



November 2013

EHR Work-Group (EHR WG)

Cumulative-FY14 Summary-Report

Last Updated on Dec 7, 2013 by SHufnagel@tiag.net, facilitator

Edmond Scientific subcontractor to Veterans Health Administration/

Health Informatics/ Office of Informatics & Analytics/ Knowledge Based Systems

The complete-and-latest version of the Summary-Report is available at:

[http://wiki.hl7.org/images/0/0a/Hufnagel - FY2014 HL7-EHR-WG Summary-Report.pdf](http://wiki.hl7.org/images/0/0a/Hufnagel_-_FY2014_HL7-EHR-WG_Summary-Report.pdf)

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.

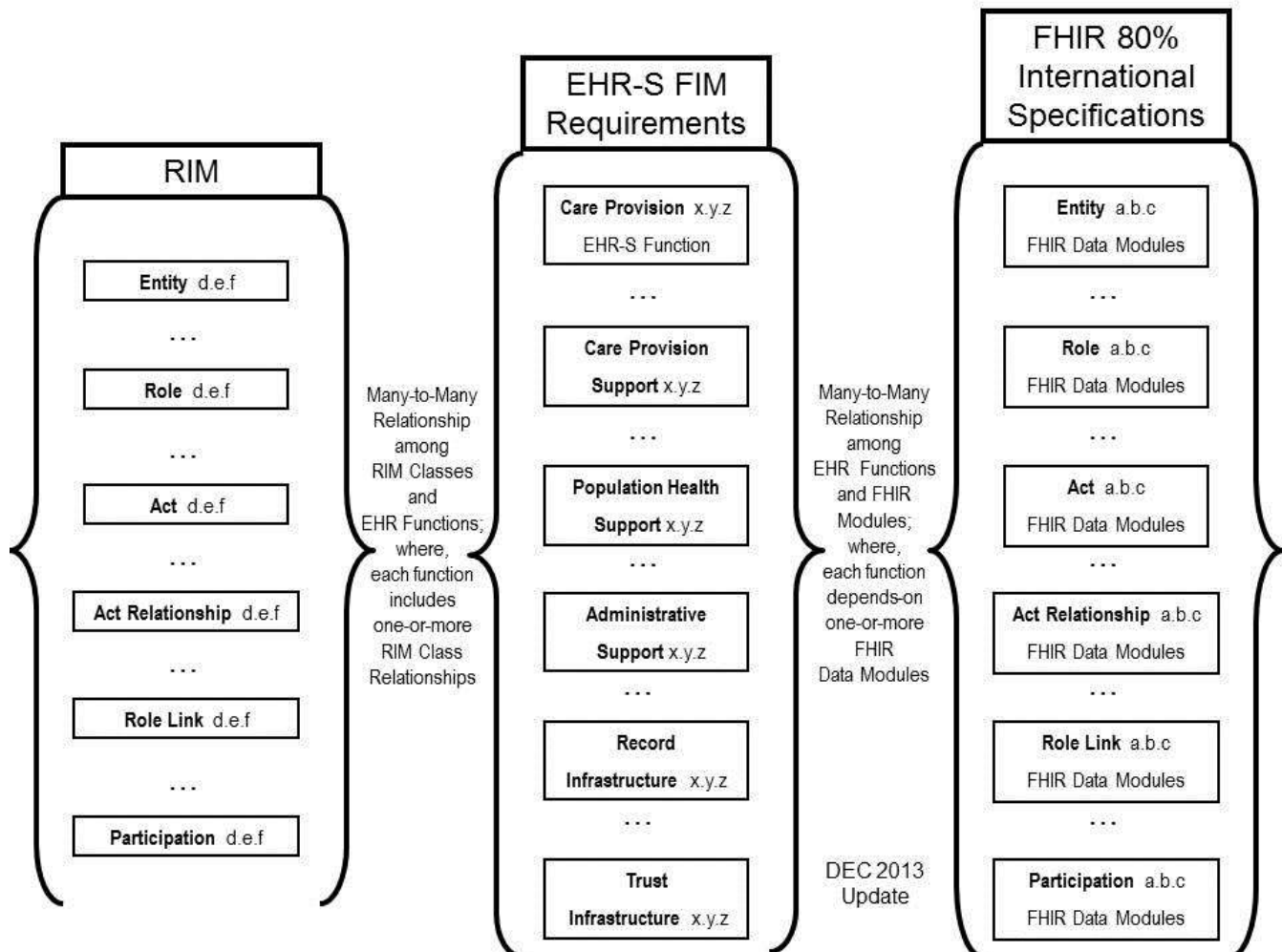


Figure 1 RIM-and-FHIR Relationship with EHR-S FIM release-3 [2012 PSS #688]

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-**specifications** 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:
[http://wiki.hl7.org/images/0/0a/Hufnagel - FY2014 HL7-EHR-WG Summary-Report.pdf](http://wiki.hl7.org/images/0/0a/Hufnagel_-_FY2014_HL7-EHR-WG_Summary-Report.pdf)

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/managelistsevs.cfm>
- HL7 Workgroup Call-Schedule: <http://www.hl7.org/concalls/default.aspx>
- EHR WG Wiki: <http://wiki.hl7.org/index.php?title=EHR>

Health Level Seven – Electronic Health Record Work Group Weekly Teleconference Schedule Revised: 20 November 2013						
Day	Time US ET	Activity	Lead(s)	Dial-In	Screen Sharing	List Server (for agendas, announcements)
Mon	1200	Records Management/ Evidentiary Support	Warner, Gelzer	1-877-668-4493 Code 927 002 088#	Link	EHR Legal
Tues	1300	EHRs FM Release 3 Planning	Hufnagel, Dickinson	1-770-657-9270, Passcode 510269#	Link	EHR Interop
	1400	Meaningful Use Functional Profile	Datta, Dickinson	1-770-657-9270, Passcode 510269#	Link	EHR Interop
	1500	FULL EHR WG	Co-Chairs	1-770-657-9270, Passcode 510269#	Link	EHR WG
Wed	1200	Personal Health Record WG	Ritter, Dickinson, Doo	1-770-657-9270, Passcode 510269#	TBA	EHR PHR
	1300	EHR System Usability WG	Mon, Ritter, Rocca, Gartner	1-770-657-9270, Passcode 510269#	Link	EHR Usability
Thur	Open					
Fri	0930	EHR WG Co-Chairs	Co-Chairs	1-770-657-9270, Passcode 510269#	TBA	N/A

- **[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 **MXV** for immunology
- f) **HITSP C32**, **HL7 CCD** and **CCDA-CCD** for VLER Health data
- g) **ICD9 CPT4/HCPCS** ICD9PCS 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

- vii) POP.7 Public Health Related Updates
- viii) POP.8 De-Identified Data Request Management
- ix) POP.9 Support Consistent Healthcare Management of Patient Groups or Populations
- x) POP.10 Manage Population Health Study-Related Identifiers

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 Lifespan
- 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: AdverseReaction, AllergyIntolerance, CarePlan, FamilyHistory, 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

2	2	October 2013	8
3	3	September 2013	15

MONTHLY SUMMARIES

(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.oughtibridge@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-S FM 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]

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."

- 52 d) EHR-S contains sets-of (Record, Event, Signature), organized-into encounters, lists, documents. [Gary & Steve]
- 53 3) **RI.1.1.1 Notional Description (Scenario):** The Record Entry Manager can **Capture, Create, Copy, Record,**
- 54 **Transcribe, Identify, Link, Tag, Encode, Mirror, Integrate** Record-Entry structured-data or unstructured-data and link-
- 55 to associated Event-Metadata and Signature; where,
- 56 4) The **pre-condition** "for each Record Entry"
- 57 a) **If the system is down, the** Record Information (Action instance-and-context) SHALL be recordable.
- 58 5) The **post-conditions** "for each Record Entry"
- 59 a) The record entry SHALL corresponds to an external Action instance-and-context,
- 60 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
- 61 in RI.1.1 (Record Lifecycle) and all child functions.
- 62 c) **If the system was down; then, the** Record Information SHALL be Transcribed into a Record Entry; where
- 63 i) **Transcribed** Record Entry should be **Integrated**
- 64 d) Record Entry SHALL have a unique Instance-Identifier
- 65 e) Record Entry SHALL be structured-or-unstructured
- 66 f) Record Entry may be **Copied** from another Record Entry; where,
- 67 i) **Copied** Record Entry should be linked to the source's Event-Metadata
- 68 g) Record Entry SHALL be linked to the Signature-Event of the Origination Entry-Author
- 69 h) **Unstructured** Record Entry may be tagged
- 70 i) Record Entry may be a standard-based Data Object
- 71 j) Record Entry may **Mirror** a standard-based Data Object
- 72 k) EventDate-Times should include time of event: occurrence, reported, record-entry
- 73 l) Record Entry should be managed according to scope of practice, organizational policy and/or jurisdictional law.
- 74 6) **QUESTIONS / ISSUES / ACTIONS:**
- 75 a) **ISSUE (consistency):** When a function defines a context (Create record), should it be consistently be stated as a CC
- 76 pre-condition (trigger) or implicitly be assumed [Steve].
- 77 b) **ISSUE:** What is the scope of a Record Entry?
- 78 i) Is it an encounter record?
- 79 ii) Is it a Data Module (e.g., FHIR Immunization data module)?
- 80 iii) Is it a Data Element?
- 81 c) **ISSUE:** Guideline to use/distinguish EHR-S FM verb-hierarchy vs. EHR-S FM Lifecycle-event verbs?
- 82 d) **ACTION:** Entity (concept nouns) need to be consistently used and defined in a data dictionary.
- 83 e) **ACTION:** Manager Operations (e.g., verbs) need to be defined in a data dictionary
- 84 i) **ISSUE:** What does it mean to **Integrate Record Entries**?
- 85 f) **ACTION:** UML Model of the Function's Entities and Manager(s) needs to be done (✓ done for RI.1.1.1 below)
- 86 g) **ACTION:** Do a similar analysis-document for CP.6.2 (Immunization Management)
- 87 h) **ACTION:** Model-and-map FHIR to CP.6.2 and RI.1.1.1
- 88 i) **ACTION:** Model-and-map CONTsys Entities (concept-nouns) to CP.6.2 and RI.1.1.1
- 89 j) **INITIAL CONCLUSION & ISSUE:** Building an UML Model of Managers and Data-Modules and creating a structured
- 90 notional scenario for each function appears to be an effective way to make the overall model consistent, but,
- 91 i) Maintaining **traceability** from Function and UML class model operations and attributes (Managers & Data
- 92 Module elements) will be important as changes in structure of the EHR-S FM conformance criteria occur.
- 93 ii) Additionally, we need to develop the data dictionary and CONTsys mapping
- 94 iii) Initial thoughts suggest that this can best be done with an enormous Excel Workbook and set of worksheets.
- 95 (1) **Workbook 1:** UML Model Class attributes & operations mapped-to EHR-S FM r2.0 Functions and CCs
- 96 (a) This is the primary r2 Function-model to UML-model traceability
- 97 (i) (Column "A"): Class Name
- 98 (ii) (Column "B"): Class attributes mapped-to EHR-S FM r2.0 LOCAL CC#
- 99 (iii) (Column "C"): Class **operations** mapped-to EHR-S FM r2.0 LOCAL CC#

- 100 (iv) (Row 1) EHR FM r2 Function # and LOCAL Conformance Criteria (CC) #
 101 (b) Excel row-column Intersections coded with Shall, should, may (S, s, m)
 102 (c) Function # CC # linked-to full Function Name and CC in separate workbook
 103 (d) Excel functions and classes roll-ups to simplify model use
 104 (e) Excel EHR-S FM r2.0 5-sections roll-ups to simplify model use
- 105 **(2) Workbook 2 UML Model Class attributes & operations mapped to EHR-S FIM r3.0 Functions and CCs**
 106 (a) **This is the primary r3 Function-model to UML-model traceability**
 107 (i) (Column "A"): Class Name
 108 (ii) (Column "B"): Class attributes mapped-to EHR-S FM r3.0 LOCAL CC#
 109 (iii) (Column "C"): Class operations mapped-to EHR-S FM r3.0 LOCAL CC#
 110 (iv) (Row 1): EHR FIM r3.0 UNIVERSAL Conformance Criteria #
- 111 **(3) Workbook 3 EHR-S FM r2.0 Functions and LOCAL Conformance Criteria (CC)**
 112 (a) **This is the full r2 model**
 113 (i) (Column "A"): **EHR-S FM Function #**
 114 (ii) (Column "B"): **EHR-S FM Function Statement**
 115 (iii) (Column "C"): **EHR-S FM CC #**
 116 (iv) (Column "D"): **EHR-S FM CC Statement**
- 117 **(4) Workbook 4 EHR-S FIM R3.0 Functions and UNIVERSAL Conformance Criteria (CC)**
 118 (a) **This is the full r3 model**
 119 (i) (Column "A"): **EHR-S FM Function #**
 120 (ii) (Column "B"): **EHR-S FM Function Statement**
 121 (iii) (Column "C"): **EHR-S FM CC #**
 122 (iv) (Column "D"): **EHR-S FM CC Statement**
- 123 **(5) Workbook 5 EHR-S FM r2.0 Functions and CCs mapped-to EHR-S FIM r3.0 Functions and CCs**
 124 (a) **This is the primary r2 to r3 traceability**
 125 (i) (Column "A"): EHR FIM r3 Function # and UNIVERSAL Conformance Criteria (CC) #
 126 (ii) (Row 1): EHR FM r2 Function # and LOCAL Conformance Criteria (CC) #
- 127 **(6) Workbook 6 Master Data Dictionary (MDD)** (If we use FHIR or FHIM; then, MDD is already done by FHIR & FHIM teams)
 128 (i) (Column "A"): Class Name
 129 (ii) (Column "B"): Class attributes
 130 (iii) (Column "C"): Class operations
 131 (iv) (Column "D"): Data Dictionary Definition
- 132 **(7) Workbook 7 EHR-S FM UML-Model mapped-to FHIR (optional)**
 133 **(8) Workbook 8 EHR-S FM UML-Model mapped-to FHIM (Federal Health Information Model) (optional)**
 134 **(9) Workbook 9 FHIR mapped-to FHIM (Federal Health Information Model) (optional)**
 135 **(10) Workbook 10 EHR-S FM UML Model mapped-to FHIR (optional)**
 136

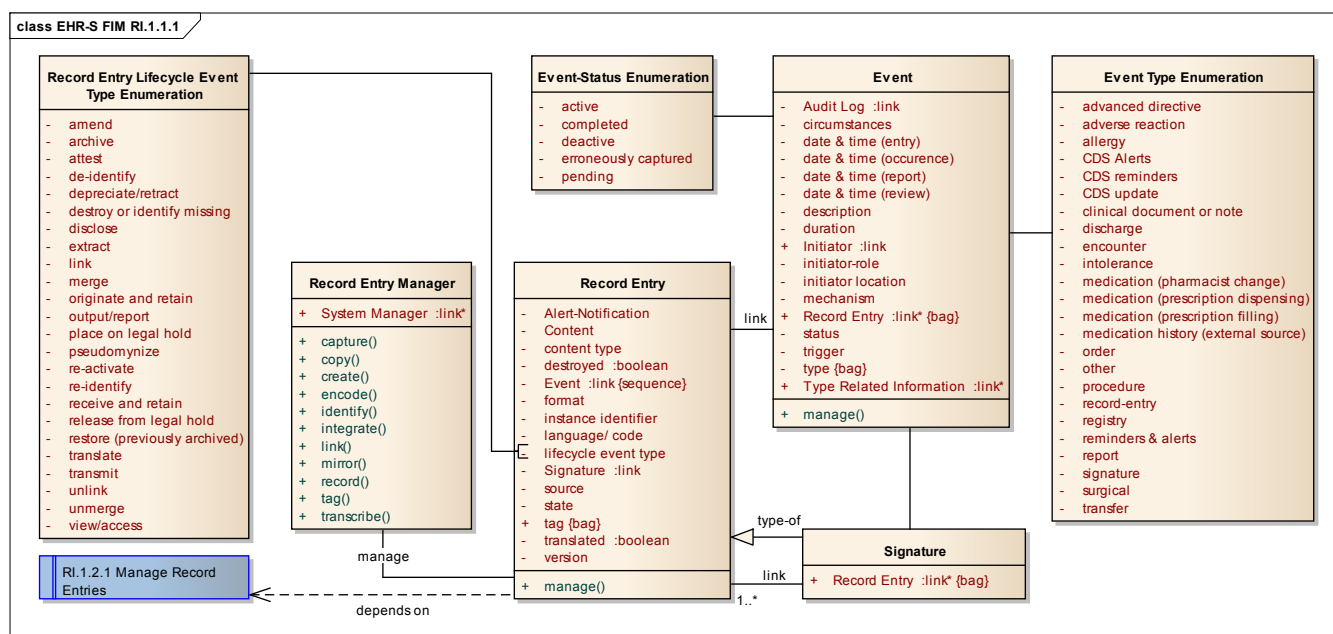


Figure 11 EHR-S RI.1.1.1 Originate and Retain Record Entry (Logical Data and Manager View)

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.

Telecom Discussion 18 October 2013

- 1) EHR-SFM r2.0 Meaningful Use Profile methodology was presented for new attendees by Hetty Khan.
- 2) Julie Roberts and Hetty Khan are 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 CIMI initiative.
 - ii) EHR-S FM and ISO EN 13606 lifecycle events should be made consistent

- c) Nicholas Oughtibridge, 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.oughtibridge@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 spread sheet)
- 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.
- ix) 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.
- xi) 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.

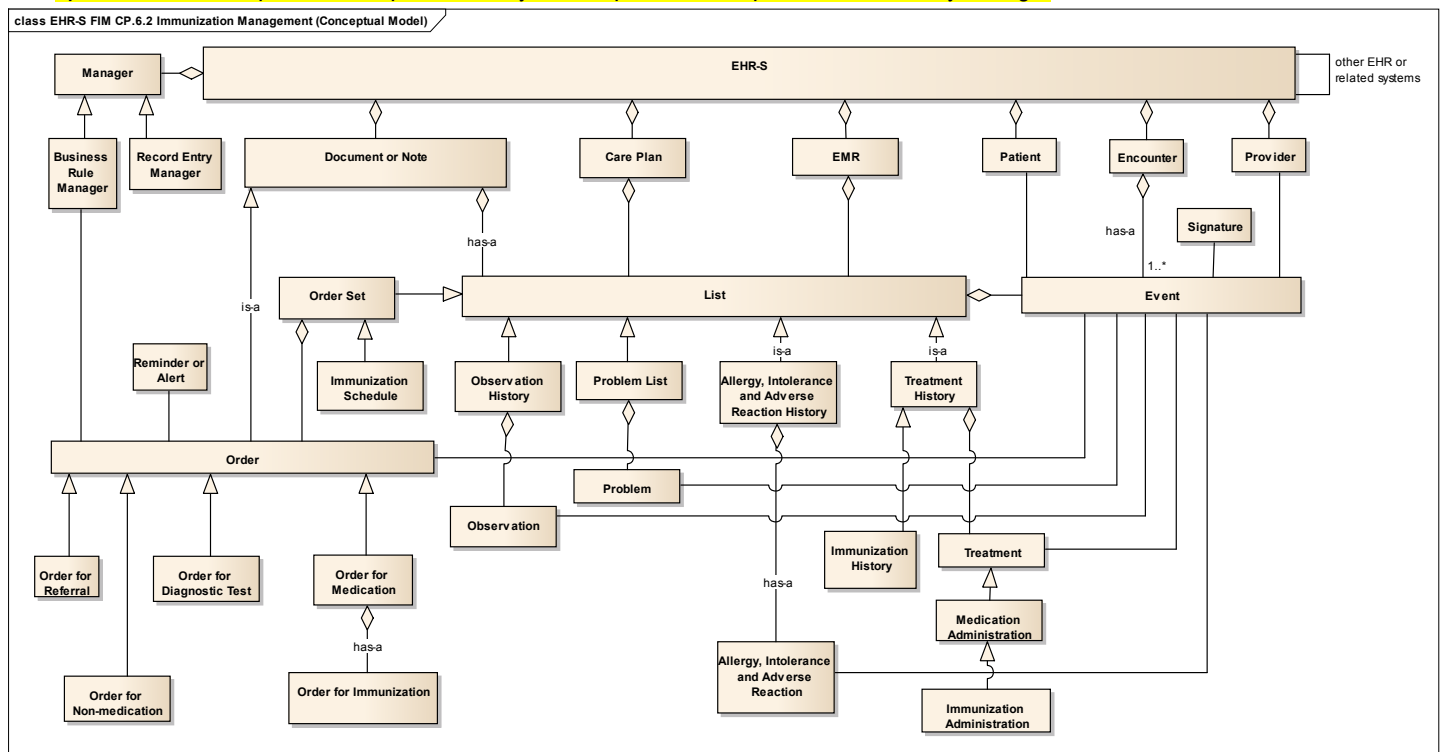


Figure 12 EHR-S Conceptual View for CP.6.2 Immunization Management

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.

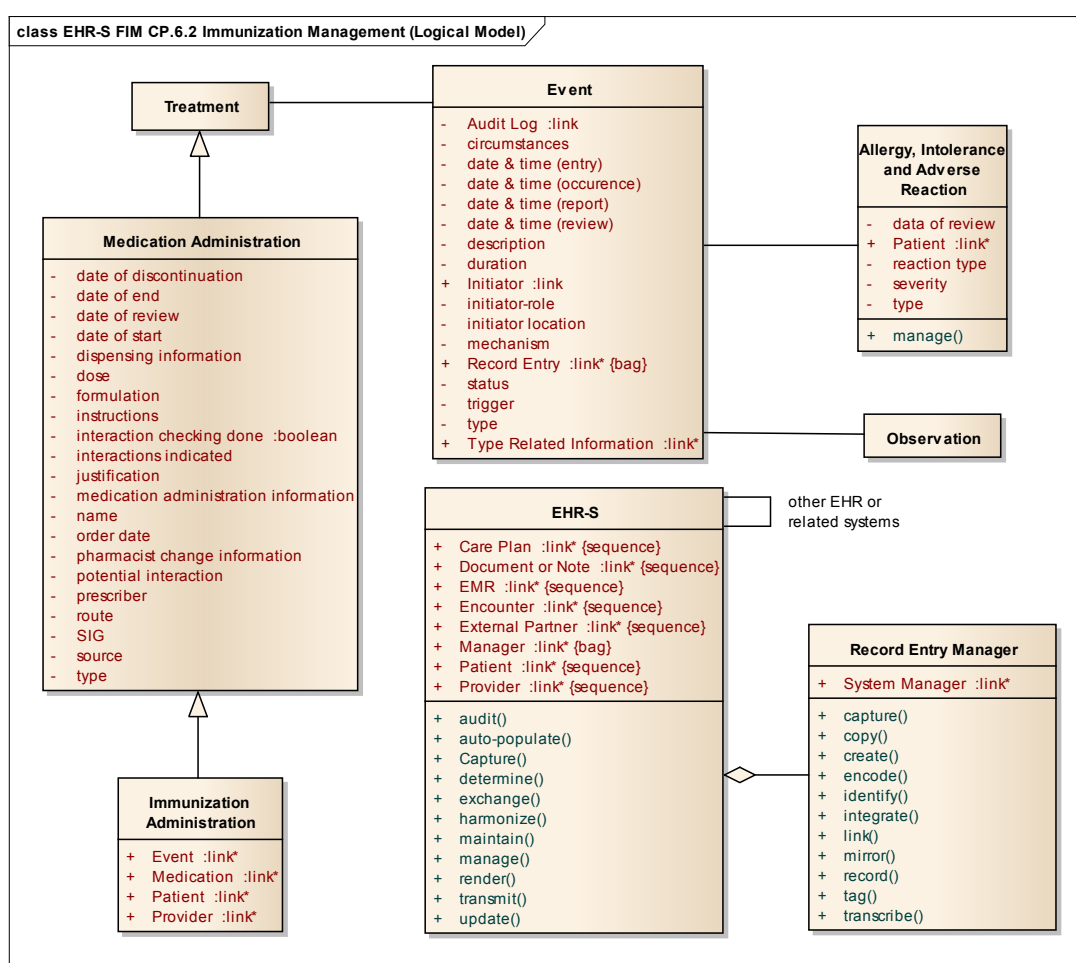


Figure 13 CP.6.2 Immunization Management (Logical Data and Manager View)

260 **3 September 2013**

261 **See “CIMI and HL7 Trip Report”**, Cambridge, MA, 20-26 September 2013, Stephen Hufnagel,
262 SHufnagel@tiag.net, dated 3 October 2013
263

264 **POCs**

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