Standards Insight

An Analysis of Health Information

Standards Development Initiatives

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The EHR System Functional Model and Draft Standard for Trial Use (DSTU) did not pass on its first ballot.

The EHR System Functional Model DSTU ballot closed on September 5th and was reviewed by the Electronic Health Record Special Interest Group (EHR SIG) at the Health Level Seven (HL7) Annual Plenary and Working Group Meeting September 8 through 12 in Memphis. It received a negative ballot.

This result was not unexpected given the nature of consensus building. This was the largest ballot pool in HL7 history reflecting the broad community of interest. There were 223 votes cast: 83 affirmative, 124 negative and 16 abstentions. This represents a 60 percent negative vote. To pass the DSTU required a 67 percent affirmative vote.[1]

It is more informative to look at the breakdown of the vote. Providers and vendors represented about 70 percent of the total vote on this ballot. Presumably these two groups would be the most immediately impacted by the standard and together they voted two-thirds against. Consultants and general interest parties, including the US.

[1] To become a full ANSI standard there must be a 90 percent affirmative vote.

government, voted two-thirds in favor. If one construed more than three individuals from a single entity casting essentially the same ballot as an organizational vote, then there were nine organizations that accounted for 43 percent of the total affirmative and negative votes cast. Affirmative organizational voting accounted for 37 percent of the total affirmative vote. Negative organizational voting accounted for 48 percent of the total negative vote.

Reasons behind the negative vote

Certainly the ballot document reflected a rush to deliver the DSTU against a very aggressive schedule that was greatly complicated by the agreement to accept the input of the Institute of Medicine (IOM).[2] That the latter was also rushed and only available for six days prior to the publication of the DSTU added to the lack of clarity and coherence. This message came through loud and clear in both the report from the EHR Collaborative[3] and in the ballot results.

There were many reasons for the negative vote.

- The lack of clarity in defining functions and the meaning of “essential” and “desirable” caused confusion and misunderstanding or provided insufficient information to generate support.

- There are deep concerns within the provider community over the potential use of the standard by the Centers for Medicare and Medicaid Services (CMS) in “pay for performance” demonstration projects. The objections were manifest in substantive disagreement with the appropriateness of functions deemed essential and concern that the DSTU would go from a draft standard in a demonstration project to become a broad regulatory mandate.

- There was great concern that the timeline was too short and aggressive and did not allow proper consideration and consensus building.

- Several international affiliates were concerned that the standard was directed at U.S. needs without consideration of other national EHR initiatives.

Some key decisions were made during the HL7 working group meeting this week in Memphis.

The EHR SIG was unable to address all negative votes and concerns within the three days. The meetings were at times contentious but much progress was made.

The DSTU was greatly simplified. The list of Care Delivery Functions was also simplified and reorganized into a more coherent outline. Functionality Assumptions were eliminated. Infrastructure Functions were cut to six key functions that were then added to the consolidated outline. The EHR SIG also recast the characteristics of a function in a care setting from “essential” or “desirable” to “essential immediate,”, “essential future,”, “optional,” and “not applicable.”

[2] Committee on Data Standards for Patient Safety, Institute of Medicine “Key Capabilities of an Electronic Health Record System” Letter Report. July 31, 2003. http://books.nap.edu/html/ehr/NI000427.pdf
[3] www.ehrcollaborative.org

Realm Specific Care Setting Profiles

The most important decision, however, was to split the standard into two parts: 1) the model, outline and functional definitions and 2) realm specific care setting profiles. The model, if you recall, sets up lists of functions on one axis and care setting profiles on the other. The intersection of a function and a care setting profile was characterized as to its importance and was to be a part of the formal standard.

The second part of the standard is to be realm specific and would in fact produce the care setting profiles for that realm. In HL7 terminology a realm has equated to an international affiliate. To date there are 24 countries that have become affiliates. The missing nation in the list has been the United States, which simply participated in HL7 in general. The breakthrough within the EHR SIG was the recognition that different affiliates have different EHR use cases, existing initiatives and political interests, and that defining common care settings, let alone agreeing on single care setting profiles, would be a daunting and divisive task. Thus the recommendation by the SIG, not yet approved by the HL7 board, was to move the care setting profiles to each affiliate and to create a U.S. affiliate to handle care setting profiles here. While this approach will create new dynamics within HL7, it essentially frees up the various national affiliates to shape the standard to their national needs and priorities. The HL7 Board plans to address this issue later this month.

HIMSS voted for the standard with considerable suggestions for improvement.

HIMSS, one of the sponsors of the EHR System Functional Model initiative, voted affirmatively on the DSTU ballot but with an extensive list of suggestions and comments for improvement in the next ballot. We believe that most of the issues we raised were addressed or will be considered in the next ballot cycle. We believe the scope was adequately narrowed although it has not yet been fully defined. We continue to think that there remain administrative and financial functions, while necessary for healthcare operations, which are inappropriate for inclusion in an Electronic Health Record System (EHR-S). Steps to clarify and simplify the model, functions and care setting profiles were taken where we had expressed concerns. We remain concerned that some essential functions that improve care delivery processes, such as medication administration and clinical workflow, do not have the proper emphasis. We are optimistic however, that this open, consensus based method will result in an effective and useful standard.

Next steps

The EHR SIG agreed to pursue a new ballot on as fast a track as possible, targeting February 2004 for publication. There was agreement that the ballot comments and feedback from the broader community should be incorporated into the next version prior to the formal ballot. Thus the new ballot document will be essentially ready for review by December 1 and circulated to the sponsors and the community for feedback. Comments and revisions would be made at the HL7 January Working Group meeting. With this plan in place, along with the simplifying decisions outlined above and the general commitment of the EHR SIG members to push forward, we are optimistic that a successful DSTU can be produced in this next ballot cycle.

Bottom line

HIMSS continues to support this standard development process. We believe it is the best opportunity to advance the adoption and use of an EHR-S with its promise of improving effectiveness of care, patient safety, chronic disease management, efficiency of care and personal health care. We share many of the anxieties and concerns about how the standard might be used by CMS. But that is a separate issue and we fundamentally believe it is our industry's obligation to produce the best standard possible. Your continued input and recommendations to HIMSS regarding this effort are valued. Details on participation in the HL7 EHR SIG are available at www.hl7.org/ehr.

Please direct any questions, suggestions or comments regarding *Standards Insight* to Joyce Sensmeier (jsensmeier@himss.org) or its author, Ed Larsen (erlarsen@erlinc.com).