

HL7 Electronic Health Record System (EHR-S) Functional Model and Standard

Ambassador Briefing



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HL7 Ambassador

- **This presentation is being delivered by an authorized speaker of HL7, called HL7 Ambassador. The HL7 Ambassador personally participates and contributes to the HL7 standards in HL7 Technical committee meetings and can speak first hand about the standard.**



Agenda

- **HL7 Overview**
- **Background and Overview of EHR System (EHR-S) Functional Model**
- **Walk through of EHR-S FM**
- **Conformance Clause and Profiles**
- **Distinction between Standards and Product Certification**
- **Current Activities**



HL7 Vision

To create the best and most widely used standards in healthcare.



HL7 Mission

- **HL7 provides standards for interoperability that improve care delivery, optimize workflow, reduce ambiguity and enhance knowledge transfer among all of our stakeholders, including healthcare providers, government agencies, the vendor community, fellow SDOs and patients. In all of our processes we exhibit timeliness, scientific rigor and technical expertise without compromising transparency, accountability, practicality, or our willingness to put the needs of our stakeholders first.**



Executive Summary of the standard

- **HL7 builds on its solid foundation of international healthcare information technology standards by promoting the Electronic Health Record System Functional Model (EHR-S FM) to an ISO standard for Electronic Health Record System functionality**
 - **ISO 10781, published November 2009**



EHR vs. EHR-S

● EHR

- The underlying single, logical patient record
- The data elements comprising the record
- Serving as the legal record

● EHR-S

- Software that provides functionality to:
 - Manage and maintain the health record
 - Accomplish various clinical, research, and business purposes of the health record
- May be monolithic system or system of systems



PHR - EHR: What Are the Differences?

● EHR

- Provider or Health Service controlled
- Business, operations and legal record
- Captures clinical, administrative, financial data

● PHR

- Typically controlled/managed by patient or their representative
- Captures patient's health/healthcare info across multiple providers and includes self-entered data
- Not a legal record



How It Started - Request from US Govt

- **May, 2003: US Centers for Medicare and Medicaid Services asked**
 - **US Institute of Medicine for guidance on care delivery functions**
 - **IOM & HL7 to coordinate development of a functional model for an EHR *system*, not transaction-oriented**
 - **Needed as basis for pay for performance**



From DSTU to Full ANSI Accreditation

- **Approved July 2004 as a draft standard for trial use (DSTU)**
 - **2 year period to continuously improve DSTU, become an ANSI accredited standard**
 - **Core, not exhaustive, functionality**
 - **Good enough for industry to begin using as a standard**
- **Approved February 2007 as full normative HL7 and ANSI accredited standard**



The EHR-S Functional Model

Is Not...

- A messaging specification
- An EHR record specification
- An implementation specification (what, why, not how)
 - Does not prescribe technology
 - Does not dictate how functions must be implemented (e.g., user interface, database design)

Is...

- An EHR system specification
- A reference list of functions that may be present in an EHR-S (the “what”)
 - Enables consistent expression of functionality
 - Provides flexibility for innovation and product differentiation
 - Gold standard, sensitive to what can practically be done by a system, future system development



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EHR-S Functional Model at a Glance

Direct Care	C1.0	Care Management
	C2.0	Clinical Decision Support
	C3.0	Operations Management and Communication
Supportive	S1.0	Clinical Support
	S2.0	Measurement, Analysis, Research, Reporting
	S3.0	Administrative and Financial
Information Infrastructure	I 1.0	EHR Security
	I 2.0	EHR Information and Records Management
	I 3.0	Unique identity, registry, and directory services
	I 4.0	Support for Health Informatics & Terminology Standards
	I 5.0	Interoperability
	I 6.0	Manage business rules
	I 7.0	Workflow

Functions describe the behavior of an EHR system in user-oriented language



EHR-S Functional Model & Standard

- **Function names & statements provide a reference list of functions that:**
 - May be present in an EHR-S
 - Are understandable from a user's perspective
 - Enable consistent expression of functionality
- **Conformance criteria**
 - Required/mandatory: The system **SHALL...**
 - Preferred: The system **SHOULD...**
 - Optional: The system **MAY...**



The Structure of the Functional Model

ID#	Type	Name	Statement/Description	See Also	Conformance Criteria
DC.1.1.1	F	Identify and Maintain a Patient Record	<p>Statement: Identify and maintain a single patient record for each patient.</p> <p>Description: A single record is needed for legal purposes, as well as to organize it unambiguously for the provider. Health information is captured and linked to the patient record. Static data elements as well as data elements that will change over time are maintained. The patient is uniquely identified, after which the record is tied to that patient. Combining information on the same patient, or separating information where it was inadvertently captured for the wrong patient, helps maintain health information for a single patient. In the process of creating a patient record, it is at times advantageous to replicate identical information across multiple records, so that such data does not have to be re-entered. For example, when a parent registers children as new patients, the address, guarantor, and insurance data may be propagated in the children's records without having to re-enter them.</p>	S.1.4.1 S.2.2.1 S.3.1.2 S.3.1.5 IN.2.1 IN.2.3	1.The system SHALL create a single logical record for each patient.
					1.The system SHALL provide the ability to create a record for a patient when the identity of the patient is unknown.
					1.The system SHALL provide the ability to store more than one identifier for each patient record.
					1.The system SHALL associate key identifier information (e.g., system ID, medical record number) with each patient record.
					1.The system SHALL provide the ability to uniquely identify a patient and tie the record to a single patient.
					1.The system SHALL provide the ability, through a controlled method, to merge or link dispersed information for an individual patient upon recognizing the identity of the patient.
					1.IF health information has been mistakenly associated with a patient, THEN the system SHALL provide the ability to mark the information as erroneous in the record of the patient in which it was mistakenly associated and represent that information as erroneous in all outputs containing that information.
					1.IF health information has been mistakenly associated with a patient, THEN the system SHALL provide the ability to associate it with the correct patient.
1.The system SHALL provide the ability to retrieve parts of a patient record using a primary identifier, secondary identifiers, or other information which are not identifiers, but could be used to help identify the patient.					



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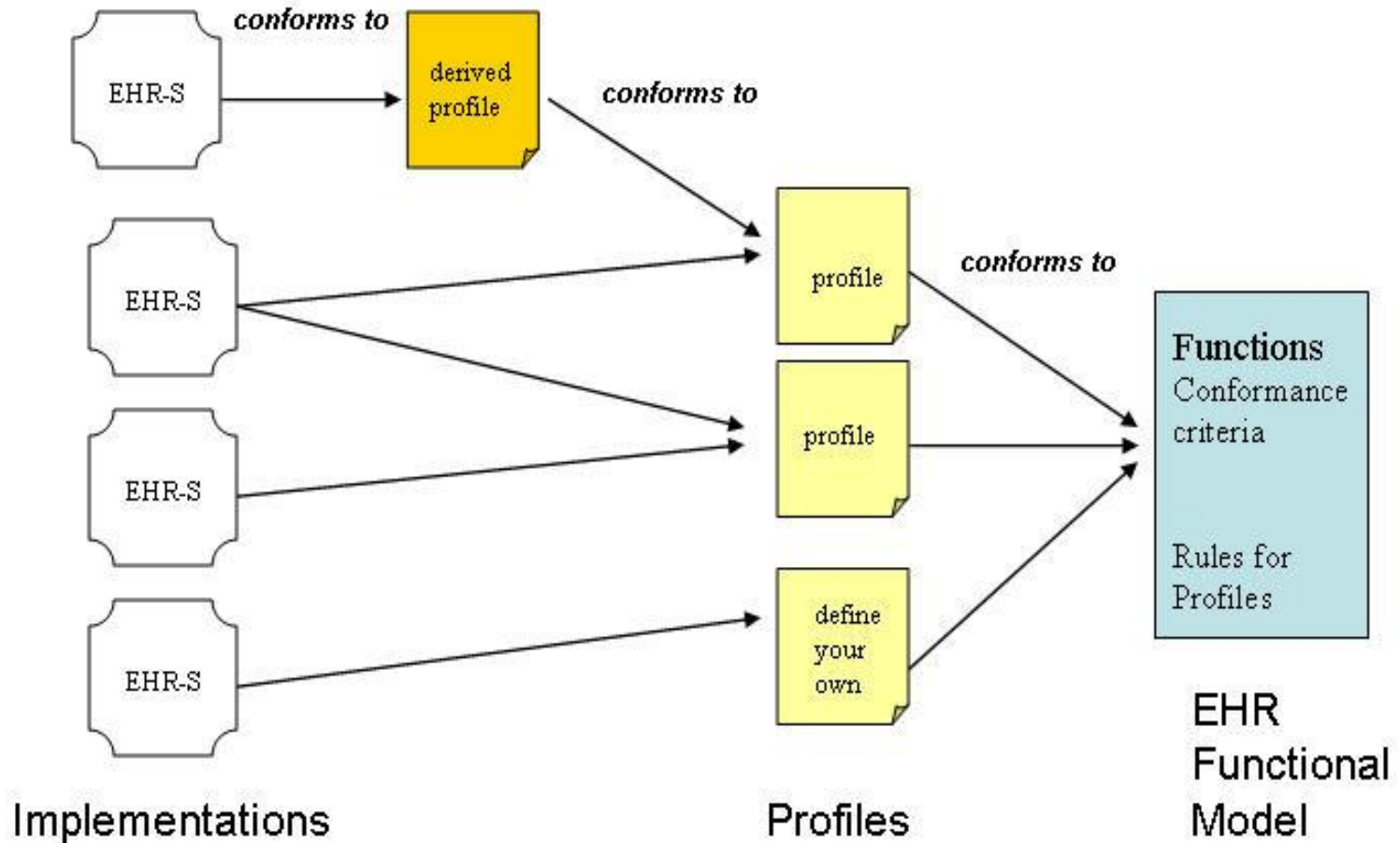


Profiles Can Be Derived from the FM

	Inpatient	Outpatient				Home		
	Medication Administration Record					Medication Admin Record		
	Bed management					Lifestyle		
		Wellness Reminders				Wellness Reminders		
	Drug-Drug Interaction	Drug-Drug Interaction	Drug-Drug Interaction	Drug-Drug Interaction	Drug-Drug Interaction	Drug-Drug Interaction	Drug-Drug Interaction	
	Notes	Notes	Notes	Notes	Notes	Notes	Notes	
	Results Reporting	Results Reporting	Results Reporting	Results Reporting	Results Reporting	Results Reporting	Results Reporting	
	Order Management	Order Management	Order Management	Order Management	Order Management	Order Management	Order Management	
	Event Capture	Event Capture	Event Capture	Event Capture	Event Capture	Event Capture	Event Capture	
	Security	Security	Security	Security	Security	Security	Security	Security
	Demographic Management	Demographic Management	Demographic Management	Demographic Management	Demographic Management	Demographic Management	Demographic Management	
	Record Management	Record Management	Record Management	Record Management	Record Management	Record Management	Record Management	



Conformance to Profiles



Profiles Developed/Under Development

- Ambulatory Care
- Ambulatory Oncology
- Behavioral Health
- Child Health
- Clinical Research, Clinical Trials
- Dentistry
- ePrescribing/Pharmacy
- Emergency Department
- Long Term Care
- Public Health
- Records Management & Evidentiary Support
- Vital Records, Statistics Reporting
- Also: Canadian EHR Blueprint 2015 (Infoway Project)



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Differs between Standards & Certification

- **Gold standard vs. specific purpose incentives**
 - Pay for performance programs
 - US HITECH Act (2009): EHR Incentive Program
- **Standards development organization (SDO) vs. public/private collaborative**
- **Avoid perceived conflict of interest**
 - Where one organization both develops the standard and certifies against it
- **Product certification references standards**



Definitions: Fitting it all together

Certification

qualified bodies to do the testing and certification
control board - advisory and arbiter

Validation

Process - policy and procedures for testing

Conformance Testing

Test suite, Test tool
(test software, test scripts, test criteria)

Profile

Standard

Conformance clause, conformance criteria

We are
concerned
with



HL7 & CCHIT Working Together

HL7 EHR-S Standard				CCHIT Product Certification			
Function ID	Function	Conformance Criteria		Certification Criteria	Certification Year		
		No.	Clause		2008	2009	2010
1.0	ABC						
1.1		1	...SHALL.....	...SHALL.....	X		
		2	...SHOULD.....	...SHALL.....		X	
		3	...SHALL.....	...SHALL.....	X		
		4	...MAY.....	...(Did not adopt)			
		5	...SHOULD.....	...SHALL.....		X	
		6	...SHALL.....	...SHALL.....			X

- **Granularity:** Individual conformance criterion may be certified in a year different from other criteria in the same function
- **Dependent on EHR functionality essential now vs. future, market availability and priorities for improving quality of care**



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Current Activities

- **Additional profiles under development**
 - Including realm (country)-based profiles
- **Release 2 under development**
 - ISO/HL7 Joint Ballot (ISO 10781)
- **Personal Health Record System FM**
 - DSTU, Release 1 normative under development
 - Also planned as ISO/HL7 Joint Ballot
- **Incorporate HL7 EHR Interoperability and EHR Lifecycle Model DSTUs**



Status of PHR-S FM

Draft Standard for Trial Use Ballot

The PHR-System Functional Model:

- **Balloted in November 2007**
- **Reconciliation Complete in March 2008**
- **Published as DSTU in July 2008**
- **Lists the functions that PHR systems shall, should or may perform**
- **Provides support for a certification framework**
- **Serves as an anchor point for PHR system interoperability**



Want to Participate or Know More?

- **Join HL7**
- **Access the HL7 EHR Wiki site**
 - <http://wiki.hl7.org/index.php?title=EHR>
- **Subscribe to HL7 EHR WG List server**
 - Open to all
- **Participate on Work Groups calls**
 - Tuesdays, 3PM US Eastern time, 90 minutes



HL7 EHR System Functional Model and Standard

Q & A



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