Next Steps for the EHR Draft Standard: Core Functionality and Conformance Critera Key for Accreditation

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The Health Level 7 electronic health record draft standard for trial use (HL7 EHR DSTU) passed convincingly in July 2004. As per the requirements of a draft standard, HL7 now has two years to refine it into a fully accredited standard. What are the next steps that will move the EHR closer to a full standard? More importantly, what are the implications of those next steps for the industry, EHR products and services, and our jobs?

Critical Next Steps: Core Functionality and Conformance Criteria

To get the EHR from a draft to a fully accredited standard the HL7 EHR technical committee is working on a number of incremental steps. Defining core functionality and developing conformance criteria for each function by care setting are two key steps in the accreditation process.

The EHR draft standard currently contains approximately 130 functions. To define core functionality, one of four values—essential, essential future, optional, or not applicable—is assigned to each function for each of the four care settings, forming a matrix. Each function must be assigned a value by care setting because functions vary from setting to setting. For example, admitting a patient may be essential for the inpatient acute care setting but not applicable for the home healthcare setting.

The functions that are deemed essential for an individual care setting forms the core functionality for that setting. Further, since the values for a function may change by care setting, each setting will undoubtedly have a different number of core functions in its set.

Each function must also have one or more statements describing how an EHR system conforms to such criteria. For example, the data retention, availability, and destruction function may have the following conformance criteria:

- The system shall provide for the storage and retrieval of health record data and clinical documents for legally proscribed time.
- The system shall retain source documents (to health records) as originally received (unaltered) for legally proscribed time.
- The system shall provide the ability to identify specific EHR data and records for destruction and review and confirm destruction before it occurs.
- The system shall be capable of destroying EHR data and records so that all traces are removed and unrecoverable according to policy and legal retention periods.

Note that as with the values for the core functions, conformance criteria may differ by care setting.

Why Are Core Functionality and Conformance Criteria Important?

Aside from refining the draft to a fully accredited standard, what are the implications of core functions and conformance criteria for the industry, EHR products and services, and our jobs?

At the healthcare policy level, this part of the EHR standard could serve as one of the underpinnings for EHR product certification. How? The report "The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care: Framework for Strategic Action," released by David Brailer, national coordinator for health information technology, underscored the role of HIT—and specifically, EHR systems—in improving quality, increasing patient safety and

operational efficiency, and reducing costs. With much of healthcare being delivered in physician offices, the report stated that now is the time to get EHR systems into physician offices so that patients and physicians can reap such benefits.

But there have always been major barriers preventing the widespread adoption of such systems in ambulatory settings, including cost and maintainenance. To break down those barriers, the report described two strategies to accelerate the adoption of EHR systems in physician offices: reimbursing physicians for using them and reducing their risk of investing in them.

However, such strategies are not without their concerns. To reimburse physicians for using EHR systems, the Department of Health and Human Services (HHS) must have assurances that the system adopted by a physician qualifies. As HHS has often stated, they're not going to reimburse clinicians who "use a spreadsheet and call it an EHR." As for clinicians, since an EHR system may likely cost them thousands of dollars per physician in the office, many clinicians want similar assurances that the system they purchase will have the functionality to help them achieve their quality outcomes and get paid by the federal government for the use of them.

The key here is product certification. Through certification, a product will contain the necessary functionality. This is where core functionality and conformance criteria come into play. For a product-certifying organization, such as the newly formed Certifying Commission for Healthcare Information Technology, core functionality can help identify the minimum set of certified functions within a care setting. Similarly, a product-certifying organization can use the conformance criteria as a way of describing how the function must conform in order to be certified.

It is important to note that a product-certifying organization can be flexible in how it uses core functionality and conformance criteria. For example, if 15 of the 130 EHR functions are deemed essential by HL7, the product-certifying organization may decide that only seven of those 15 functions will be considered for certification in the first year. Each year thereafter additional functions can be added, making product certification discriminating enough to separate a spreadsheet from an EHR system, yet achievable for many products on the market.

Core functionality and conformance criteria can also play a role in our jobs. For example, when requests for proposals (RFPs) are developed for selecting an EHR system, both core functionality and conformance criteria can guide how RFP questions are written. Here, conformance criteria play an especially important role. In many EHR systems, RFPs, descriptions for clinical, administrative, and financial functionality are often requested, as well they should be. Many times, however, descriptions for electronic records management are given less attention.

Yet consider the conformance criteria for the data retention, availability, and destruction function above. If those kinds of conformance statements are not considered during the system selection process, then there may be no assurance that the EHR system under consideration will satisfy, in this example, the legal aspects of data retention, availability, and destruction. To the extent that the EHR system cannot satisfy all the legal aspects of a health record, the paper record may be the default legal record, defeating the purpose of an EHR. Thus, it is extremely important to include the electronic records management and the legal aspects of the record conformance criteria—along with that for the clinical, administrative, and financial functions—in order for the EHR system to effectively replace the paper record.

Core functionality and conformance criteria are more than just the incremental steps to move the HL7 EHR from a draft to a fully accredited standard. They have practical implications for products and services, as well as for our professional roles.

Reference

Brailer, David, and Tommy Thompson. "The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care: Framework for Strategic Action." 2004. Available online at www.hsrnet.net/nhii/materials/strategic_framework.pdf.

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Article citation:
Mon, Donald T. "Next Steps for the EHR Draft Standard: Core Functionality and

Conformance Criteria Key for Accreditation." *Journal of AHIMA* 75, no.10 (Nov-Dec 2004): 50-51.