HL7 Annual Plenary and Working Group Meeting

Memphis, 7-12 September 2003

Meeting report by Peter Schloeffel

This report is not intended to be a complete record of this six-day meeting but rather, a personal perspective on points of significance for Australia from the sessions I attended. This was my first US HL7 meeting and my main objectives were:

1. To gain an appreciation for the HL7 standards development process, particularly in the context of my experience with Standards Australia, CEN, and ISO which all use a quite different meeting structure and standards development process compared to HL7;

2. To contribute to the EHR related activities of HL7 which take place mainly in the EHR SIG and the Structured Documents and Templates TCs of HL7; and

3. To transfer the insights and experience gained at this meeting to the GPCG, Standards Australia and HL7 Australia to assist in the development and harmonisation of EHR standards for Australia.

There were nearly 500 delegates from 19 countries who attended this meeting and approximately 20% of the delegates were from the international affiliates. Australia was well represented with 12 delegates but it still difficult/impossible with this number to cover all of the 31 Technical Committees and Special Interest Groups plus 17 other meetings during this six day event.

The main points from the sessions I attended are outlined by meeting type (TC, SIG, other) rather than chronologically. The majority of my time was spent in the EHR SIG meetings.

International Affiliates Meeting

- This was a whole day meeting on Sunday. Much of the meeting was concerned with administrative issues in regard to the IA Committee. This was the largest attendance by far at an IA meeting and there was a widespread view that it had become too large and unwieldy for the current meeting structure. Much time was spent discussing possible alternatives for future meetings, such as limiting the active participation to two delegates per country and dividing the meeting into separate technical and administrative components. No final decision on future meeting format was made.

- Harmonisation: Graham Grieve gave a report on the CEN/HL7 data types harmonisation work, which he has been leading. He believes that it is technically possible to have a single HL7/CEN data types standard but there are still some organisational and political issues to be resolved. Woody Beeler expressed his opinion that harmonisation should be secondary to developing implementable standards (ie HL7 V3). Gra-

ham noted that this may be true but harmonisation may in fact be necessary to make standards implementable and he cited examples of UML and XML Schema in regard to the problems of making V3 implementable.

- EHR Functional Specification project: Sam Heard gave an update on the progress of this project (see further detail below) and Peter Schloeffel gave an update on the ISO "EHR Definition, Scope and Context" project which is relevant to the HL7 EHR Functional Spec in regard to the use of ISO EHR definitions. Sam noted that the EHR Functional Spec is currently very US-centric and a way needs to be found to make it more international if it is to become a true international HL7 standard.

  The concept of "realm-specific" versions of the standard was proposed and this met with widespread support from the international delegates. However, it was noted that there is currently no US affiliate so the question of who would participate in the development and balloting of a US-realm specific version of the standard was debated at some length. Woody Beeler stated that the US-realm ballot would need to be restricted to US citizens but several international delegates noted that there may be legitimate interests in the US-realm standard outside of the US and US citizens, particularly since US vendors make much of the health applications software used in many other countries.

Plenary session

- Public health: The half day plenary session had a strong emphasis on public/population health with presentations on health emergency response information exchange (CDC), agro-terrorism (American Veterinary Association), patient safety (AHRQ), and population health data analysis (WHO). James Battle from AHRQ (Agency for Health Research & Quality) noted that healthcare in the US (and it would not be much different in Australia) has the same relative risk of injury as bungy jumping! He announced that the final IOM report in the series on patient safety, called "Patient Safety: A New Standard of Care", will be available in late October.

- HL7 updates: Wes Rishel and Woody Beeler gave updates on the status of V3 and Klaus Veil gave a key issues and messaging standards update. He announced that V2.5 has now been published and will be available by the end of September. He also noted that all of the Australian issues, including those for pharmacy, have been included in V2.5.

- Appointments: Australia is well represented in executive positions within HL7. Klaus Veil was re-elected to the HL7 Board as a general director after having served a maximum two terms as the HL7 International Affiliates representative. Sam Heard continues as a co-Chair of the EHR SIG whilst Grahame Grieve was elected as a co-Chair of the Control/Query TC and Peter MacIsaac was elected as a co-Chair of the Medicines Information SIG (formerly the Pharmacy SIG).

EHR Special Interest Group

This was my main area of activity during the five days of the meeting. Sam Heard, one of three co-Chairs of the EHR SIG (the other two being Linda Fischetti and Gary Dickenson from the US) chaired the majority of the 10 sessions. All of these sessions were devoted

to the EHR Functional Specification project and there were also joint meetings with the Structured Documents and the Templates TCs.

Sam did a superb job in maintaining control and harmony with probably the largest group ever in an HL7 TC or SIG (up to 100 delegates at times), and a very complex and at times contentious work item. Thomas Beale reported that Linda Fischetti described Sam's management and facilitation of the EHR SIG's functional specification process as "masterful and irreplaceable". She also mentioned that she thinks that the archetype/template approach is right for the EHR in the US (this view was also expressed by a number of other US delegates in the Templates and Structured Documents TC meetings).

The main events and issues in regard to the EHR System Functional Specification project were:

- Project history: This project was initiated by the US Veterans Health Administration (VA) and the Centres for Medicare and Medicaid Services (CMS is roughly the equivalent of our HIC) in April 2003. CMS foreshadowed that it intends to use the EHRS Functional Specification as the basis for incentive payments to clinicians who use EHR systems which comply with the Functional Spec. HL7 was given the job of coordinating the development of the spec as an HL7 standard, with input from several other organisations, most notably the IOM (US Institute of Medicine). The timeline given to produce the standard was considered by most people to be unachievable – first ballot in August 2003 and a second ballot in October 2003. The three co-Chairs of the EHR SIG are the joint project leaders of this work.

- Structure of the standard: The first ballot for this DSTU (Draft Standard for Trial Use) contained over 1,500 EHR system functional data points presented in a complex four-level hierarchy. The functions were broadly divided into care-delivery functions and infrastructure functions. The functional model consists of a two-dimensional table with the function points in the table rows and care setting profiles in the columns. Four care profiles were defined for the first ballot: "Hospital Care", "Ambulatory Care", "Nursing Home Care", and "Care in the Community/Personal Healthcare". For each care profile, an entry is made for each function point to indicate if it is essential, desirable, or not applicable. A second column for each profile shows the year by which a function must be implemented (2004-2005, 2006-2007, or 2008-2010).

- The first ballot: Following the release of the first ballot documents in August, a series of six public consultation meetings were held around the US which were attended by over 1,000 people including a large number of clinicians. This was pleasing because it is widely regarded that not enough clinicians participate in HL7 standards development. The ballot closed on 1st September and received 247 responses, by far the largest ballot in HL7 history. Because of the wide publicity, interest and importance of this project beyond HL7, non-HL7 members were allowed to vote in the ballot by payment of a $100 fee. The ballot vote was negative but not disastrously so. This outcome was probably in everyone's best interests since it was indeed impossible to produce a quality useable standard in just four months, despite the huge amount of work put in by the team, including Sam Heard and other Australian and international delegates. One disturbing feature of the ballot was a well-foundered rumour that some organisations who opposed the standard were paying non-HL7 members $100 to vote negative.

- Ballot reconciliation: Hundreds of ballot comments were received from over 60 organisations and individuals – again, without parallel in HL7 history. The task of the EHR SIG set itself during the four days of its meetings was to do a complete ballot reconciliation of the comments. Several sessions were spent addressing the comments in detail, starting with comments submitted by people at the meeting. However, it soon became apparent that this was an impossible task in the time available, particularly given the large number of people participating in the EHR SIG meetings. With more than 200 comments still to be addressed, it was decided to complete the task in small working groups after the Memphis meeting.

- A way forward: It was agreed that the size and complexity of the standard (both the number of function points and the number of categories in the hierarchy) needs to be substantially reduced to ensure acceptability by clinicians and to ensure a quality useable standard. Small volunteer groups were formed to work out of session (i.e. at nights) to initially develop a simplified hierarchy and a simplified process for the necessary work before a second ballot. The results on both counts were very positive. An additional aspect of simplification/consensus building was the adoption of the concept of realm-specific versions of the standard, first suggested at the International Affiliates meeting on day 1.

- The process: A series of 5 working groups will be established to undertake different aspects of the work with significant milestone reviews each month and consolidation of the work at the next HL7 JWG meeting in San Diego in January. The second ballot will then be issued on 15 February 2004.

- The politics: A motion was put and carried on the second day that ensured that the second ballot would not be rushed through before the end of this year. This was moved by the Chair of HL7 UK, David Markwell, who spoke strongly of the need for more time, particularly to enable the UK and other International Affiliates to undertake a thorough review of the EHRS functions. The realm-specificity helps to some extent but this applies only to the care setting profiles and not to the set of EHRS functions which will be the same for all countries.

  The process outlined above was predicated on the outcome of this motion and it appeared that the majority of delegates were happy with this. However, in the second to last session of the EHR SIG meeting on Thursday afternoon, a motion was put and carried to rescind the earlier motion. The rationale for this was to enable the second ballot to be carried out before the end of the year if the work is completed in time. The vote was very close and the result caused major concern to a number of people, particularly the international delegates. I was not present for the final session as I had to fly to Washington for further meetings, but a compromise appears to have been struck in that session, which means that the process outlined above will in fact be adhered to.

Templates – Structured Documents – EHR SIG joint meeting

This was another very large and lively meeting. It was moved to a smaller room than originally scheduled and people were literally overflowing out the doorway and into an adjacent room. The two main issues discussed were:

- Agreement was reached on a harmonised set of structural levels for use in HL7 RIM-based structures, *open*EHR, and CEN. The levels are: EHR / Folder / Composition / Section / Cluster / Element / Data Value. This will require a change to the Level Code in the RIM and this proposal will be submitted to the Modelling & Methodology TC for approval.

- Sam Heard demonstrated his prototype VB Archetype Editor which was very well received. However, Sam generated some controversy when he raised the subject of the relationship of terminology to archetypes. His statement that much can be achieved by archetypes without any connection to an external terminology was widely misinterpreted as saying that terminology was no longer necessary for interoperability. He also stated that it is essential for archetypes to be independent of any external terminology.

  What he was talking about was the use of small coded term-sets within archetypes to label archetype nodes and provide values for variables within the archetype (e.g. "sitting | standing | reclining" for blood pressure measurement position). These internal term sets are bound to particular external terminologies (e.g SNOMED, LOINC) at runtime. This is very similar to the approach being adopted by HL7 in its Clinical Terminology Service project, which already has some 400 "micro vocabularies". Despite this controversy, the archetype approach received strong support from many people at the meeting such as Mark Shafarman (HL7 Chair Elect), Martin Kernberg (UCSF) and Charles Parisot (GE).

Clinical Genomics

I attended a single session of the Clinical Genomics SIG to hear a presentation by Peter Elkin from the Mayo Clinic on the EHR requirements of clinical genomics and proteomics. This was a very interesting if rather technical discussion (from a genomics/proteomics viewpoint) and it appears that so far, a new data type for haplotypes is the only requirement not already satisfied by existing HL7 and CEN/*open*EHR models. Even this may not in fact be necessary as it may be able to be handled by an archetype. However, it is early days in this new discipline and there may well be other unmet requirements for the EHR, which have not yet been identified.

Structured Documents – Medical Records – EHR SIG Joint Meeting

This meeting was a presentation and demonstration by Thomas Beale of ADL (Archetype Definition Language – developed by Tom and Sam Heard) and the prototype "Engineer's Workbench" Tom has built to parse ADL-based archetypes. A number of archetypes were demonstrated being parsed successfully, including an HL7 Lab Observation RMIM. This generated considerable interest and proved that archetypes can be used for HL7 artefacts, potentially replacing the need for RMIMs.

Summary

This was a very interesting and productive introduction to HL7 Joint Working Group meetings. I believe my objectives listed in the introduction were achieved and I look forward to continued participation in HL7 activities. In particular, I believe that the GPCG should develop an realm-specific EHRS care profile for Australian General Practice and I would be keen to participate in this project. The IBM GPCS Functional Specification will be an important resource for this task.

Acknowledgements

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