EXECUTIVE SUMMARY

This executive summary and report specifically address potential EHR impacts and/or EHR trends, which are important for the VA, IPO and DOD to be aware of.

Figure 1 RIM-and-FHIR Relationship with EHR-S FIM release-3

[2012 PSS #688]
**GOAL:** The goal of the Electronic Health Record (EHR) Work Group (WG) is to support the HL7 mission of developing standards for EHR data, information, functionality, and interoperability. The Work Group creates and promotes appropriate and necessary standards, including:

- Functional and Information Requirements-Specifications for Electronic Health Records (EHR) and systems (EHR-S),
- Functional and Information Requirements-Specifications for Personal Health Records (PHR) and systems (PHR-S),
- Definition of a high-level framework to support the interoperability requirements and life cycles, and
- Identification of existing and emerging information interoperability requirements and related HL7 artifacts.

An objective of the EHR Interoperability WG team, under the System Function-and-Information Model release-3 (EHR-S FIM r3) project #688 based-on UML-specified EHR/PHR Concept-of-Operations (CONOPS), Reference Model (RM), Function Use-Cases and Conformance-Criteria Scenarios; where, EHR-S FIM r3

- is create a clear, complete, concise, correct, consistent and easy-to-use
- is HL7 ballot-publishable from the Sparx Systems Enterprise-Architect tool. EHR-S FIM r3 is targeted for 3-to-5 years from now; because,
  - joint ISO-HL7 ballots are very challenging to manage and
  - sufficient-time is needed to address the structural issues identified by the EHR-S FM r2 ballot.
  - VA voted negative, due to inconsistency, non-intuitiveness and unnecessary-complexity/non-usability.

A second-objective of the EHR Interoperability WG is to produce a Meaningful Use profile for EHR-S FM r2 and r3.

The objective of the Resource Management Evidentiary Support (RM-ES) project team is to provide expertise to the EHR work group, other standards groups and the healthcare industry on records management, compliance, and data/record integrity for, EHR systems and related to EHR governance to support the use of medical records for clinical care and decision-making, business, legal and disclosure purposes.

The objective of the EHR Usability Project is to translate existing, well established usability guidelines and health information management principles into functional conformance-criteria in the EHR-S FM standard.
SITUATION REPORT
EHR-S FIM Release-3 Preparation
The complete-and-latest version of the Summary-Report is available at:

EHR/PHR Concept-of-Operation was defined-and-refined into a System Reference-Model (RM); where,
1) System Function is defined by a Use-Case lexicon-of system-operations bound-to Record-Entries; where,
   a) System-operations are verbs refined into a “manage” operation-type-model (aka verb-hierarchy) and
   b) System-entities are subject-and-object nouns refined into a “Record-Entry” data-type-model (aka information model)
2) Conformance Criteria is defined-by a scenario-constrained use-case of
   a) business-context and
   b) subject-verb-object-terminology binding; where,
3) Scenario-Constrained Business-Context is defined by
   a) pre-condition triggers,
   b) applicability of
      i) “SHOULD” or “SHALL” or “MAY” plus
      ii) “provide-the-ability-to-manage Record-Entries” or “directly-manage Record-Entries,” where,
         (1) a use-case constrained verb-hierarchy applies and
         (2) a use-case constrained data-model applies; where,
   c) post-condition Business-Rules are “according-to
      i) scope-of-practice, organizational-policy,
      ii) jurisdictional-law, and patient-preferences."
4) Information-Exchange is defined by a scenario subject-verb-object-terminology binding mapped to
   a) FHIR (Fast Healthcare Interoperability Resource), which is representative of the International-Realm,
   b) FHIM (Federal Health Information Model), which is representative of US-Realm FHIR-profiles,
   c) IHE information-exchange behavioral-protocols, which may be refined-or-replaced by,
      i) Service-level-agreement workflow-protocols and
      ii) Key Performance Parameters (KPPs).
5) EHR-S/PHR-S Profile is defined by a set-of (System-Function Use-Cases) with further constrained scenario
   a) applicability
   b) business-context
   c) subject-verb-object-terminology binding.
6) Interoperability-Specifications are generated with the EHR-S/PHR-S FIM r3 “Easy-Button (aka report-tool).”

CURRENT ACTIONS
1. HL7 Board to approve EHR-S FIM Release-3 open-IP; where, the EHR-S FIM home page is www.hl7.org/EHRS-FIM
2. Coordinate with FHIR WG to integrate EHR-S FIM & FHIR into a joint Sparx Enterprise Architect (EA) model; where,
   EA can generate integrated EHR-S FIM-FHIR interoperability requirements-specifications
3. Call for Participation in EHR-S/PHR-S FIM r3 based on a common EHR-S/PHR-S RM (Reference Model), where,
   an estimated 6 Full Time Equivalent (FTE) level of effort is estimated (2-FTEs per year for three-years)
WORKGROUP AND PROJECT LOGISTICS

- HL7 List Server Registration:  http://www.hl7.org/myhl7/managelistservs.cfm
- HI7 Workgroup Call-Schedule:  http://www.hl7.org/concalls/default.aspx

### Health Level Seven – Electronic Health Record Work Group
Weekly Teleconference Schedule
Revised: 20 November 2013

<table>
<thead>
<tr>
<th>Day</th>
<th>Time</th>
<th>Activity</th>
<th>Lead(s)</th>
<th>Dial-In</th>
<th>Screen Sharing</th>
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<td>Mon</td>
<td>1200</td>
<td>Records Management/Evidentiary Support</td>
<td>Warner, Gelzer</td>
<td>1-877-666-4493 Code 927 002 088#</td>
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<td>EHRS FM Release 3 Planning</td>
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<td>1-770-557-9270, Passcode 510269#</td>
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<td>1400</td>
<td>Meaningful Use Functional Profile</td>
<td>Datta, Dickinson</td>
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<td>Link</td>
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<td>1500</td>
<td>FULL EHR WG</td>
<td>Co-Chairs</td>
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<td>Personal Health Record WG</td>
<td>Ritter, Dickinson, Doo</td>
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<td>EHR System Usability WG</td>
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<td>0930</td>
<td>EHR WG Co-Chairs</td>
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<td>1-770-557-9270, Passcode 510269#</td>
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<td>N/A</td>
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- **EHR CCD to Blue Button Tool Project Wiki** - This project defined the conversion of an HL7 Continuity of Care Document (CCD) to the Blue Button format via an XSLT style sheet tool. Project contact: Lenel James and Keith Boone. List Service: EHRTeamCCD@lists.hl7.org

- **EHR-S FM Profile Tool Project Wiki** – This project, sponsored by the HL7 Tooling Workgroup, will produce a (web-based and/or desktop) tool to create EHR-S FM profiles (starting with the EHR-S FM R2), with enforced profiling rules, and exports as documents, support for and XML interchange format for reuse across profile tool instances or for use in other tools. Project contact: John Ritter; johnritter1@verizon.net

- **EHR Usability Project Wiki** - This project has been launched to translate existing, well established usability guidelines and health information management principles into functional criteria in the EHR System Functional Model (EHR-S FM) standard. Project contact: John Ritter, Don Mon, Mitra Rocca and Walter Suarez List Service: ehrwgusability@lists.hl7.org

- **PHR Project Wiki** - The HL7 Personal Health Record System Functional Model provides a reference list of functions that may be present in a Personal Health Record System (PHRS). Project contact: John Ritter; johnritter1@verizon.net

- **Diabetes Data Strategy Project Wiki** - The scope for this project is to focus on the minimum data set and data standards in EHR systems for diabetes assessment in children in outpatient clinic settings, based on clinical and business requirements. Project contact: Don Mon; donmon@rti.org
REFERENCE INFORMATION

1) Common Clinical informatics standards:
   a) SNOMED CT for problems, smoking status
   b) DICOM for radiology
   c) LOINC for laboratory anatomical pathology, LOINC taxonomy for document types for inpatient notes
   d) RxNorm for pharmacy
   e) CVX and MVX for immunology
   f) HITSP C32, HL7 CCD and CCDA-CCD for VLER Health data
   g) ICD9 CPT4/HCPCS ICD9PCSC for TRICARE billing data
   h) ICD-10 and SNOMED CT for outpatient visits, ICD-10 and LOINC for admissions encounter data
   i) CPT4 and HCPCS for procedures
   j) PDA-F for scanned paper reports
   k) CDC value set race codes for demographics
   l) UCUM for units of lab measures
   m) NUCC Health provider taxonomy for provider types

2) Common technical standards:
   a) CTS or Common Terminology Service
   b) FHIR or Fast Healthcare Interoperability Resource with RESTful API
   c) CDS or Clinical Decision Support API
   d) CCDa is Consolidated CDA
   e) VPR or Virtual Patient Record
   f) RDF or Resource Description Framework for semantic web applications
   g) RLUS or Retrieve Locate Update Service for heterogeneous database facades
   h) JSON or JavaScript Object Notation
   i) WS* or Web Service Standards

3) EHR-S FM r2.0 Perspectives
   a) Care Provision
      i) CP.1 Manage Clinical History
      ii) CP.2 Render Externally Sourced Information
      iii) CP.3 Manage Clinical Documentation
      iv) CP.4 Manage Orders
      v) CP.5 Manage Results
      vi) CP.6 Manage Treatment Administration
      vii) CP.7 Manage Future Care
      viii) CP.8 Manage Patient Education & Communication
      ix) CP.9 Manage Care Coordination & Reporting
   b) Care Provision Support
      i) CPS.1 Record Management
      ii) CPS.2 Support Externally Sourced Information
      iii) CPS.3 Support Clinical Documentation
      iv) CPS.4 Support Orders
      v) CPS.5 Support for Results
      vi) CPS.6 Support Treatment Administration
      vii) CPS.7 Support Future Care
      viii) CPS.8 Support Patient Education & Communication
      ix) CPS.9 Support Care Coordination & Reporting
   c) Population Health Support
      i) POP.1 Support for Health Maintenance, Preventive Care and Wellness
      ii) POP.2 Support for Epidemiological Investigations of Clinical Health Within a Population
      iii) POP.3 Support for Notification and Response
      iv) POP.4 Support for Monitoring Response Notifications Regarding a Specific Patient’s Health
      v) POP.5 Donor Management Support
      vi) POP.6 Measurement, Analysis, Research and Reports
   d) Administration Support
      i) AS.1 Manage Provider Information
      ii) AS.2 Manage Patient Demographics, Location and Synchronization
      iii) AS.3 Manage Personal Health Record Interaction
      iv) AS.4 Manage Communication
      v) AS.5 Manage Clinical Workflow Tasking
      vi) AS.6 Manage Resource Availability
      vii) AS.7 Support Encounter/Episode of Care Management
      viii) AS.8 Manage Information Access for Supplemental Use
      ix) AS.9 Manage Administrative Transaction Processing
   e) Trust Infrastructure
      i) TI.1 Security
      ii) TI.2 Audit
      iii) TI.3 Registry and Directory Services
      iv) TI.4 Standard Terminology and Terminology Services
      v) TI.5 Standards-Based Interoperability
      vi) TI.6 Business Rules Management
      vii) TI.7 Workflow Management
      viii) TI.8 Database Backup and Recovery
      ix) TI.9 System Management Operations and Performance
   f) Record Infrastructure
      i) RI.1 Record Lifecycle and Lifsanp
      ii) RI.2 Record Synchronization
      iii) RI.3 Record Archive and Restore

4) FHIR (Fast Healthcare Interoperability Resources)
   a) FHIR Data Dictionary is at: http://www.hl7.org/implement/standards/fhir/
   b) FHIR Administrative
      i) Attribution: Patient, RelatedPerson, Practitioner, Organization
      ii) Resources: Device, Location, Substance, Group
      iii) Workflow Management: Encounter, Alert, Supply, Order, OrderResponse
      iv) Financial: Coverage
   c) FHIR Clinical
      i) General: Adverse Reaction, Allergy Intolerance, CarePlan, Family History, Condition, Procedure, Questionnaire
      ii) Medications: Medication, MedicationPrescription, MedicationAdministration, MedicationDispense, MedicationStatement, Immunization, ImmunizationProfile
      iii) Diagnostic: Observation, DiagnosticReport, DiagnosticOrder, ImagingStudy, Specimen
      iv) Device Interaction: DeviceCapabilities, DeviceLog, DeviceObservation
   d) FHIR Infrastructure
      i) Support: List, Media, Other, DocumentReference, (Binary)
      ii) Audit: Provenance, SecurityEvent
      iii) Exchange: Document, Message, OperationOutcome, Query
      iv) Conformance: Conformance, ValueSet, Profile
e) Acronyms

- aka also known as
- CC EHR-S FIM Conformance Criteria
- CDA Clinical Document Architecture
- DD Data Dictionary
- CIM Conceptual Information Model
- CP Care Provision
- CPS Care Provisioning Support
- EA Enterprise Architect
- EHR-S EHR System
- EHR-S FIM EHR-S Function and Information Model
- FHA US Federal Health Architecture
- FHIM US Federal Health Information Model
- FHIR Fast Healthcare Interoperability Resources
- FIM EHR-S Function and Information Model
- FIM(MU) EHR-S FIM Meaningful Use profile
- FM Function Model
- FY Fiscal Year
- IHE Integrating the Healthcare Enterprise
- IM Information Model
- MDHT Model Driven Health Tools
- MU US Meaningful Use objectives and criteria
- ONC US Office of the National Coordinator
- OHT Open Health Tools
- POA&M Plan of Actions and Milestones
- R 2/3 Release 2 or 3
- RI Resource Infrastructure
- RIM HL7 Reference Information Model
- S&I ONC Standards & Interoperability Framework
- WBS Work Breakdown Structure
- WG Work Group
MONTHLY SUMMARY

(Reverse Chronological Order)

LEGEND
1) Capitalized and Underlined nouns and adjectives are concepts, which should be in the EHR-S FM data dictionary; and, they should also correspond to ISO 13940 Continuity-of-Care "CONTsys" concepts. See www.skmtglossary.org for standard healthcare data-dictionary / glossary.
2) Blue terms are recommended terms to be added to the conformance criteria.
3) Red terms are recommended terms to be removed from the conformance criteria.
4) Highlighted Yellow Sections are issues and/or new material for the main EHR WG to review and to comment on.
2 October 2013

For details see http://wiki.hl7.org/images/d/d9/HL7_EHR-WG_Summary-Presentation_2013-10-31-Final.pdf

2013-10-29 (Tu) 3-4 PM ET EHR WG

1) Gary Dickinson returned from the ISO meeting in Sydney, Australia and reported that

a) ISO/HL7 10781:2009 Electronic Health Record-System Functional Model, Release 1.1 is under ballot to be consistent with HL7 EHR-S FM r2. Ballot comments are due by December 2013

b) Health informatics - Electronic Health Record Communication (EN 13606) European Standard is being updated to define a rigorous and stable information architecture for the communicating part or all of the Electronic Health Record (EHR) of a single subject of care (patient). This is to support the interoperability of systems and components that need to communicate (access, transfer, add or modify) EHR data via electronic messages or as distributed objects:
   i) Stan Huff and Thomas Beal are updating sections 2 and 3 to be consistent with the CIMI initiative.
   ii) EHR-S FM and ISO EN 13606 lifecycle events should be made consistent

c) Nicholas Oughtibridghe, UK National Health Service http://systems.hscic.gov.uk/ is updating the CONTsys http://www.contsys.net European Standard EN 13940 "Health Informatics - System of concepts to support continuity of care". This standard has now been passed by CEN to the ISO Technical Committee 215 to be further developed as a multi-part International Standard as well as a European Standard, with a broadened scope that beyond basic concepts, also includes process-related ones. Inquiries should be made to nicholas.oughtbridge@nhs.net
   i) EHR-S FIM r3.0 should be made consistent with EN 13940.

d) HL7 has been invited to comment on EN 13606 and EN 13940; where, John Quinn is distributing the drafts to interested reviewers.

2) Don Mon notes that the NIST Report 7804 ("Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Record", February 2012) is "chock full" of information related to functional requirements.

3) Anneke and William Grossen and Michael van der Zel are upgrading the EHR-SFM r2 model, which is hosted in Sparx Enterprise Architect to support the creation of profiles, using the tool.
   a) Project contact is John Ritter; johnritter1@verizon.net
   b) For information, go to EHR-S FM Profile Tool Project Wiki

2013-10-29 (Tu) 2-3PM ET EHR Interoperability WG Technical-Summary

1) 2013-10-29 RI.1.1.1 Originate and Retain Record Entry was analyzed

   a) Conformance Criteria (CCs) were restructured into
      i) pre-condition, EHR-S manager(s) (actions, entities), post-condition (see separate RI.1.1.xlsx spread sheet)

2) COMMENTS/ OBSERVATIONS:

   a) ACTION: Let's prototype CP.6.2 and RI.1.1.1 for EHR WG comment-and-review [Gary]

   b) "We should introduce managers and Data Models" [Gary] see "Notional Description (Scenario)" below

   c) RecordEvent DateTime should include Occurred-DateTime, Reported-DateTime, Entered-DateTime [Gary]

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1 According to the Organization for the Advancement of Structured Information Standards (OASIS) a reference model is "an abstract framework for understanding significant relationships among the entities of some environment, and for the development of consistent standards or specifications supporting that environment. A reference model is based on a small number of unifying concepts and may be used as a basis for education and explaining standards to a non-specialist. A reference model is not directly tied to any standards, technologies or other concrete implementation details, but it does seek to provide a common semantics that can be used unambiguously across and between different implementations."
d) EHR-S contains sets-of (Record, Event, Signature), organized-into encounters, lists, documents. [Gary & Steve]

3) **RI.1.1.1 Notional Description (Scenario):** The Record Entry Manager can **Capture, Create, Copy, Record, Transcribe, Identify, Link, Tag, Encode, Mirror, Integrate** Record-Entry structured-data or unstructured-data and link- to associated Event-Metadata and Signature; where,

4) The **pre-condition** "for each Record Entry":
   a) If the system is down; then, the **Record Information** (Action instance-and-context) SHALL be recordable.

5) The **post-conditions** "for each Record Entry":
   a) The record entry SHALL corresponds to an external Action instance-and-context.
   b) RI.1.1.01 The system SHALL conform to function RI.1.2.1 (Manage Record Entries) as the final step to conclude each Record Lifecycle Event in RI.1.1 (Record Lifecycle) and all child functions.
   c) If the system was down; then, the **Record Information** SHALL be Transcribed into a **Record Entry**; where
      i) **Transcribed** Record Entry shall be **Integrated**
   d) Record Entry SHALL have a unique Instance-Identifier
   e) Record Entry SHALL be structured-or-unstructured
   f) Record Entry may be **Copied** from another Record Entry; where,
      i) **Copied** Record Entry should be linked to the source’s Event-Metadata
   g) Record Entry SHALL be linked to the Signature-Event of the Origination Entry-Author
   h) Unstructured Record Entry may be tagged
   i) Record Entry may be a standard-based Data Object
   j) Record Entry may **Mirror** a standard-based Data Object
   k) Event-Date-Times should include time of event-occurrence, reported, record-entry
   l) Record Entry should be managed according to scope of practice, organizational policy and/or jurisdictional law.

6) **QUESTIONS / ISSUES / ACTIONS:**
   a) **ISSUE (consistency):** When a function defines a context (Create record), should it be consistently be stated as a CC
      pre-condition (trigger) or implicitly be assumed [Steve].
   b) **ISSUE:** What is the scope of a Record Entry?
      i) Is it an encounter record?
      ii) Is it a Data Module (e.g., FHIR Immunization data module)?
      iii) Is it a Data Element?
   c) **ISSUE:** Guideline to use/distinguish EHR-S FM verb-hierarchy vs. EHR-S FM Lifecycle-event verbs?
   d) **ACTION:** Entity (concept nouns) need to be consistently used and defined in a data dictionary.
   e) **ACTION:** Manager Operations (e.g., verbs) need to be defined as a data dictionary
      i) **ISSUE:** What does it mean to Integrate Record Entries?
   f) **ACTION:** UML Model of the Function’s Entities and Manager(s) needs to be done (√ done for RI.1.1.1 below)
   g) **ACTION:** Do a similar analysis-document for CP.6.2 (Immunization Management)
   h) **ACTION:** Model-and-map FHIR to CP.6.2 and RI.1.1.1
   i) **ACTION:** Model-and-map CONTsys Entities (concept-nouns) to CP.6.2 and RI.1.1.1
   j) **INITIAL CONCLUSION & ISSUE:** Building an UML Model of Managers and Data-Modules and creating a structured notional scenario for each function appears to be an effective way to make the overall model consistent; but,  
      i) Maintaining traceability from Function and UML class model operations and attributes (Managers & Data Module elements) will be important as changes in structure of the EHR-S FM conformance criteria occur.
      ii) Additionally, we need to develop the data dictionary and CONTsys mapping
      iii) Initial thoughts suggest that this can best be done with an enormous Excel Workbook and set of worksheets.

1) **Workbook 1:** UML Model Class attributes & operations mapped-to EHR-S FM r2.0 Functions and CCs
   a) This is the primary r2 Function-model to UML-model traceability
      (i) (Column “A”): Class Name
      (ii) (Column “B”): Class attributes mapped-to EHR-S FM r2.0 LOCAL CC#
      (iii) (Column “C”): Class operations mapped-to EHR-S FM r2.0 LOCAL CC#
(iv) (Row 1) EHR FM r2 Function # and LOCAL Conformance Criteria (CC) #
(b) Excel row-column intersections coded with Shall, should, may (S, s, m)
(c) Function # CC # linked to full Function Name and CC in separate workbook
(d) Excel functions and classes roll-ups to simplify model use
(e) Excel EHR-S FM r2.0 S-sections roll-ups to simplify model use

(2) Workbook 2 UML Model Class attributes & operations mapped to EHR-S FIM r3.0 Functions and CCs
(a) This is the primary r3 Function-model to UML-model traceability
(i) (Column "A"): Class Name
(ii) (Column "B"): EHR-S FM Function #
(iii) (Column "C"): EHR-S FM Function Statement
(iv) (Column "D"): EHR-S FM CC Statement

(3) Workbook 3 EHR-S FM r2.0 Functions and LOCAL Conformance Criteria (CC)
(a) This is the full r2 model
(i) (Column "A"): EHR-S FM Function #
(ii) (Column "B"): EHR-S FM Function Statement
(iii) (Column "C"): EHR-S FM CC #
(iv) (Column "D"): EHR-S FM CC Statement

(4) Workbook 4 EHR-S FIM R3.0 Functions and UNIVERSAL Conformance Criteria (CC)
(a) This is the full r3 model
(i) (Column "A"): EHR-S FM Function #
(ii) (Column "B"): EHR-S FM Function Statement
(iii) (Column "C"): EHR-S FM CC #
(iv) (Column "D"): EHR-S FM CC Statement

(5) Workbook 5 EHR-S FM r2.0 Functions and CCs mapped to EHR-S FIM r3.0 Functions and CCs
(a) This is the primary r2 to r3 traceability
(i) (Column "A"): EHR FIM r3 Function # and UNIVERSAL Conformance Criteria (CC) #
(ii) (Row 1): EHR FM r2 Function # and LOCAL Conformance Criteria (CC) #

(6) Workbook 6 Master Data Dictionary (MDD) (If we use FHIR or FHIM; then, MDD is already done by FHIR & FHIM teams)
(i) (Column "A"): Class Name
(ii) (Column "B"): Class attributes
(iii) (Column "C"): Class operations
(iv) (Column "D"): Data Dictionary Definition

(7) Workbook 7 EHR-S FM UML-Model mapped to FHIR (optional)
(8) Workbook 8 EHR-S FM UML-Model mapped to FHIM (Federal Health Information Model) (optional)
(9) Workbook 9 FHIR mapped to FHIM (Federal Health Information Model) (optional)
(10) Workbook 10 EHR-S FM UML Model mapped to FHIR (optional)
INTERIM CONCLUSION 1: So far, in the EHR-S FM Resource Infrastructure (RI) section, we have only looked at the RI.1.1.1 function; yet, in Figure 11 EHR-S RI.1.1.1 Originate and Retain Record Entry (Logical Data and Manager View) we can see that the concepts of a common Event, Record Entry and Record Entry Manager are emerging; where, the Record Entry Manager can Capture, Create, Copy, Record, Transcribe, Identify, Link, Tag, Encode, Mirror, Integrate Record-Entry structured-data or unstructured-data and link-to associated Event-Metadata and Signature. This shows the advantage of creating an EHR-S Function and Information Model, which defines a consistent-set of data-modules (e.g., classes) and managers, which are associated with appropriate EHR-S Functions.

Proceeding 18 October 2013

1) EHR-S FM r2.0 Meaningful Use Profile methodology was presented in new attendee ny Hetty Khan.
2) Julie Roberts and Hetty Khan were taking the 50 test procedures from HHS on MU2 and mapping back to the r2 FM functions.

Telecom Discussion 11 October 2013

4) Gary Dickinson returned from the ISO meeting in Sydney, Australia and reported that
   a) ISO/HL7 10781:2009 Electronic Health Record-System Functional Model, Release 1.1 is under ballot to be consistent with HL7 EHR-S FM r2. Ballot comments are due by December 2013
   b) Health informatics - Electronic Health Record Communication (EN 13606) European Standard is being updated to define a rigorous and stable information architecture for the communicating part or all of the Electronic Health Record (EHR) of a single subject of care (patient). This is to support the interoperability of systems and components that need to communicate (access, transfer, add or modify) EHR data via electronic messages or as distributed objects:
      i) Stan Huff and Thomas Beal are updating sections 2 and 3 to be consistent with the CMI initiative.
      ii) EHR-S FM and ISO EN 13606 lifecycle events should be made consistent
c) Nicholas Oughtibridghe, UK National Health Service http://systems.hscic.gov.uk/ is updating the CONsys http://www.contsys.net European Standard EN 13940 "Health Informatics - System of concepts to support continuity of care". This standard has now been passed by CEN to the ISO Technical Committee 215 to be further developed as a multi-part International Standard as well as a European Standard, with a broadened scope that beyond basic concepts, also includes process-related ones. Inquiries should be made to nicholas.oughtbridge@nhs.net

i) EHR-S FIM r3.0 should be made consistent with EN 13940.

5) HL7 has been invited to comment on EN 13606 and EN 13940; where, John Quinn is distributing the drafts to interested reviewers.

2013-10-29 (Tu) 2-3 PM ET EHR Interoperability WG, Topic: EHR-S FIM r3.0

1) 2013-10-15 CP.6.2 Immunization Management was analyzed

2) Objective: Create a clear, complete, concise, correct and consistent EHR-S Function and Information Model (EHR-S FIM r3.0) from EHR-S FM r2.0, which is HL7 ballot-publishable from Sparx Systems Enterprise Architect tool.

a) Conformance Criteria (CCs) were restructured into

i) pre-condition, EHR-S manager(s) (actions, entities), post-condition (see separate CP.6.2.xlsx spreadsheet)

b) COMMENTS/OBSERVATIONS:

i) ACTION: Let's prototype RI.1.1.1 for comparison of CCs in a different section of the model [Steve]

3) CP.6.2 Notional Description (Scenario): The System Manager can Capture, Auto-populate, Maintain, Render, Transmit, Exchange, Harmonize, Update, Determine Immunization Administrations, Events, Schedules, Plans and Educational Materials; where,

a) The pre-condition “The System provides the capability to”

i) SHALL conform to function CP.3.2 (Manage Patient Clinical Measurements) to capture other clinical data pertinent to the immunization administration (e.g., vital signs).

ii) SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).

iii) SHALL conform to function CP.1.6 (Manage Immunization List).

iv) SHALL Capture an Immunization Administration; where, an Immunization Administration Record Entry contains details as discrete data,

including:

1) immunization name/type, series, strength and dose

2) date and time of administration

3) manufacturer, lot number, expiration date

4) route and site of administration

5) administering provider

6) observations, reactions and complications

7) reason immunization not given

v) SHALL Determine and Render Required Immunizations; where, Required Immunizations includes when they are due, based on widely accepted immunization schedules, when Rendering encounter information.

vi) SHALL Maintain a Patient specific Immunization Schedule.

vii) SHALL Render a Patient's Immunization Administration History upon request from appropriate authorities such as schools or day-care centers.

viii) SHALL Render an Immunization Order as written (e.g., exact clinician order language or as mandated - such as by a public health requirement), when rendering administration information.

ix) SHALL Determine due-and-overdue Immunization Orders including earliest through latest date ranges and Render a Immunization Order Notification according to organizational policy and/or jurisdictional law.

x) SHALL Render a Patient Immunization Administration Educational Information regarding the administration (e.g., Vaccine Information Statement (VIS)).

xi) SHALL Capture that Patient Immunization Administration Educational Information (e.g., VIS) was provided at the time of immunization administration.

xii) SHOULD Update Patient's Immunization Administration History at the time of capturing an immunization administration.

xiii) SHOULD Capture, in an Immunization Administration discrete-field, an Allergy/Adverse Reaction to a Specific Immunization Administration.

xiv) SHOULD Link Standard Codes (e.g., NDC, LOINC, SNOMED or CPT) with discrete data elements associated with an Immunization Administration.
xv) SHOULD Transmit required Patient Immunization Administration information to a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law.

xvi) SHOULD Exchange Patient Immunization Administration History with public health immunization registries according to scope of practice, organizational policy and/or jurisdictional law.

xvii) SHOULD Harmonize Patient Immunization Administration History with a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law.

xviii) SHOULD Capture and Render Patient Immunization Administration History from a public health immunization registry.

xix) SHOULD Capture that Patient Immunization Administration Educational Information (e.g., VIS) including to whom the information was provided and the date/time that it was provided.

xx) SHOULD Capture and Maintain immunization refusal reasons as discrete data.

xxi) SHOULD Capture Patient Immunization Administration Preferences regarding receipt of immunization (e.g., refusal of certain vaccines) at time of immunization administration.

xxii) MAY auto-populate the immunization administration record as a by-product of Verification of Administering Provider, Patient, Medication, (dose, route) and Time.

b) The post-conditions “The System provides the ability to”

i) SHALL be managed according to scope of practice, organizational policy and/or jurisdictional law.

4) QUESTIONS / ISSUES / ACTIONS:

a) ISSUE: It is important to separate the system capabilities vs. policies, which may change.

INTERIM CONCLUSION 2: In the CP section, we have looked at medication management, orders management and Immunization management. We can see that Figure 12 EHR-S Conceptual View for CP.6.2 Immunization Management is generally applicable for all of the Care Provisioning (CP) section of the EHR-S FM; where, minor element additions and modifications will likely occur as we analyze the rest of the CP section; but, we can already see an 80% to 90% view.

INTERIM CONCLUSION 3: So far, in the EHR-S FM Care Provision (CP) section, we have only modeled the medication management, orders management and Immunization management functions; yet, in Figure 13...
CP.6.2 Immunization Management (Logical Data and Manager View) we can see that substantially more immunization-applicable data-elements are available than were defined by CP.6.2 alone. This shows the consistency-advantage of creating an EHR-S Function-and-Information Model, which defines a consistent-set of data-modules (e.g., classes) and associates them with appropriate EHR-S Functions.

We can also see a high-level EHR System defined as a set of Patients, Providers, External Partners, Encounters, EMRs, Care Plans, Lists, Managers, Documents and Notes; where, the EHR-S Manager can Capture, Auto-populate, Maintain, Render, Transmit, Exchange, Harmonize, Update, Determine the RI.1.1 Record Entry content, which in CP.6.2 is Immunization Administrations, Events, Schedules, Plans and Educational Materials. Because of the ad-hoc nature of the EHR-S FM r2.0 creation, we cannot be sure that the attributes or operations for any class are fully populated until the entire EHR-S FM r2.0 has been modeled.

![Figure 13 CP.6.2 Immunization Management (Logical Data and Manager View)](image-url)
3 September 2013

See “CIMI and HL7 Trip Report”, Cambridge, MA, 20-26 September 2013, Stephen Hufnagel,
SHufnagel@tiag.net, dated 3 October 2013

POCs

This information is NOT shown is publically-distributed PDF versions of the document.