ISO/HL7 10781 EHR System Functional Model Standard

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  CentriHealth
- Co-Chair, HL7 EHR Work Group
- Lead, S&I Framework Cross-Initiative Simplification Work Group

Ambassador Briefing
March 2013
The Drivers

- **International Focus on**
  - EHR System Functionality
  - EHR System(/Record) Interoperability

- **Concerns about privacy/security, cost, quality, operational efficiency and data/record integrity**

- **By many stakeholders**
  - Healthcare providers
  - Consumers
  - Government
  - Employers
The Need

- Complete patient health record, trusted record management
- Starting at:
  - Point of service, point of care,
  - Point of EHR record entry (origination)
- Continuing to:
  All subsequent points of EHR record access and use
EHRS FM within HL7 Family

- Health Level Seven (HL7) is an ANSI-Accredited international Standards Development Organization (SDO)
- The term “HL7” is often used synonymously for the HL7 organization and the HL7 messaging standard
- HL7 standards have multiple foci:
  1. Healthcare-related data/information/routing Standards:
     - Messaging Standards (V2.x and V3)
     - Document Standards (CDA)
  2. Healthcare-related Functional Standards (EHR-S FM)
  3. Other Standards (Mobile Health, CCOW, Vocabulary, Security, Healthcare Devices...)

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How It Started – Request from US Government

- April, 2003: CMS asked
  - Institutes of Medicine (IOM) for guidance on care delivery functions
  - IOM & HL7 to coordinate development of a functional model for an EHR system, not a transaction standard
  - Need: Pay for performance
  - Sponsors: HHS ASPE, VA, HIMSS, RWJ Foundation
- April, 2003: HL7 EHR WG began work on EHR-S FM
- July, 2004: Approved as a draft standard for trial use (DSTU)
From DSTU to ANSI/ISO/CEN

- February 2007: Release 1.0 approved as a fully American National Standards Institute (ANSI) accredited standard
- November 2009: Release 1.1 approved as a International Organization for Standardization (ISO) standard
  - Three way joint ballot between: HL7, ISO TC215, CEN TC251
- April 2013: Release 2.0 continues 2\textsuperscript{nd} round ballot as normative international standard
  - Six way joint ballot between: HL7, ISO TC215, CEN TC251, IHTSDO, CDISC and GS1.
EHR vs. EHR-S

- **EHR**
  - The underlying single, logical patient record
  - The data objects and elements comprising the record
  - Serving as the record of care for clinical, operations/business legal and disclosure purposes

- **EHR-S**
  - Software that provides functionality to:
    - Manage and maintain the record
    - Accomplish the various clinical, business, research and other purposes of the EHR record
  - May be single monolithic system or a system of systems
EHR System Functional Model

Is Not...
- A messaging specification
- An EHR design specification
- An implementation specification (not the “how”)
  - Does not prescribe technology
  - Does not dictate how functions must be implemented (e.g., via the user interface, database design)

Is...
- A system specification
- An EHR system specification
- A reference list of functions that may be present in an EHR-S (the “what” and “why”)
  - 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
Standards Plus Strategy

Meets applicable certification criteria

Capabilities beyond certification criteria could be specified by the EHR-S FM
Functional Model Scope

- Defines a standardized model of the functions that may be present in EHR Systems.
  - Makes no distinction regarding implementation.
  - Does not address whether the EHR-S is a system-of-systems or a single system providing the functions required by the users.
  - Makes no statement about which technology is used.
EHR System Functional Model

- Enables consistent expression of functionality
- Provides a reference list of functions that:
  - May be present in an EHR-S
  - Understandable from a user’s perspective
- Conformance criteria
  - Required criteria: Mandatory (SHALL)
  - Optional criteria: Two levels (SHOULD, MAY)
The EHR-S FM R.1.1 contains approx. 160 functions and 1000 conformance criteria across 3 sections.

Functional and ancillary profiles are subsets derived from the FM. EHR systems conform to profiles.

HL7 EHR System Functional Model

- Functional Profiles (Care Setting)
  - Emergency
  - Long Term and Post Acute Care
  - Behavioral Health
  - Child Health

- Ancillary Profiles (Specific Purpose)
  - Records Management & Evidentiary Support (RM-ES)
  - Vital Records
  - Clinical Research
Functional Model Conformance

EHR System Functional Model (EHR-S FM)

DC 1.1, CC 3
... SHALL ...

DC 1.1, CC 4
... SHOULD ...

To develop a robust, yet flexible FM

Child Health FP

RM&ES FP

Derived FP<sub>1</sub>

LTPAC FP

Derived FP<sub>2</sub>

LTPAC FP

Child Health FP

Derived FP<sub>1</sub>

C<sub>2</sub> LTPAC FP

Derived FP<sub>1</sub>

Country<sub>1</sub>

DC 1.1, CC3: SHALL
DC 1.1, CC4: SHOULD

Country<sub>2</sub>

DC 1.1, CC3: SHALL
DC 1.1, CC4: SHALL

DC 1.1, CC 3: SHALL
DC 1.1, CC 4: SHOULD

DC 1.1, CC 3: SHALL
DC 1.1, CC 4: SHOULD

DC 1.1, CC 3: SHALL
DC 1.1, CC 4: SHALL
Additional Functional Profiles

- US Meaningful Use/EHR Incentive Program (new)
- EHR System Usability (pending)
- Dietetics/Food & Nutrition (jointly with ADA)
- Public Health (jointly with CDC)
- E-Prescribing (jointly with NCPDP)
- Pharmacist/Pharmacy (jointly with NCPDP)
- Dentistry (jointly with ADA)
## Functional Model & Certification

### HL7 EHR-S Standard

<table>
<thead>
<tr>
<th>Function ID</th>
<th>Function</th>
<th>Conformance Criteria</th>
<th>Certification Criteria</th>
<th>Certification Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
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<tr>
<td></td>
<td></td>
<td>Clause</td>
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</tr>
<tr>
<td>1.1</td>
<td>ABC</td>
<td>1</td>
<td>SHALL</td>
<td>SHALL</td>
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<tr>
<td></td>
<td></td>
<td>2</td>
<td>SHOULD</td>
<td>SHALL</td>
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<td></td>
<td></td>
<td>3</td>
<td>SHALL</td>
<td>SHALL</td>
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<td>4</td>
<td>MAY</td>
<td>(Did not adopt)</td>
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<td></td>
<td>5</td>
<td>SHOULD</td>
<td>SHALL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6</td>
<td>SHALL</td>
<td>SHALL</td>
</tr>
</tbody>
</table>

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

**Product Certification**

<table>
<thead>
<tr>
<th>Certification Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
</tr>
<tr>
<td>2009</td>
</tr>
<tr>
<td>2010</td>
</tr>
</tbody>
</table>

- X
EHR System Functional Model

Functions describe the behavior of a system in user-oriented language so as to be recognizable to the key stakeholders of an EHR System.

This represents the Release 1.1 Structure.

<table>
<thead>
<tr>
<th>Direct Care</th>
<th>Supportive</th>
<th>Information Infrastructure</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1.0 Care Management</td>
<td>S1.0 Clinical Support</td>
<td>11.0 EHR Security</td>
</tr>
<tr>
<td>C2.0 Clinical Decision Support</td>
<td>S2.0 Measurement Analysis, Research, Reporting</td>
<td>12.0 EHR Information and Records Management</td>
</tr>
<tr>
<td>C3.0 Operations Management and Communication</td>
<td>S3.0 Administrative and Financial</td>
<td>13.0 Unique identity, registry, and directory services</td>
</tr>
<tr>
<td></td>
<td></td>
<td>14.0 Support for Health Informatics &amp; Terminology Standards</td>
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<tr>
<td></td>
<td></td>
<td>15.0 Interoperability</td>
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<tr>
<td></td>
<td></td>
<td>16.0 Manage business rules</td>
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<tr>
<td></td>
<td></td>
<td>17.0 Workflow</td>
</tr>
</tbody>
</table>
## Structure of the Functional Model

<table>
<thead>
<tr>
<th>ID#</th>
<th>Name</th>
<th>Statement/Description</th>
<th>See Also</th>
<th>Conformance Criteria</th>
</tr>
</thead>
</table>
| DC.1.1.1 | Identify and Maintain a Patient Record             | **Statement**: Identify and maintain a single patient record for each patient. **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. | 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.  
2. The system **SHALL** provide the ability to create a record for a patient when the identity of the patient is unknown.  
3. The system **SHALL** provide the ability to store more than one identifier for each patient record.  
4. The system **SHALL** associate key identifier information (e.g., system ID, medical record number) with each patient record.  
5. The system **SHALL** provide the ability to uniquely identify a patient and tie the record to a single patient.  
6. 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.  
7. 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. |
Inputs to Release 2.0 (R2)

- Vital Reports
- Records Mgmt
- Behavioral
- Long-Term Care
- EHR-S Profiles
- Alignment
- Lifecycle
- Provider Based
- Interop Model
- PHR-S FM & Profiles

SOA
SAIF
R1.1 Adjustments, Enhancements

Other Industry Initiatives

- Privacy, Security, Confidentiality
- Certification (CCHIT, Q-Rec)
- Health Info Exchange
- Data Use
  - Fraud Mgt
  - Quality
  - Rev Cycle

International Stds
(ISO TC215, ISO 20514, 18307, 18308, 13606, 21089)

Others

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R1.1 → R2 Chapter Reorganization

- Direct Care (DC)
- Supportive (S)
- Information Infrastructure (IN)

- Overarching (O)
- Care Provision (CP)
  - Care Provision Support (CP)
  - Population Health Support (POP)
  - Administrative Support (AS)
- Record Infrastructure (RI)
- Trust Infrastructure (TI)
# Extension of Functions/Criteria

**HL7 EHR-S Functional Model, Release 2**

## Summary Breakdown of Functions and Conformance Criteria

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Functions</th>
<th>Conformance Criteria</th>
<th>Conformance Criteria</th>
<th>Conformance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>OV</td>
<td>Overarching Criteria</td>
<td>2</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>CP</td>
<td>Care Provision</td>
<td>41</td>
<td>494</td>
<td></td>
</tr>
<tr>
<td>CPS</td>
<td>Care Provision Support</td>
<td>76</td>
<td>559</td>
<td></td>
</tr>
<tr>
<td>POP</td>
<td>Population Health Support</td>
<td>18</td>
<td>108</td>
<td></td>
</tr>
<tr>
<td>AS</td>
<td>Administration Support</td>
<td>55</td>
<td>249</td>
<td></td>
</tr>
<tr>
<td>RI</td>
<td>Records Infrastructure</td>
<td>37</td>
<td>186</td>
<td></td>
</tr>
<tr>
<td>TI</td>
<td>Trust Infrastructure</td>
<td>93</td>
<td>681</td>
<td></td>
</tr>
</tbody>
</table>

**TOTALS:**  
322 | 2,310 | 972 | 983
## Care Provision

- Focus on functions required to provide care to a specific patient and enable hands-on delivery of healthcare
- Organized in general order of an encounter

<table>
<thead>
<tr>
<th>Care Provision</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CP.1</td>
<td>Manage Clinical History</td>
</tr>
<tr>
<td>CP.2</td>
<td>Render Externally-sourced Information</td>
</tr>
<tr>
<td>CP.3</td>
<td>Manage Clinical Documentation</td>
</tr>
<tr>
<td>CP.4</td>
<td>Manage Orders</td>
</tr>
<tr>
<td>CP.5</td>
<td>Manage Results</td>
</tr>
<tr>
<td>CP.6</td>
<td>Manage Treatment Administration</td>
</tr>
<tr>
<td>CP.7</td>
<td>Manage Future Care</td>
</tr>
<tr>
<td>CP.8</td>
<td>Manage Patient Education &amp; Communication</td>
</tr>
<tr>
<td>CP.9</td>
<td>Manage Care Coordination &amp; Reporting</td>
</tr>
</tbody>
</table>

### CP.1 Manage Clinical History

- CP.1.1 Manage Patient History
- CP.1.2 Manage Allergy, Intolerance and Adverse Reaction List
- CP.1.3 Manage Medication List
- CP.1.4 Manage Problem List
- CP.1.5 Manage Strengths List
- CP.1.6 Manage Immunization List
- CP.1.7 Manage Medical Equipment, Prosthetic/Orthotic, Device List
- CP.1.8 Manage Patient and Family Preferences
## Care Provision Support

- Focus on functions required to support the provision of care to a specific patient to enable hands-on delivery of healthcare
- Organized to align with Care Provision chapter

| Care Provision Support | CPS.1 Record Management | CPS.2 Support Externally-sourced Information | CPS.3 Support Clinical Documentation | CPS.4 Support Orders | CPS.4.1 Manage Order Set Templates | CPS.4.2 Support Medication & Immunization Orders | CPS.4.2.1 Support for Medication Interaction & Allergy Checking | CPS.4.2.2 Support for Patient Specific Dosing and Warnings | CPS.4.2.3 Support for Medication Ordering Efficiencies | CPS.4.2.4 Support for Medication Recommendations | CPS.4.3 Support for Non-Medication Ordering | CPS.4.4 Support Orders for Diagnostic Tests | CPS.4.5 Support Orders for Blood Products and Other Biologics |
|------------------------|--------------------------|---------------------------------------------|-----------------------------------|---------------------|------------------------------------|---------------------------------|-------------------------------------------------|---------------------------------|-----------------------------------------------|---------------------------------|--------------------------------|---------------------------------|---------------------------------|--------------------------------|
## Population Health Support

<table>
<thead>
<tr>
<th>Population Health Support</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>POP.1</td>
<td>Support for Health Maintenance, Preventive Care and Wellness</td>
</tr>
<tr>
<td>POP.2</td>
<td>Support for Epidemiological Investigations of Clinical Health Within a Population</td>
</tr>
<tr>
<td>POP.3</td>
<td>Support for Notification and Response</td>
</tr>
<tr>
<td>POP.4</td>
<td>Support for Monitoring Response Notifications Regarding a Specific Patient’s Health</td>
</tr>
<tr>
<td>POP.5</td>
<td>Donor Management Support</td>
</tr>
<tr>
<td>POP.6</td>
<td>Measurement, Analysis, Research and Reports</td>
</tr>
<tr>
<td>POP.7</td>
<td>Public Health Related Updates</td>
</tr>
<tr>
<td>POP.8</td>
<td>De-Identified Data Request Management</td>
</tr>
<tr>
<td>POP.9</td>
<td>Support Consistent Healthcare Management of Patient Groups or Populations</td>
</tr>
<tr>
<td>POP.10</td>
<td>Manage Population Health Study-Related Identifiers</td>
</tr>
</tbody>
</table>

### Example child functions:

- POP.6.1 Outcome Measures and Analysis
- POP.6.2 Performance and Accountability Measures
- POP.6.3 Support for Process Improvement
- POP.6.4 Support for Care System Performance Indicators (Dashboards)
Administrative Support

<table>
<thead>
<tr>
<th>AS.1</th>
<th>Manage Provider Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS.2</td>
<td>Manage Patient Demographics, Location and Synchronization</td>
</tr>
<tr>
<td>AS.3</td>
<td>Manage Personal Health Record Interaction</td>
</tr>
<tr>
<td>AS.4</td>
<td>Manage Communication</td>
</tr>
<tr>
<td>AS.5</td>
<td>Manage Clinical Workflow Tasking</td>
</tr>
<tr>
<td>AS.6</td>
<td>Manage Resource Availability</td>
</tr>
<tr>
<td>AS.7</td>
<td>Manage Encounter/Episode of Care Management</td>
</tr>
<tr>
<td>AS.8</td>
<td>Manage Information Access for Supplemental Use</td>
</tr>
<tr>
<td>AS.9</td>
<td>Manage Administrative Transaction Processing</td>
</tr>
</tbody>
</table>

**Example child functions:**

- AS.1.1 Manage Provider Registry or Directory
- AS.1.2 Manage Provider's Location Within Facility
- AS.1.3 Provider's On Call Location
- AS.1.4 Manage Provider's Location(s) or Office(s)
- AS.1.5 Team/Group of Providers Registry or Directory
- AS.1.6 Provider Caseload/Panel
- AS.1.7 Manage Practitioner/Patient Relationships
Record Infrastructure

- Focus on records, record entries and record management, including R1.1 functions/criteria and key provisions of the RM-ES Functional Profile, EHR Interoperability and Lifecycle Model DSTUs.

| RI.1  | Record Lifecycle and Lifespan |
| RI.2  | Record Synchronization        |
| RI.3  | Record Archive and Restore    |

<table>
<thead>
<tr>
<th>RI.1.1</th>
<th>Record Lifecycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>RI.1.1.1</td>
<td>Originate and Retain Record Entry</td>
</tr>
<tr>
<td>RI.1.1.2</td>
<td>Amend Record Entry Content</td>
</tr>
<tr>
<td>RI.1.1.3</td>
<td>Translate Record Entry Content</td>
</tr>
<tr>
<td>RI.1.1.4</td>
<td>Attest Record Entry Content</td>
</tr>
<tr>
<td>RI.1.1.5</td>
<td>View/Access Record Entry Content</td>
</tr>
<tr>
<td>RI.1.1.6</td>
<td>Transmit and/or Disclose Record Entries</td>
</tr>
<tr>
<td>RI.1.1.7</td>
<td>Receive and Retain Record Entries</td>
</tr>
<tr>
<td>RI.1.1.8</td>
<td>De-identify Record Entries</td>
</tr>
<tr>
<td>RI.1.1.9</td>
<td>Pseudonymize Record Entries</td>
</tr>
<tr>
<td>RI.1.1.10</td>
<td>Re-identify Record Entries</td>
</tr>
<tr>
<td>RI.1.1.11</td>
<td>Extract Record Entry Content</td>
</tr>
</tbody>
</table>

Example child functions:
## Trust Infrastructure

- Contains the remaining Release 1.1 Infrastructure functions, including Audit.

<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>TI.1 Security</td>
<td>TI.1.1 Entity Authentication</td>
<td>TI.1.2 Entity Authorization</td>
<td>TI.1.3 Entity Access Control</td>
<td>TI.1.4 Patient Access Management</td>
<td>TI.1.5 Non-Repudiation</td>
<td>TI.1.6 Secure Data Exchange</td>
<td>TI.1.7 Secure Data Routing</td>
<td>TI.1.8 Information Attestation</td>
<td>TI.1.9 Patient Privacy and Confidentiality</td>
</tr>
</tbody>
</table>

Example child functions:
Next Steps

- Update R1.1 functional profiles to R2
- Create new realm (country)-based profiles
- Map Functional Model to HL7 messages, documents, data
- Development of Release 3 – Function and Information Model
Want to Know More?

- Join HL7
- Review the HL7 web site
- Subscribe to HL7 EHR WG list serve
- Join a Sub-Group: PHR, RM-ES, Interop
- Join a Functional Profile Team
- Join our Tuesday Work Group calls
  - 3:00-4:30 PM Eastern

www.hl7.org/ehr
HL7 EHR System Functional Model and Standard Q & A