Model EHR: Status and Next Steps for an International Standard on EHR System Requirements

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By Donald T. Mon, PhD

Six years in the making, the HL7 EHR System Functional Model is now a worldwide standard.
Work on the next version's wish list is already under way.

In November 2009 the International Organization for Standardization and Health Level Seven International (HL7) published the jointly approved HL7 Electronic Health Record-System Functional Model, Release 1.1. The EHR-S FM became the first international standard to specify functional requirements for an EHR system.

The publication of Release 1.1 marked a six-year journey from the model's start in the HL7 EHR Work Group in 2003. The model had been approved as a Draft Standard for Trial Use in July 2004 and then as Release 1.0, a fully ANSI-accredited standard, in February 2007.1,2

From draft to a fully accredited standard, the functional model has received wide acceptance. Countries and organizations have employed the standard to establish system requirements, certification criteria, and even a national EHR system framework. Individual stakeholder groups have derived requirements from the standard to apply to their care settings and specific purposes.

Work on future releases has already begun, prompted in part by requests from users. Further enhancements under consideration include incorporating records management and evidentiary support criteria as well as international privacy standards.

Components of the Model

The EHR-S FM is comprised of approximately 160 functions and 1,000 conformance criteria across three sections-direct care, supportive, and information infrastructure (see "Three Sections of the EHR-S FM"). The direct care section describes the functions used by clinicians during the hands-on delivery of care, including the problem list, order management and results, medication management, clinical decision support, and communications with the care team.

The supportive section describes functions that offer further clinical support through the EHR system's interaction with registries and reporting of quality measures and indicators, as well as public health and population health measures. It also provides the functionality whereby EHR systems interact with practice management and financial systems.

The information infrastructure section provides the technical requirements that enable the direct care and supportive functions. For example, when a clinician amends health information through a direct care function, the authentication and audit traceability requirements to document that action are enabled by information infrastructure functions.

The modularity of the information infrastructure section enables the functional model to be parsimonious, in that all such requirements can be found in one place and, similar to a loop in a computer program, can be consistently executed by direct care and supportive functions.

Three Sections of the EHR-S FM

The functional model contains approximately 160 functions and 1,000 conformance criteria in three sections: direct care, supportive, and information infrastructure.
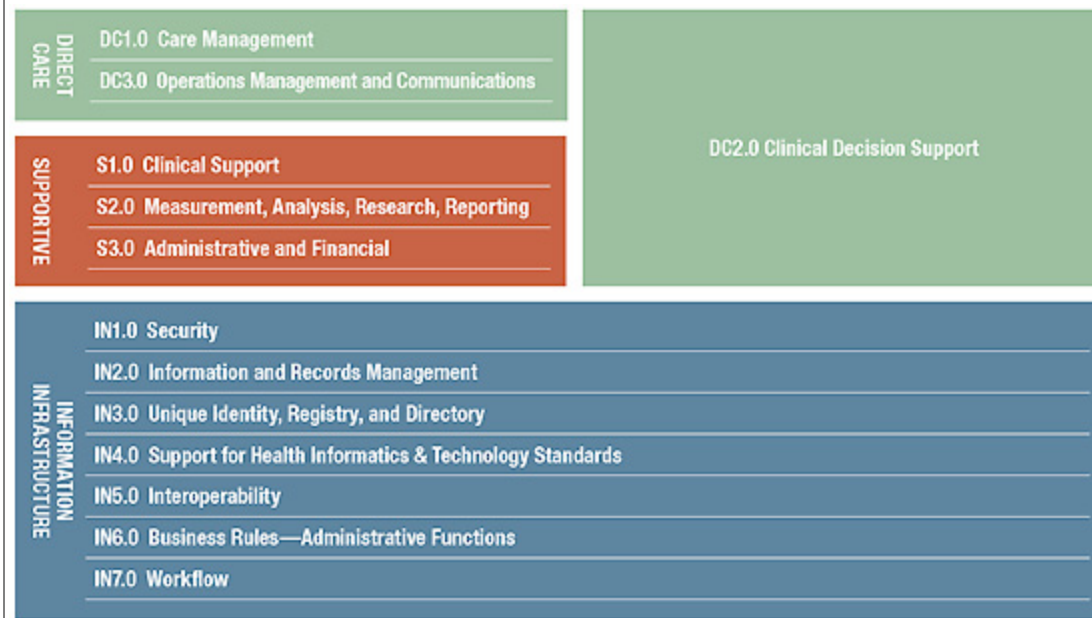

Increasing Acceptance

Since the functional model's inception, a number of stakeholders have derived subsets from it and made customizations to it to better fit their care settings or purposes. These subsets and customizations are called functional profiles and ancillary profiles, respectively. (See "Customized Profiles for Care Settings and Special Purposes" below for the profiles that have been developed to date.)

Stakeholders who have developed profiles thus far have generally found four benefits in doing so. Profiles have helped them clarify the standard set of EHR system functions needed to support:

- Individual care settings-a standard set of functions that can enhance core operations for a specific care setting without stifling product innovation.
- Continuity of care-the functions needed to support the exchange of health information between systems in different settings; for example, from acute care to post-acute care. In this example, the post-acute care community could request acute care stakeholders and their vendors to include functionality in acute care EHR systems that they might not otherwise have considered.
- Secondary data use-system functions to support clinical research, vital records, and other downstream uses of data. As above, secondary data users could request care setting providers and their vendors to include appropriate functionality in their respective EHR systems.
- Records management and evidentiary support-practices that will help care delivery organizations maintain a record of care for legal, business, and disclosure purposes.

Customized Profiles for Care Settings and Special Purposes

To date, four customized functional profiles have been created from the EHR-S FM to address specialized care settings. Three ancillary profiles have been adapted for specific purposes.
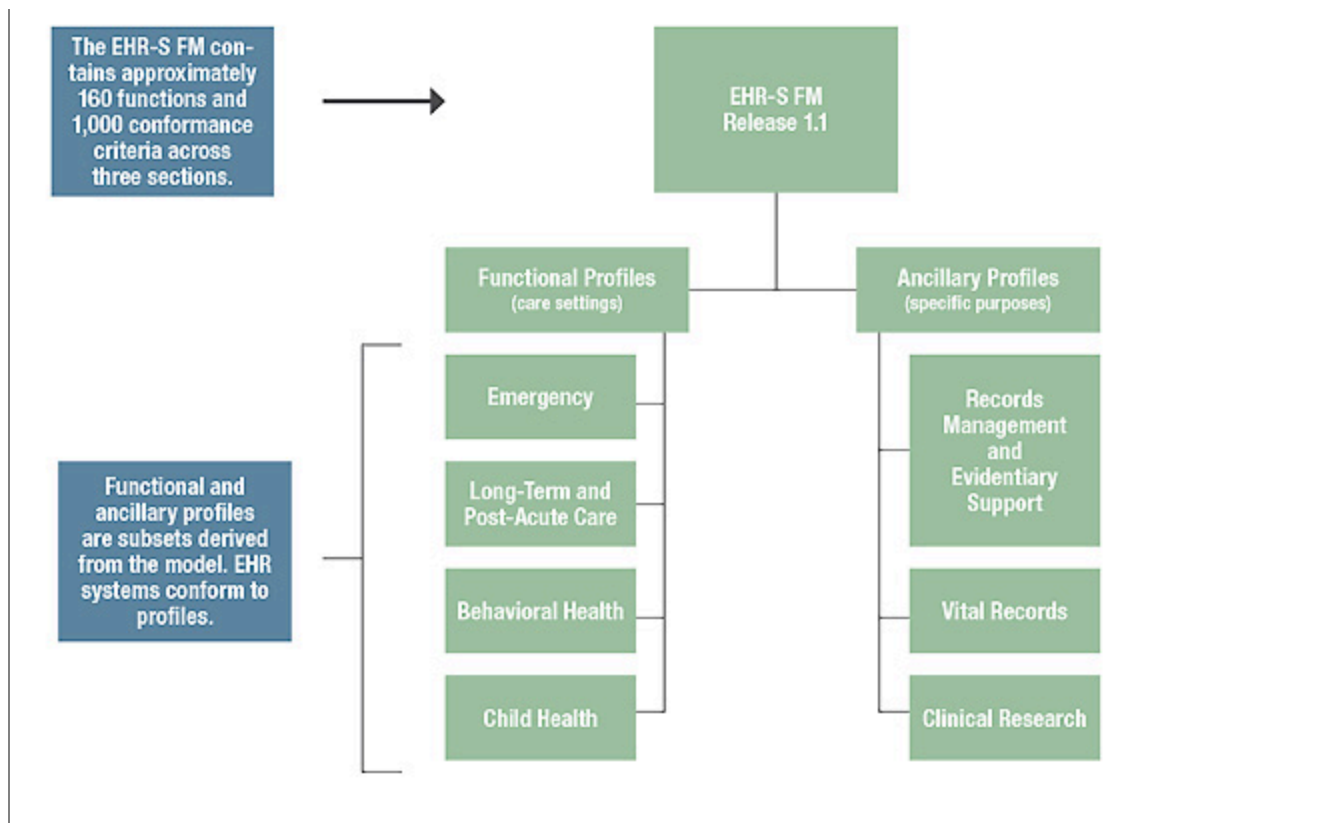
Other Vital Uses of the Functional Model and Profiles

In the United States, the EHR-S FM has been leveraged for health IT certification.

In response to pay-for-performance programs that required the use of certified EHR systems, stakeholders in various settings submitted their profiles to the Certification Commission for Health Information Technology. CCHIT work groups-which contained some of the individuals who helped develop the profiles, providing continuity in the necessarily independent but related standards development and certification processes-adopted and adapted a number of criteria from profiles for emergency services, long-term and post-acute care, behavioral health, child health, records management and evidentiary support, and clinical research.

Other countries have employed the EHR-S FM for certification as well. In Ireland, for example, the General Practice Information Technology Group used Release 1 of the EHR-S FM to define requirements for the certification of GP software systems. Certification requirements and test plans were developed through a consensus process that included software vendors.

By the end of 2009, six vendors applied for certification. A new cycle of certification will begin in 2010 and extend to 2012. The first step for this new cycle will be to review the functionality for certified systems using the most current release of the EHR-S FM to determine the most important additional capabilities required to assist GPs in improving patient care.

The EHR-S FM also has been used for system selection. The Association for Behavioral Health in the Netherlands developed and adopted a reference model for an EHR within a six-month period using the EHR-S FM. Such a process could have taken a year, if not more, otherwise. The behavioral health profile was used to compare software offerings from both incumbent and new international vendors.

In addition, a group of Dutch provider organizations is preparing a joint request for proposal based on the profile for a combined EHR and hospital information system. For this purpose, more traditional health information system functions in the areas of care logistics and care registration were added to the profile.

In Korea the EHR-S FM has been used to develop a national EHR system framework. The Center for Interoperable EHR developed a national EHR functional standard based on the EHR-S FM to be implemented in Korean public hospitals.

Moreover, the prototype EHR system developed for national university hospitals incorporated the EHR-S FM.3

The EHR-S FM has proven useful in complex services oriented architecture (SOA) efforts. The US Department of Defense has used the EHR-S FM to support the development of an HL7 EHR System Design Reference Model.

This project will develop version 2.0 of the 2008 Healthcare Services Oriented Reference Architecture. Version 2.0 will then be integrated into an EHR System Design Reference Model using the following elements:

- HL7 SOA-Aware Enterprise Architecture Framework
- Health Information Technology Standards Panel (HITSP) Multi-Enterprise Architecture of Networked Services Standards
- EHR-S FM

The Department of Defense will monitor HITSP, the nationwide health information network, and CCHIT conformance by maintaining information exchange requirements and data requirements. Further, it will map and analyze HL7 messaging and document standards they have implemented against the EHR-S FM to help them identify gaps in their deployment of standards and services.4

Finally, in the US, the National Quality Forum leveraged the EHR-S FM when defining the Quality Data Set (QDS), a framework for supporting automated quality measurement using electronic data sources. As part of the QDS development process, the direct care section of the EHR-S FM was compared to the draft QDS framework to help define QDS data types and identify functional requirements that support the automated capture of quality measurement data from EHR data sources.5

Next Steps for the Standard

The examples above illustrate that the EHR-S FM has been increasingly accepted as a standard. Though many countries and organizations have already used the functional model for their vital purposes, these and other entities have already requested enhancements to the EHR-S FM. The HL7 EHR work group is currently working on many such enhancements, including:

- Incorporating criteria from the Records Management and Evidentiary Support Ancillary Profile into the functional model, enabling downstream profiles to inherit appropriate requirements per the rules of conformance6
- Determining if certain conformance criteria that are currently optional should be elevated to mandatory requirements
- Creating greater alignment with international standards on health record architecture and privacy and security
- Synchronizing certification criteria and conformance criteria in the EHR-S FM
- Developing criteria for preventing and detecting fraud
- Enhancing the functional model's descriptions of how to document the lifecycle of clinical actions (e.g., the clinician creating a note, later amending that note, etc.)

It is anticipated that the HL7 EHR-S FM Release 2 will be made available for voting approval in late 2010.

Resources

Members of ISO and HL7 can access the **HL7 Electronic Health Record-System Functional Model, Release 1.1** through the normal membership process. Nonmembers can purchase a licensed copy through ISO (copyright@iso.org, www.iso.org) or obtain a licensed copy with no licensing fees through HL7 (hq@hl7.org, www.hl7.org).

The **functional and ancillary profiles** can be obtained via HL7 (www.hl7.org) and the NIST Functional Profile Registry (http://xreg2.nist.gov:8080/ehrsRegistry/index.jsp). **CCHIT requirements** can be found at www.cchit.org (click on the "Get Certified" tab).

The **Irish Requirements for Certification** document, version 1.3, final, is available at www.icgp.ie/go/in_the_practice/information_technology/publications_reports.

Notes

1. 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.
2. Dougherty, Michelle. "It's Official: HL7's EHR Model Becomes Approved Standard." *Journal of AHIMA* 78, no. 5 (May 2007): 56–57.
3. Personal communication with staff of Health Level Seven International.
4. Personal communication with Stephen Hufnagel, a contractor supporting The Informatics Applications Group of the Military Health Service, December 14, 2009.
5. National Quality Forum. Health Information Technology Automation of Quality Measurement: Quality Data Set and Data Flow. Washington, DC: NQF, 2009.
6. HL7 EHR Work Group. Electronic Health Record-System Functional Model, Release 1.1, Chapter Two: Conformance Clause. June, 2009. Health Level Seven International, Ann Arbor, MI.

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