG 5.
69. Resolved that ISO/TC 215 acknowledges the contributions and thanks Grant Gillis, former Convenor of WG 1 Data Structure for his contributions to TC 215 during his years of participation.
70. Resolved that ISO/TC215 thank our host, BSI, Connecting for Health, and the Royal College of Surgeons for their excellent meeting arrangements and social event, as well as their assistance throughout the meeting, which contributed to a successful and productive meeting.
71. Resolved that ISO/TC215 thanks the drafting committee of Sharon Stanford and Patricia Village.
72. Resolved that ISO/TC215 acknowledges and thanks the country Singapore for the contribution of their members to the ISO/TC215 Plenary meeting in Edinburgh Scotland in the UK.

73. Resolved that ISO/TC215 approves that the next ISO/TC215 Joint Working Groups meeting will be held in Durham North Carolina in the United States and be it further resolved that a half day plenary meeting will be held in conjunction with the Joint Working Groups Durham North Carolina 18-21 October 2009.

Attachment 2 - Proposed JWG/JIC Project Template

Project Template Version 2.0 - January 14, 2009

Draft Content

- Project Name
- Project proposed– Proposing organization
- Contact person with contacting information

- Project Intent– Informative – Technical Report
- Informative/normative – Technical Specification/
- <DSTU(Draft Standard for Trial Use)>
- Normative – International Standard

- Project Purpose– Why this project is needed - justification
- Why this project should be JIC
- What is the market need for this standard?

- Project Scope – What will be covered in this project
- What will not be covered in this project

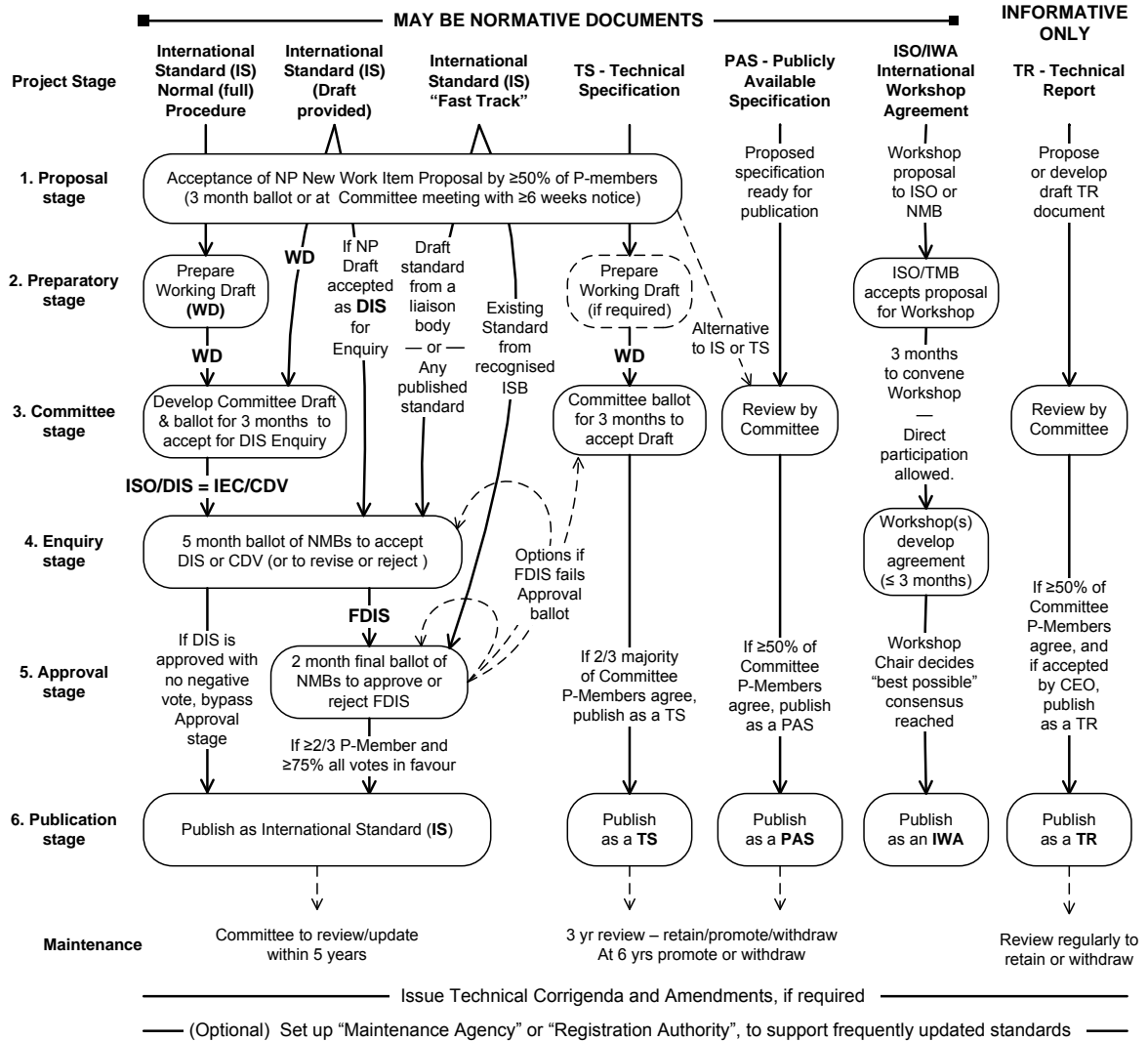
- Participating SDOs: for each SDO (usually more than one)– Name of SDO
- Name and ID of project
- Date project approved for harmonization effort by the sponsoring SDO
- Is the SDO already working on this specific project?
- Lead within each SDO
- Approximate number of persons from SDO working on project

- Host SDO
- Project Objectives and deliverables (commitment levels)– Time line
- Where work will be done (primarily) in HOST SDO or combined SDO WG?

- Project dependencies– Other documents/standards
- Other groups, including liaisons
- Volunteer or funded

- Comments
- Date of JIC approval
- Date of JIC approval

Attachment 3 – Diagram of ISO standards pathways



Acronyms and Abbreviations

ADL	Archetype Definition Language
AHIC	American Health Informatics Community
AHML	Australian Healthcare Messaging Laboratory
ANSI	American National Standards Institute
CCHIT	(US) Certification Commission for Health Information Technology
CDA	Clinical Document Architecture
CDISC	Clinical Data Standards Interchange Consortium
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CMET	Common Message Element Type
CfH	Connecting for Health [within UK NHS]
DAM	Domain Analysis Model (comprehensive model of a domain)
DCM	Detailed Clinical Model
DHHS	US Department of Health & Human Services
DICOM	Digital Imaging and Communications in Medicine
DIS	[ISO] Draft International Standard
DMIM	Domain Message Information Model
DoHA	(Australian Government) Department of Health and Ageing
DMP	Dossier Médical Personnel (Personal Medical Record)
DSTU	Draft Standards for Trial Use
EC	European Commission [the administrative arm of the EU]
ECG	Electrocardiography
EHR	Electronic Health Record
EHR or EHR-S	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
IMHC	InterMountain Health Care, Utah, USA
IS	International Standard
ISO	International Organization for Standardization
IT-014	Standards Australia Committee IT-014 (Health Informatics)
ITS	(HL7) Implementation Technical specification
JI	Joint Initiative [of ISO, CEN and HL7]
JTC 1	ISO/IEC Joint Technical Committee 1 Information Technology
JWG	Joint Working Group [under the JI, unless otherwise specified]
LOINC	Logical Observation Identifiers Names and Codes
NCI	(US) National Cancer Institute

List of Acronyms (continued)

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