



Standards Insight

An Analysis of Health Information

Standards Development Initiatives

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Report on the EHR System Functional Model and Standard

Background

The Health Level Seven (HL7) Electronic Health Record Special Interest Group (EHR SIG) has been modifying the Electronic Health Record System (EHR-S) Functional Model¹ and Draft Standard for Trial Use (DSTU) since its September 2003 meeting. At that meeting the EHR SIG determined that it must simplify and clarify the DSTU in order to achieve a successful second ballot. (See the July and September issues of *Standards Insight*, available on the HIMSS web site at https://www.himss.org/asp/standards_insight.asp for further background and history).

¹ In its most basic form, the EHR-S Functional Model includes a list of EHR System functions and a framework and method for creating profiles that map functions from the outline to priorities specific to the profile setting or use case. The functional outline will include descriptions, rationales and, in later versions, conformance statements.

The functional outline, which is central to the model, was divided into three sections: direct care, supportive and infrastructure. A working group was assigned to each. During twice-weekly teleconferences in late December, these working groups edited their sections and produced a new functional outline. This outline reduced the number of functions to just over 200. Concurrently, different working groups began addressing other components of the model: the care setting profiles and prioritization within those profiles.

HL7 and the EHR SIG also determined at the September meeting that the care setting profiles would be realm (or country) specific. The “U.S. realm” working groups began with a list provided by the Institute of Medicine (i.e., inpatient, ambulatory, nursing home and community based care) and set out to better define each care setting. Scenarios were built to support the mapping of functions from the outline to the profile and their prioritization (i.e., essential now, essential future, optional or not applicable). The EHR Collaborative² presented the model and revised functional outline to various stakeholders in late November to elicit feedback. All of these work products were to be reviewed by the full EHR SIG at the January Working Group meeting in preparation for a new ballot in March.

During the December-January timeframe, concerns were raised that the March ballot would again be too complex and rushed, particularly given the compressed time available for preparing the care setting work products. The Department of Health and Human Services (HHS), a prime sponsor of the initiative, expressed these concerns in a January letter to the EHR SIG³. To assure a successful ballot outcome, HHS recommended that the March ballot include only the functional outline, which would be balloted as an “international” HL7 standard. Given the dynamic nature of care settings and concerns about how HHS might use the functional EHR-S DSTU, HHS recommended deferring inclusion of care setting profiles for the U.S. Obviously this was an important redirection.

January EHR SIG Meeting Outcome

Once again, the EHR SIG meetings drew a large number of attendees, averaging over 50 per session. A group of this size with many diverse views is a challenge to HL7’s culture and experience, which typically includes smaller, technically focused and more cohesive work groups. Nonetheless, after some debate, the agenda and objectives were established, and the sessions proceeded to the business of reviewing the functional outline and the other work products.

It was apparent that a series of strategic issues needed resolution in order to gain EHR SIG consensus on the functional outline and ballot content. These included the concern that the outline remained too detailed, particularly in the infrastructure section, and that the care settings profiles should not be part of the ballot. It should be noted that the EHR

² The EHR Collaborative is made up of the following organizations: American Health Information Management Association (AHIMA), American Medical Association (AMA), American Medical Informatics Association (AMIA), College of Healthcare Information Management Executives (CHIME), eHealth Initiative (eHI), Healthcare Information and Management Systems Society (HIMSS) and National Alliance for Health Information Technology (NAHIT).
www.ehrcollaborative.org

³ Available on the EHR SIG list server in e-mail from Gary Dickinson dated January 6, 2004.

SIG never fully defined an EHR system. The SIG clearly accepted the notion that EHR-S functions were more than automating the paper medical record. The EHR-S DSTU includes automating clinical documentation as part of direct care functions but it also includes clinical workflow, such as ordering and decision support functions. In addition, the EHR-S “supported” other administrative, financial and research functions (within or without the EHR-S itself).

However, it was only the infrastructure functions that explicitly viewed the EHR-S as a system of “enterprise” systems. The infrastructure component of the EHR-S defined functions such as security and interoperability both in terms of intra-enterprise and cross-enterprise functions. This resulted in the number of infrastructure functions outnumbering the direct care functions by two to one. To some this suggested an imbalance of focus and became a source of controversy. Parenthetically, we note that the outreach responses to the functional outline and model were generally positive and did not question the overall balance. However, achieving that consensus required much explanation by the presenters, something that is not possible in written documents.

After hearing criticisms and recommendations, the SIG divided into three groups, each representing one of the three sections to edit and, potentially, consolidate functions. Although inclusion criteria options were adopted, there was still room for dispute as to whether a minimalist or comprehensive approach was needed. The outcome of these edits is not yet known, and the revised functional outline will be published by early February. The functional outline is intended, upon final ballot, to be a required part of the standard, or in standards development terms "normative". All other ballot items will be informative, including the functional model and the methods for creating profiles. For the purpose of the balloted standard, care setting profiles would be one of many possible functional profiles that could be published in the various HL7 realms by any interested stakeholder. In other words, instances of functional profiles including priorities would not be part of the ballot but would instead be left to realms and their stakeholders to determine their use.

In regards to the U.S. care settings and profiles, the SIG decided to publish a separate reference document of their definitions, scenarios, profiles and priorities, subject to the condition that the information is available and approved by the time the ballot is ready. Functional profiles from any other realm would also be included in this reference document if available. If the profiles were not available in a timely fashion, they would be published at a later time. Any future decision about realm-based balloting of this reference material was deferred.

Next Steps for the EHR–S Functional Model and DSTU

The functional outline and ballot narrative are to be available in early February for review and outreach activities. These materials will be presented to key stakeholders at general public sessions during 2004 Annual HIMSS Conference and Exhibition. Presuming no significant negative feedback is received from outreach activities, final edits will be made for a go-no-go decision on March 10 as to whether to publish the final ballot. That puts the EHR-S Functional Model and DSTU ballot on a track to be reconciled at the May HL7 Working Group meeting.

Representatives of HHS reiterated their interest towards ensuring a successful second ballot, in this case, even at the expense of missing the March date. More information should be available at the HIMSS conference in the HL7 booth and at the outreach meetings. In the meantime, interested parties should access the HL7 EHR web site and list server.⁴

A Larger Perspective on EHR Interoperability in the United States

It should be clearly understood that the EHR-S functional DSTU, while including a requirement for interoperability, in and of itself does not define EHR content, structure or methods for interoperability. Thus there are many other technical standards initiatives, both within and without HL7, that are needed to enable an interoperable EHR system or system of systems. We will examine, in other venues, the role of HL7 in these areas. However, the EHR SIG took time during its meeting to hear two new approaches to EHR interoperability, potentially within the context of the National Health Information Infrastructure (NHII). One was from HL7 and the other from representatives of the Integrating the Healthcare Enterprise (IHE) initiative.

The HL7 presentation was a brief overview of an early proposal to enable transferring entire EHRs (this is the record not the system) from one provider to another, analogous to the GP2GP model in the United Kingdom. Undoubtedly the proposal will expand to include the concept of partial or abstracted records, such as the ASTM Continuity of Care Record.⁵ The proposal would use existing and evolving standards, most notably HL7 Version 3 messages and documents, including the new HL7 CDA based medical record standard. Although some sort of intermediate translator or mapping service will be needed, the proposal appears to be based on a common information model, i.e., the HL7 RIM and common interoperability standards usage *within* the various EHR systems. Thus it is a top-down strategy that expects some level of homogeneity among all providers' systems.

In contrast, the IHE proposal separates the EHR into two concepts, an inter-enterprise long-term electronic health record (LR) and the existing and evolving EHRs (care records) in various provider enterprises (the CR). The IHE starts from what exists today and moves, bottom-up, by implementing existing standards in increments towards a target EHR framework. Importantly by clearly uncoupling the CR system from a longitudinal LR system, it does not interfere with current or planned enterprise EHR system investments. The IHE framework would require that CR systems publish and interact with the "LR system" according to existing or new standards. By implementing existing standards, the IHE methodology identifies gaps and then goes to the responsible SDO to ask for a new or revised standard. Such early implementations will also begin to define the role and need for infrastructure, such as directories and repositories. An example of the power of early implementations is illustrated by lessons being learned in the HL7-IHE Joint Demonstration at the 2004 Annual HIMSS Conference and Exhibition.

⁴ Go to www.hl7.org to sign up for list serves and www.hl7.org/ehr for information on the EHR-S model.

⁵ See the *Standards Insight* for December 2003 for more CCR information.

Both approaches are technical and neither begins with defining the business requirements, i.e., providing effective and efficient quality healthcare. Without addressing and resolving policy, economic and stakeholder requirements, neither technical approach to inter-enterprise or the NHII is likely to produce successful implementations. Without the business requirements and executive leadership, both approaches lack the direction and accountability to move from studies, reports and demonstrations to successfully implemented systems. The top down HL7-centric approach, particularly if led from within, is likely to take longer if it fully depends on the successful maturation and rollout of HL7 Version 3. The bottoms-up approach could potentially yield incremental results and more quickly identify problems without disrupting current EHR system implementations, if it clarifies its internal business direction. Both approaches will converge on the same technical integration in the distant future. The question is which will yield a successful system of interoperable EHR systems.

The tipping point between the two approaches is the e-prescribing initiative resulting from the new Medicare Prescription Drug law. It will drive a pragmatic approach to the NHII because with or without a roadmap or framework, physicians, pharmacies and prescription drug plans will be implementing mini-EHRs in the next few years. This argues for a flexible, bottoms-up approach that is able to subsume e-prescribing while enfolding its decision support functions into a larger EHR system framework.

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