Using HL7 Standards to Evaluate an EHR

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The Health Level Seven (HL7) electronic health record (EHR) system functional model can prove very useful to organizations as they migrate to EHRs. This article reviews HL7's functional model and offers suggestions on how it can be used to prepare requests for information or proposals for information systems. It may also assist organizations in determining the policies and procedures necessary to comply with the standard after it becomes official later this year. Additionally, it provides guidance when requesting changes or enhancements to an existing EHR.

The EHR-S DSTU

Traditionally, HL7 develops standards around messaging and interoperability; however, it collaborated with public and private healthcare leaders to develop the EHR functional standard in July 2003. (AHIMA was an early supporter and contributor to the HL7 EHR standard and continues to participate fully in the standards development process.)

The electronic health record system draft standard for trial use (EHR-S DSTU) was passed in May 2004. The draft standard summarizes possible EHR system functions and provides a common language for communicating its behaviors and capabilities. Its scope is limited to functionality. It does not address data content for the EHR, nor does it endorse the use of specific technology.[1] (The complete HL7 standard is available online at www.hl7.org/ehr/documents/Documents.asp.)

In January 2006 HL7 took the next steps in moving the EHR-S DSTU to an American National Standards Institute (ANSI) standard. Interested parties will participate in the HL7 balloting and reconciliation process during the second quarter of 2006. If that process is successful, it is anticipated that the HL7 EHR-S DSTU will become a fully approved ANSI standard in the summer of 2006.

Conformance Criteria

The functional model has been described as a "super set" of functions that are needed across all care settings to document the delivery of healthcare. No single setting is likely to need all of the functions. However, the complete set provides a starting point from which individual care settings can select the functions that are relevant to them. They then can tailor the requirements for their settings by drilling down to the appropriate level of system behaviors required to produce needed outcomes and documenting the selected functions in a profile specific to that care setting.

Since May 2004 HL7's EHR Technical Committee has worked on numerous projects to move the EHR functional standard from a draft to a full-fledged ANSI standard. One of the committee's projects was writing conformance criteria for each of the EHR-S DSTU functions. Conformance criteria explain how systems must behave in order to carry out specific functions in the model. As such, conformance criteria provide an excellent basis for determining necessary requirements for an organization contemplating an EHR to replace paper-based records.

As defined by the National Institute of Standards and Technology, conformance is the fulfillment of a product, process, or service of the specified requirements. A conformance clause is that section of a specification that defines at a high level the requirements, criteria, or conditions to be satisfied in order to claim conformance with a standard. Conformance criteria are the requirements for how the system must behave or act in order to implement the function.[2]

Conformance criteria will also be used to develop test software and tools used to determine whether or not software meets the functional standards.

Practical Suggestions for Using the Criteria

Healthcare organizations can use HL7 criteria and conformance criteria to help generate their EHR requirements. The following steps provide a good start in taking advantage of the functional model and conformance criteria tools.

Learn the lingo of conformance criteria. There are key words used in developing conformance criteria. Of special significance are:

- *Shall*--used to indicate a mandatory requirement for an EHR system to achieve conformance with the standard
- *Should*--indicating an optional recommended action for an EHR system
- *May*--indicating an optional or permissible action for an EHR system

Learn to read the functional model. The model is presented as a hierarchical list of functions, consisting of headers and functions. There are more than 125 functions in the EHR-S DSTU, broken into three sections: direct care, supportive, and information infrastructure. The February 2005 practice brief "Understanding the EHR System Functional Model Standard" is an excellent primer on reading the EHR-S DSTU standards and is available online in the FORE Library: HIM Body of Knowledge at www.ahima.org.

Obtain a copy of the HL7 EHR System Functional Model. HL7's functional model is available online, free of charge, at www.hl7.org/ehr/documents/Documents.asp.

Review the HL7 EHR System Functional Model and select the relevant sections that apply to a specific healthcare setting. The three functions in the table on the following page provide a look at the functional model with the conformance criteria. Not everything is included here, but the skeleton of the model is presented.

S.1 Clinical Support Function			
ID	**Name**	**Statement**	**Conformance Criteria**
S.1.1	Registry notification	Enable the automated transfer of formatted demographic and clinical information to and from local disease specific registries (and other notifiable registries) for patient monitoring and subsequent epidemiological analysis	1. The system should enable the automated transfer of formatted demographic and clinical information to local disease specific registries (and other notifiable registries). 2. The system may enable the automated retrieval of formatted demographic and clinical information from local disease specific registries (and other notifiable registries).
S.1.5	Deidentified data request management	Provide patient data in a manner that meets local requirements for deidentification	1. The system shall provide deidentified data according to realm-specific law or custom when requested by an authorized internal or external party. 2. The system should comply with I.2.4, Extraction of health record information (conformance criteria 2). (The system should provide deidentification functionality for extracted information.) 3. The system may provide the ability to export deidentified data to authorized recipients. 4. The system may provide a key with deidentified data to enable re-identification of the data or the contact of primary care provider.
S.2.2.1	Health record output	Support the definition of the formal health record, a partial record for referral purposes, or sets of records for other necessary disclosure purposes	1. The system shall be capable of generating reports consisting of all or part of an individual patient's record (e.g., patient summary). 2. The system should allow authorized users to define the records or reports that are considered the formal health record for disclosure purposes. 3. The system should generate reports in both chronological and specified record elements order.

			4. The system may allow the specification of defined reporting groups (i.e., print sets) for specific types of disclosure or information sharing. 5. Reports generated should be capable of including patient identifying information on each page. 6. The system should have the ability to customize reports to match mandated formats.

Practice using the functional model to create organizational requirements. Evaluate each of these functions and conformance criteria for whether they are appropriate for the organization. Create a list of the selected functions. Organizations must then determine how they want the EHR system to behave to carry out each function. These statements become requirements to be included in a request for information or proposal or requests for system fixes or enhancements.

Requirements for an EHR system should reflect an organization's mission, vision, and strategic plan. Goals might include supporting workflow for clinicians and business processes, providing improved availability of data, or streamlining the billing process. Taking the time to evaluate the goals of the organization in light of the opportunity available in an EHR system should make for the best possible investment of money for the company.[3]

It is imperative that the required system behaviors reflect the organization's needs. For example, an organization may not expect its EHR system to carry out specific functions. There may be existing systems that fill these needs, such as updating patient demographics, or there may be dedicated software used to perform required notification to local disease or birth registries. It is also possible that HL7 conformance criteria labeled as "should" or "may" in the functional model only translates to a "shall" behavior in the organization. Keep in mind that HL7 EHR-S conformance criteria are the lowest level conformance that an EHR system should attain, not the highest level for conformance.

For example, functionality S.2.2.1, health record output (shown above), is used as the basis for generating organizational requirements for an EHR system. It involves analyzing the workflow and day-to-day needs for producing copies or information from a patient's record. Based on the organization's needs, requirements could be:

2.2.1.1—The system shall be capable of generating reports consisting of all or part of an individual patient's record.

> 2.2.1.1.1—The system shall be capable of generating a transfer summary consisting of defined portions of an individual patient's record on demand.
> 2.2.1.1.2—The system shall be capable of generating a complete copy of an individual patient's record on demand.
> 2.2.1.1.3—The system shall allow reports to be generated in either a predefined or ad hoc order.
> 2.2.1.1.4—The system shall allow specification of predefined sets of reports to meet business needs of the organization.
> 2.2.1.1.5—Reports shall be capable of including patient identifying data on each page. 2.2.1.1.6—The system shall allow customization of reports to respond to mandated formats.

In the example above, the health record output is described as the organization wants it to function. If a vendor answers these specific requirements as part of its proposal, the organization is able to evaluate the product for how closely it matches its requirements. Compromises may be made, but an organization should start evaluating systems from a position of stating what it wants from the EHR system.

Notes

1. Dougherty, Michelle. "Understanding the EHR System Functional Model Standard." *Journal of AHIMA* 76, no. 2 (2005): 64A-D.
2. Rosenthal, Lynne. "Everything You Need to Know to Build EHR-S Conformance Criteria." PowerPoint presentation, April 2005. Available online at http://lists.hl7.org/read/attach ment/62799/1/ConformanceCriteria-chicago.ppt#334, 15, Principles when creating criteria.
3. Amatayakul, Margret, and Steven Lazarus. *Electronic Health Records: Transforming your Medical Practice*. Englewood, CO: MGMA, 2005.

Reference

HL7. "EHR System Functional Model Draft Standard for Trial Use - Supportive Functions." January 2006. Available online at www.hl7.org/ctl.cfm?action=ballots.home.

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Article citation:
Quinsey, Carol Ann. "Using HL7 Standards to Evaluate an EHR" *Journal of AHIMA* 77, no.4A (April 2006): C-.