Monthly Summary Briefing

HL7 EHR Work Group (EHR-WG)

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December 30, 2013

Frequently-Updated Working-Draft
EHR Work Group
Goal & Objectives

• **Electronic Health Record (EHR) Work Group’s goal** is to support the HL7 mission of developing standards for EHR data, information, functionality, and interoperability.
  – Functional and Information Requirements for Electronic Health Records (EHR) and systems (EHRS),
  – Functional and Information Requirements for Personal Health Records (PHR) and systems (PHRS),

• **EHR Interoperability WG’s objectives are**
  1. to create a clear, complete, concise, correct and consistent EHR-S FIM r3.0 in the Sparx Systems Enterprise Architect (EA) tool; where, it addresses the issues identified by the VA negative r2.0 ballot.
  2. to produce a Meaningful Use profile for r2.0.

• **Resource Management Evidentiary Support (RM-ES) project’s objective** is to provide expertise on records management, compliance, and data/record integrity and governance to support the use of medical records for clinical care and decision-making, business, legal and disclosure purposes.

• **EHR Usability WG’s objective** is developing a usability profile for the EHR-S FM

• **PHR-S WG’s objective** is to maintain a Patient Healthcare System Functional Model (PHR-S FM).

**NOTE:** EHR-S FIM is **NOT** intended to imply a specific implementation architecture or workflow!
## EHR WG Logistics

### Schedule:  [http://www.hl7.org/concalls/default.aspx](http://www.hl7.org/concalls/default.aspx)
### List Server:  [http://www.hl7.org/myhl7/managelistservs.cfm](http://www.hl7.org/myhl7/managelistservs.cfm)

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

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1. Introduction, Executive-Summary, Plan-of-Actions & Milestones
2. EHR-S Concept-of-Operations Reference Use-Case and Model
3. CP.6.2 Immunization-Management Deep-Dive
4. RI.1.1.1 Originate-and-Retain Record-Entry Deep-Dive
5. EHR-S FIM linked-to FHIR for Allergy, Intolerance and Adverse-Reaction
6. EHR-S FIM linked-to FHIM for Allergy, Intolerance and Adverse-Reaction
7. Traceability

EHR-S FIM 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
USE CASE: "Jack owns a car."  "Jack drives a '2013 Ford Car."

RELATIONSHIPS: The Car has 4 wheels and depends-on gasoline.

REQUIREMENT: The car MUST be new.

The '2013 Ford Car is a realization of Jack's wife's requirement for Jack to drive a new car.
Executive Summary

EHR-S FIM r3:2016 Preparation

This executive summary specifically addresses potential work-group impacts and/or trends, which are important for VA, IPO and DOD awareness.

EHR System Function-and-Information Model (EHR-S FIM)

- **Structured, based-on a fully-specified Reference Model (RM) for**
  - Clear, complete, concise, correct, consistent and intuitive ease-of-use;
  - Sparx Enterprise Architect (EA) UML-model tool-based; where, release 3 (r3)
    - manages user-activities, system-functions, business-rules, interoperable-data separately; and,
    - Consistent-global r3 Conformance Criteria (CCs) replace ad-hoc-local r2 CCs
    - r3 Infrastructure-section contains previously-separate r2 Record-and-Trust Infrastructure-sections

- **EA Tool-generated Interoperability-Specifications based-on Use-Cases**
  - Use-Cases come-from HITSP & S&I Framework Use-Case Simplification work linked-to
  - Requirements, which come-from EHR-S r2.0 Functions’ and their restructured CCs linked-to
  - International Interoperability-Specifications based-on HL7 FHIR (Fast Healthcare Interoperability Resources)
  - US-Realm Interoperability-Specifications based-on FHA FHIM (Federal Health Information Model)
  - Behavioral Specifications can be included, based-on IHE or other Protocols.

**NOTE:** EHR-S FIM is **NOT** intended to imply a specific architecture or workflow!
1. **EHR-S FIM vision** is to become the “Easy Button” for *EHR Interoperability Specifications*
   a. Easily-customizable to user-specific profiles.
   b. Including a US-Realm Meaningful Use (MU) & FHIM profile
   c. EHR-S FIM r3:2016 within Sparx EA represents a powerful HL7 product; where,
      i. EA integrates FHIR, FHIM and S&I Framework’s Use-Case Simplification, and
      ii. The EA tool-based EHR-S FIM is consistently governed and configuration-managed
      iii. The EA tool can generate both a navigable-web-site and printable-report
      iv. user-specific profiles (e.g., WG project DAMs, DIMs, DCMs) can be supported.

2. **EHR-S FIM Release-3 needs the same IP license as FHIR to foster user engagement**

3. **HL7.org/EHRSFIM web-site** should be setup-and-managed by the EHR Interoperability WG
   a. Supporting peer review, trial-use and stakeholder-contribution during Release-3 development.

4. **EHR-S FIM development, tooling and balloting resources** = (estimated) 6-FTE Man-years
   a. 4 development FTEs + 1 Tooling FTE + 1 Balloting FTE
   b. A marketing campaign is needed to justify EHR-S FIM r3:2016 resources
Plan-of-Actions and Milestones
FY2014Q1  POA&M
EHR-S FIM Release-3:2016 Preparation

October 2013 (Identify processes, tools and issues/risks)  Completed
- Prototype CP.6.2 Immunization Management  22-Oct-13
- Prototype RI.1.1.1 Originate-and-Retain Record-Entry  29-Oct-13

November 2013 (Prototype complete process-and-products)
- Prototype FHIR integration (Allergies, Intolerance & Adverse Reaction)  5-Nov-13
- Prototype FHIM integration (Allergies, Intolerance & Adverse Reaction)  8-Nov-13
- Define & Prototype EHR-S Reference Use-Case, Model and Approach  30-Nov-13
- Prototype Report generation of Immunization Interoperability-Specification  in-progress

December 2013 (Develop production WBS and POA&M)
- Harmonize with ISO/EN 13940 Continuity-of-Care System-of-Concepts  pending
- Harmonize with Electronic Health Record Communication (ISO/EN 13606)  pending
- Prototype EHR-S FIM Ballot Production process-and-products for prototype  pending
- Create Release 3 Work-Break-Down Structure (WBS) & POA&M

January 2014 – 2016 (Approve & Execute Plan)
- Jan 2013: Present Prototype, WBS & POA&M at HL7 WG meeting; then, execute POA&M.
- Establish public website to get broad peer-review
- Setup EA tool with finalized Release 2, after ISO ballot reconciliation
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EHR-S FIM Release-3:2016 Preparation

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7. Traceability

The EHR-S reference model (RM) framework [based-on OASIS RM definition]

1. Structures significant-relationships among EHR-S entities
   - defined-by EHR-S Action-and-Information Conceptual-Models; where,
   - EHR-S RM is based-on a functional-use-case constrained hierarchical-lexicon of
     • nouns (Data-Entities) and noun qualifiers (Data-hierarchy or Sub-Types),
     • verbs (Actions) and verb qualifiers (Action-hierarchy or Sub-Types ) with
     • conditions {Business Rules based on laws, policies, preferences}; where,
   - Conformance Criteria (CC) are scenario-threads through the reference use-case & model.

2. Defines Conformance-Criteria syntax-and-semantics; where,
   - Functions and their profiles constrain the Verb sub-types, Noun sub-types and Conditions
   - Functions can-be linked-to Information Exchanges (IEs),
   - IEs can-be linked-to implementation standards-technologies-paradigms-and-patterns.

   • 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."
A Clinician and Patient and/or their designated Agents have Encounters; where, they use an EHR-S (EHR System) GUI (Graphical-User-Interface) to manage EMRs (Electronic Medical Records), in accordance with scope-of-practice, organizational-policy, jurisdictional-law, and patient-preferences; where, they can

- **review** the Patient EMR (Electronic Medical Record) and associated Information
- **observe and treat the** Patient, **write** Orders and document the Encounter
- **provide** patient Information and educational-Information
- **enter** EMR Records and associated Information; where,
  - **Record Entries** are Orders, Treatments, Observations and associated Information
  - **Lists** are Care-Plans, Care-Records, Problems-and-Concerns, Documents & Notes
- **sign** Encounter by the Clinician(s) and possibly by the Patient
Business Rules \{BRules\} constrain Clinician, Patient or their designated agents' use-of EHR-S operations "according to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent."

Operation-and-Data Types are organized into sub-type hierarchies or inheritance taxonomies.

Conformance Criteria (CCs) are scenario threads through the Use-Case Reference Model
EHR-S RM System-Actions Sub-Types aka Verb-Hierarchy

**Business Rules (BRules)**

 constrain Clinician, Patient or their designated agents’ EHR-S operations "according to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent."
ISSUE: Gora suggests only using aggregation to make the diagram more intuitive
• **System**
  – EHR or PHR

• **SF Invariant-condition** (context)
  – System Function (SF)
  – Profile

• **SF CC Identification** (Number)

• **SF CC Pre-condition** (trigger)
  – Pre-condition is a subordinate clause.
  – After a Human-Action or System-Action; then,

• **SF CC Applicability**
  – The System SHALL, SHOULD or MAY

• **SF CC Type**
  – “provide-the-ability-to”
  – “directly”

• **SF CC Bindings**
  – Operation linked-to Data-Type; where, conditionally,
  – SF the System-Actions conforms-to other-SF
  – Data-Type are associated-with other Data-Types
  – Information Exchange(s) are linked-to
    • International Interoperability-Standards (e.g., FHIR)
    • Realm Interoperability-Specifications (e.g., FHIM)
    • Implementation Guides (e.g., Consolidated CDA)
    • Behavioral Interoperability-Specifications (e.g., IHE)
    • Service Level Agreement (e.g., local workflow)

• **SF Post-Condition** (expected-outcome)
  – Post-condition is a subordinate clause.
  – “where, the System-Actions are …”

• **See Also**
  – Supporting or related SFs (e.g., Infrastructure)
CP.6.2#01 During an **Encounter**, the EHR system SHALL provide the ability to **capture** Immunization Administration details as discrete data-requirements, realized-by **FHIR** (Fast Healthcare Interoperability Resource) data-specifications; where, the Immunization-Administration Record-Entry is associated with the following resources:

- AdverseReaction and other Observations,
- Patient, Practitioner, Organization, Location;

In the US Realm, Immunization-Administration and associated resources are realized-by **FHIR-profiles** based-on **FHIM** (Federal Health Information Model) Domains of:

- Immunization, Adverse Reaction, Allergy and Intolerance, Care-Plan,
EHR-S RM
Interim Conclusions
EHR-S FIM r3.0:2016 Preparation

• We have looked at Medication-and-Immunization Management, Orders-and-Results Management and Record Entry Management; where,
  • The EHR-S RM (reference model) was used to structure EHR-S functions-and-data; where, the function’s conformance-criteria lexicon defines the grammar of nouns (entities), qualifiers (data-types), verbs (operations), qualifiers (verb-types) and constraints (conditions/business rules).

• The EHR-S Conceptual Information Model (CIM) and Conceptual Operations Model (COM) for CP.6.2 Immunization Management should generally-be-applicable for all of the Care Provisioning (CP) section of the EHR-S FM; where,
  • minor CIM modifications will likely occur as we analyze the rest of the CP & CPS sections
  • major COM components still must be substantially developed based-on the rest of the CP and CPS sections.
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Initial EHR-S FM R2 CP.6.2
Reference Use-Case

“According to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent,”

- **A Clinician uses the EHR-S, during an Encounter, to**
  - review EMR, Alerts-and-Notifications
  - enter Observations, Treatments, Orders and associated Documents and Notes
  - sign the Encounter

- **Immunization Management involves the following:**
  - **System-Actions:** auto-populate, capture, determine, exchange, harmonize, link, maintain, manage, render, transmit, update
  - **Data:** Immunization-Administration, Immunization-History, Public-Health Registry
Initial EHR-S FM R2 CP.6.2 Reference Model

**Human-Actions**  
- Patient Encounter  
  - review EMR  
  - enter Records  
  - observe Patient  
  - treat Patient  
  - write Orders  
  - sign Encounter  

**System-Actions**  
- CP.6.2 Manage Immunization Administration Actions  
  - transmit  
  - render  
  - exchange  
  - maintain  
  - determine  
  - link  
  - auto populate  
  - harmonize  
  - capture  
  - manage

**Conceptual-Information Model**  
- CP.6.2 Care Coordination Data  
  - Registry (Public Health)  
  - Immunization History  
  - Immunization Schedule  
  - Immunization Administration Record  
  - Order Set  
  - Care Plan  
  - Documents & Notes  
  - Treatment  
  - Information  
  - Observation  
  - Signature

- **Business Rules (BRules)** constrain Clinician, Patient or their designated agents’ use of EHR-S operations "according to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent."

- **Operation-and-Data Types** are organized into sub-type hierarchies or inheritance taxonomies.

- **Conformance Criteria (CCs)** are scenario threads through the Use-Case Reference Model
Initial EHR-S FM R2 CP.6.2
Conformance-Criteria

Human-Actions

System-Actions

CC Bindings

Conceptual-Information Model

Business Rules (BRules) constrain Clinician, Patient or their designated agents' EHR-S operations according to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent. Operation-and-Data Types are hierarchically refined by domain.
Where, Allergies, Intolerance and Adverse-Reaction, Immunization-Schedule, Alerts and Notifications, Education-Information are treated separately.
The Release-3 EHR System Immunization-Management Function

- captures, auto-populates, links, renders, transmits, maintains Immunization-Administration Record-Entries; where,
  - the links are with Standard-Codes
  - The transmission is to Population Health Registries
  - The auto-population is as a by-product of verification of Administering-Provider, Patient, Medication, Dose, Route and Time.
- updates Immunization-Histories from the Immunization-Administration Record-Entries
- harmonizes Immunization-Histories with Public-Health Registries
- renders and transmits Immunization-Histories
  - Where the transmissions are to Appropriate Authorities (e.g., Schools and Day Care Centers);
and where, System-Actions are according-to scope-of-practice, organizational-policy and/or jurisdictional-law.
Business Rules (BRules) constrain Clinician, Patient or their designated agents' use-of EHR-S operations "according to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent."

Operation-and-Data Types are organized into sub-type hierarchies or inheritance taxonomies.

Conformance Criteria (CCs) are scenario threads through the Use-Case Reference Model.
1. Is there one System-Wide Reference-Immunization-Schedule linked-to each Patient or does each Patient have an auto-populated and then updated Immunization-Schedule harmonized-with a reference Immunization-Schedule or don't we care?
2. Can the reference or individual Patient Immunization-Schedule be updated?
3. Should there be a Manage Immunization-Schedule sub-function?

What is the difference between decide and determine?
**EHR-S-FM R2.0:2013**

**Conformance Criteria (CCs)**

**CP.6.2 Immunization Management**

**capture, maintain and render Immunization-Administration Record-Entry**

**R2: CP.6.2#01** The system **SHALL** provide the ability to capture, maintain and render immunization administration details as discrete data, including:

1. the immunization name/type, 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 and/or immunization related activity not performed; according to scope-of-practice, organizational-policy and/or jurisdictional-law."

**R3: CP.6.2#01** During an **Encounter**, the EHR system **SHALL** provide-the-ability-to **capture-maintain-and-render** an Immunization-Administration;

- where, the System-Actions are documented in discrete **Record Entries** fields; and
- where, data-requirements may-be realized-by **FHIR** (Fast Healthcare Interoperability Resource) data-specifications;
- where, the Immunization-Administration is associated with AdverseReaction and other-Observations, Patient, Practitioner, Organization and Location resources;
- where in the US-Realm, Immunization-Administration and associated data can be realized-by **FHIR-profiles based-on** **FHAM** (Federal Health Information Model) Domains of Immunization, Adverse Reaction, Allergy and Intolerance, Care-Plan, Encounter, Health Concern, Person, Provider, Public Health Reporting, Patient Education, Vital Signs.
**auto-populate Immunization-Administration Record**

- **R2: CP.6.2#02** The system MAY auto-populate the immunization administration record as a by-product of verification of administering provider, patient, medication, dose, route and time according to scope-of-practice, organizational-policy and/or jurisdictional-law.

- **R3: CP.6.2#02** After verification of Administering-Provider, Patient, Medication, Dose, Route and Time, the System MAY directly auto-populate the Immunization-Administration Record-Entry; where, System-Actions are according to scope-of-practice, organizational-policy and/or jurisdictional-law.

**determine and render Immunization-Schedule**

- **R2: CP.6.2#03** The system SHALL provide the ability to determine and render required immunizations, and when they are due, based on widely accepted immunization schedules, when rendering encounter information.

- **R3: CP.6.2#01** The System SHALL provide-the-ability-to capture-determine-and-render the Patient’s Immunization-Schedule; where, the System-Actions are based on widely-accepted reference Immunization-Schedules.
**capture Allergy, Intolerance and Adverse Event**

- **R2: CP.6.2#04** The system SHOULD provide the ability to *capture*, *in a discrete field*, an *allergy/adverse reaction to a specific immunization*.

- **R3: CP.6.2#04** Associated-with a Patient Immunization-Administration, the system SHOULD provide-the-ability-to *capture an Allergy, Intolerance and Adverse Event*; where, System-Actions are documented as discrete-data-elements.

**capture Clinical-Data**

- **R2: CP.6.2#05** The system **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).

- **R3: CP.6.2#05** The system **SHALL** provide-the-ability-to *capture Observations*; where, they are pertinent to the immunization administration (e.g., vital signs); and where, the System-Actions are conformant-to function CP.3.2 (Manage Patient Clinical Measurements).
**link Standard-Codes**

- **R2: CP.6.2#06** The system SHOULD provide the ability to link standard codes (e.g. NDC, LOINC, SNOMED or CPT) with discrete data elements associated with an immunization.

- **R3: CP.6.2#06** For discrete-data-elements associated-with an Immunization-Administration, the system SHOULD provide-the-ability-to link-to Standard-Codes; where, examples of Standard-Codes are NDC, LOINC, SNOMED or CPT.

**maintain Immunization-Schedule**

- **R2: CP.6.2#07** The system SHALL provide the ability to maintain the immunization schedule.

- **R3: CP.6.2#07** The system SHALL provide-the-ability-to maintain the Immunization-Schedule.
render Immunization-History

- **R2**: CP.6.2#08 The system SHALL provide the ability to render a patient’s immunization history upon request for appropriate authorities such as schools or day-care centers.
- **R3**: CP.6.2#08 Upon request from appropriate authorities, such as schools or day-care centers, the system SHALL provide-the-ability-to render a Patient’s Immunization History; where, System-Actions are according-to scope-of-practice, organizational-policy and/or jurisdictional-law.

manage Allergy, Intolerance and Adverse Reaction List

- **R2**: CP.6.2#09 The system SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).
- **R3**: CP.6.2#09 As appropriate, The system SHALL manage Allergy, Intolerance and Adverse Reaction Lists; where, System-Actions are conformant-to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).
transmit Immunization-Administration Record-Entry

- **R2: CP.6.2#10** The system SHOULD transmit required immunization administration information to a public health immunization registry according-to scope-of-practice, organizational-policy and/or jurisdictional-law.

- **R3: CP.6.2#10** As appropriate, the System SHOULD directly transmit Immunization-Administration information; where, System-Actions are with Public-Health Immunization-Registries; and where, System-Actions are according-to scope-of-practice, organizational-policy and/or jurisdictional-law.

exchange Immunization History

- **R2: CP.6.2#11** The system SHOULD exchange immunization histories with public health immunization registries according-to scope-of-practice, organizational-policy and/or jurisdictional-law.

- **R3: CP.6.2#11** When Immunization History is updated, the System SHOULD directly exchange Immunization-Histories; where, the System-Actions are with Public-Health Immunization-Registries; and where, System-Actions are according-to scope-of-practice, organizational-policy and/or jurisdictional-law.
**harmonize Immunization Histories**

- **R2: CP.6.2#12** The system SHOULD harmonize Immunization histories with a public health immunization registry according to scope-of-practice, organizational-policy and/or jurisdictional-law.

- **R3: CP.6.2#12** When Immunization History is *updated*, the System SHOULD directly harmonize Immunization-Histories; where, System-Actions are with a Public Health Immunization Registry; and where, System-Actions are according-to scope-of-practice, organizational-policy and/or jurisdictional-law.

**capture and render Immunization History from a Public-Health Registry**

- **R2: CP.6.2#13** The system SHOULD capture and render immunization histories from a public health immunization registry.

- **R3: CP.6.2#13** As appropriate, the system SHOULD harmonize capture and render Immunization Histories; where, System-Actions are with a Public Health Immunization Registry; and where, System-Actions are according-to scope-of-practice, organizational-policy and/or jurisdictional-law.
manage **Immunization-Administration List (History)**

- **R2: CP.6.2#14** The system SHALL conform to function CP.1.6 (Manage Immunization List).
- **R3: CP.6.2#14** The system SHALL directly manage Immunization Lists; where, the System-Actions are conformant-to function CP.1.6 (Manage Immunization List).

**update Immunization History**

- **R2: CP.6.2#15** The system SHOULD provide the ability to update immunization histories at the time of capturing an immunization administration.
- **R3: CP.6.2#15** At the time of capturing an Immunization-Administration, the system SHOULD provide-the-ability-to update Immunization-Histories.
render Immunization Order

- **R2: CP.6.2#16** The system **SHALL** provide the ability to render the immunization order as written (i.e., exact clinician order language) when rendering administration information.

- **R3: CP.6.2#16** When *rendering Immunization-Administration Information*, the system **SHALL** provide-the-ability-to *render* the Immunization Order; where, the Immunization Order is the exact clinician order language.

determine and render Notification

- **R2: CP.6.2#17** The system **SHALL** provide the ability to determine due and overdue ordered immunizations and render a notification.

- **R3: CP.6.2#17** For due-and-overdue ordered-immunizations, the system **SHALL** provide-the-ability-to *determine and render* a Notification.
**render Patient Educational Information**

- **R2: CP.6.2#18** The system **SHALL** provide the ability to render a patient educational information regarding the administration (e.g., Vaccine Information Statement (VIS)).

- **R3: CP.6.2#18** During an **Immunization-Administration Encounter**, the system **SHALL** provide-the-ability-to **render Patient Educational-Information**; where, the System-Action is regarding the **Immunization-Administration** (e.g., Vaccine Information Statement (VIS)).

**capture Patient Educational-Information Provided-Flag**

- **R2: CP.6.2#19** The system **SHALL** provide the ability to capture that patient educational information (e.g., VIS) was provided at the time of immunization administration.

- **R3: CP.6.2#19** At the time of **Immunization-Administration**, the system **SHALL** provide-the-ability-to **capture** an **Indication**; where, System-Actions are confirming-that **Patient Educational Information** (e.g., VIS) was provided.
EHR-S-FM R2.0:2013
Conformance Criteria (CCs)
CP.6.2 Immunization Management

capture Patient Educational-Information Provided-Documentation

- R2: CP.6.2#20 The system SHALL provide the ability to capture documentation that patient educational information (e.g., VIS) was provided at the time of immunization administration.

- R3: CP.6.2#20 At the time of Immunization Administration, the system SHALL provide the ability to capture Event Documentation; where, the System-Actions document the who, what, when, where, how of the patient receiving educational information (e.g., VIS).

capture Receiving Entity

- R2: CP.6.2#21 The system SHALL provide the ability to capture the receiving entity (e.g., patient, representative, organization) when patient education information is provided at the time of immunization administration.

- R3: CP.6.2#21 During an Immunization-Administration Encounter and when Patient Education-Information is provided, the system SHALL provide the ability to capture the Entity; where, the System-Actions identify the patient, representative or organization receiving the Patient Education-Information.
**capture and maintain Justification**

- **R2: CP.6.2#22** The system SHOULD provide the ability to capture and maintain immunization refusal reasons as discrete data.

- **R3: CP.6.2#22** When Immunization-Administration is refused, the system SHOULD provide-the-ability-to capture-and-maintain Justification; where, System-Actions are to document the Justification as discrete-data-elements.

**capture Patient’s Preference**

- **R2: CP.6.2#23** The system SHOULD provide the ability to capture patient preferences regarding receipt of immunization (e.g. refusal of certain vaccine types) at time of immunization administration.

- **R3: CP.6.2#23** At the time of immunization administration, the system SHOULD provide-the-ability-to capture Patient-Preferences; where, the System-Actions are regarding refusal of certain vaccine types.
EHR-S-FIM
Conceptual Traceability Model
CP.6.2 Immunization Management

class EHR-S FIM CP.6.2 Immunization Management (Conceptual Traceability Model)

- CP.1.6 Manage Immunization List
- CP.6.2#07
- CP.6.2#13
- Immunization Schedule
- Immunization History
- Allergy, Intolerance and Adverse Reaction
- Immunization Administration
- CP.1.2 Manage Allergies
- CP.3.2 Manage Patient Clinical Measurements
- CP.6.2#08
- CP.6.2#15
- CP.6.2#20
- CP.6.2#02
- CP.6.2#04
- CP.6.2#22
- CP.6.2#10
- CP.6.2#17
- CP.6.2#18
- CP.6.2#19
- CP.6.2#21
- CP.6.2#23
- Order for Immunization

SHALL
SHOULD
MAY
SHALL
SHOULD
SHALL
SHOULD
SHALL
SHOULD
SHALL
SHOULD
SHOULD
SHOULD
SHOULD
SHOULD
SHOULD
SHOULD
SHOULD
class EHR-S FIM CP.6.2 Immunization Management (Logical Model)

Immunization Administration

+ date (recommended booster)
+ immunization type
+ series (immunization)
+ dose
- educational information received :boolean
- encounter
- future booster
- healthcare organization
- immunization order
- immunization provider
- lot
- manufacturer
- ordered immunization due date
- patient preference for immunization
- receiving entity (educational information)
- refusal of vaccine type
- route of administration
- time (administration)
- type
+ AllergyIntolerance and Adverse Reaction :link*
- Event :link*
- Medication :link*
- Patient :link*
- Provider :link*

«SHOULD»
- justification-immunization refusal

«MAY»
+ auto-populate()

«SHALL»
+ render()
+ capture()
+ maintain()

«SHOULD»
+ transmit()
**EHR-S FIM**

**Logical Traceability-Model**

**CP.6.2 Immunization Management**

class EHR-S FIM CP.6.2 Immunization Management (Logical Model-2)

- **Immunization Schedule**
  - «SHALL» + determine()
  - + maintain()
  - + render()

- **Order for Immunization**
  - «SHALL» + notification
  - «SHALL» + determine()
  - + render()

- **Immunization History**
  - exchange()
  - harmonize()
  - «SHALL» + manage()
  - render()
  - «SHOULD» + capture()
  - update()

- **Immunization Administration Record**
  - «MAY» + auto-populate()
  - «SHALL» + render()
  - + capture()
  - + maintain()
  - «SHOULD» + transmit()

- **Allergy, Intolerance and Adverse Reaction**
  - data of review
  - Patient :link*
  - reaction type
  - severity
  - type
  - source
  - «SHALL» + capture()
Based on the Medication Management, Orders Management and Immunization Management functions, we see

- A high-level EHR-S Information Model emerging as a set of
  - Patients, Providers, External Partners, Encounters, EMRs, Care Plans, Lists, Managers, Documents and Notes;
- A high-level EHR-S Manager Model is emerging to
  - Capture, Auto-populate, Maintain, Render, Transmit, Exchange, Harmonize, Update, Determine
1. Introduction, Executive-Summary, Plan-of-Actions & Milestones
2. EHR-S Concept-of-Operations Reference Use-Case and Model
3. CP.6.2 Immunization-Management Deep-Dive
4. Ri.1.1.1 Originate-and-Retain Record-Entry Deep-Dive
5. EHR-S FIM linked-to FHIR for Allergy, Intolerance and Adverse-Reaction
6. EHR-S FIM linked-to FHIM for Allergy, Intolerance and Adverse-Reaction
7. Traceability
EHR-S FIM
Conceptual Information Model (CIM)
RI.1.1.1 Originate and Retain Record Entry

class RI.1.1.1 Originate and Retain Record Entry (Conceptual Traceability View)

other EHR or related systems

EHR-S

Event

Record Entry

Signature

RI.1.1.1#01

RI.1.1.1#02

RI.1.1.1#03

RI.1.1.1#04

RI.1.1.1#05

RI.1.1.1#06

RI.1.1.1#07

RI.1.1.1#08

RI.1.1.1#09

RI.1.1.1#10

RI.1.1.1#11

RI.1.1.1#12

depends on

SHOULD

MAY

SHALL

link 0..*

depends on

SHOULD

MAY

SHALL

SHALL

SHOULD
**EHR-S FIM**

**Traceability View**

**RI.1.1.1 Originate-and-Retain Record Entry**

**Record Entry Traceability-Attributes**

- Alert-Notification
- Content
- content type
- destroyed :boolean
- Event :link (sequence)
- format
- language/ code
- lifecycle event type
- Record Entry :link (bag)
- state
- tag (bag)
- translated :boolean
- version
  «SHALL»
- instance identifier
  - Signature :SignatureEvent*
  «SHOULD»
- source
- copy()
- encode()
- exchange()
- identify()
- link()
- mirror()
- record()
- transcribe()
  «SHALL»
- capture()
  «MAY»
  capture and maintain()
  tag(unstructuredData)
  «SHOULD»
- integrate()
- transmit()
  «SHALL»
- Event :link
  - date & time (entry)
  - date & time (occurrence)
  - date & time (viewed/accessed)
  - description
  - duration
  - Initiator :link
  - initiator-role
  - initiator-location
  - mechanism
  - Record Entry :link (bag)
  - status
  - trigger
  - type (bag)
  - Type Related Information :link*

**ISSUE**: show operation conditions/constraints in report?

**SHALL/SHOULD/MAY** shown as stereotype and realization-connector-label

Name: Record Entry Traceability-Attributes
Author: Steve Hufnagel
Version: prototype
Created: 11/9/2013 11:56:33 AM
Updated: 11/9/2013 12:05:50 PM

[Diagram showing relationships between elements related to traceability and operations.]
1. RI.1.1.1#01 The system SHALL provide the ability to capture (originate) a Record Entry instance corresponding to an Action instance and context.
2. RI.1.1.1#02 The system SHALL capture a unique instance identifier for each Record Entry.
3. RI.1.1.1#03 The system SHALL conform to function TI.2.1.1.1 (Originate/Retain Record Entry Audit Trigger), including specified metadata.
4. RI.1.1.1#04 The system SHALL capture the signature event (e.g., digital signature) of the origination entry Author, binding signature to Record Entry content.
5. RI.1.1.1#05 The system SHALL provide the ability to capture both structured and unstructured content in Record Entries.
6. RI.1.1.1#06 The system SHALL provide the ability to capture Record Entries from information recorded during system downtime.
7. RI.1.1.1#07 The system SHOULD provide the ability to integrate Record Entries from Information recorded during system downtime.
8. RI.1.1.1#08 The system SHALL provide the ability to capture date/time an Action was taken or data was collected if different than date/time of the Record Entry.
9. RI.1.1.1#09 The system SHOULD capture metadata that identifies the source of non-originated Record Entry (e.g., templated, copied, duplicated, or boilerplate information).
10. RI.1.1.1#10 The system MAY provide the ability to tag unstructured Record Entry content to organize it according to need, for example, in a time-related fashion or by application-specific groups (such as photographs, handwritten notes, or auditory sounds).
11. RI.1.1.1#11 The system MAY capture and maintain a Record Entry encoded as a standards-based data object (e.g., HL7 Continuity of Care or other HL7 CDA R2 Document).
12. RI.1.1.1#12 The system MAY capture and maintain a standards-based data object to mirror (be duplicate and synchronous with) internal Record Entry representation.
RI.1.1.1 Originate and Retain Record Entry

Resultant Description (Notional Scenario)

- The EHR-S Record-Entry manager can
  - Capture, Create, Copy, Record, Transcribe, Identify,
  - Link, Tag, Encode, Mirror, and Integrate
- Record-Entries as
  - structured or unstructured-data link-to associated
    - Event-Metadata and Signatures.
we have only looked at the RI.1.1.1 function; yet,

- we see that the emergence of common Record-Entries, Events, Record Entries and a Record Entry Manager
- which can Capture, Create, Copy, Record, Transcribe, Identify, Link, Tag, Encode, Mirror, Integrate
  - structured-data or unstructured-data and link-to
  - associated Event-Metadata and Signature.
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6. EHR-S FIM linked-to FHIM for Allergy, Intolerance and Adverse-Reaction
7. Traceability

ISSUE: EHR-S FM r2.0 Implied Information Model is Ad-Hoc; where, FHIR & FHIM Information Model & Data Dictionary are Configuration Managed.

- **FHIR Administrative**
  - **Attribution**: Patient, RelatedPerson, Practitioner, Organization
  - **Resources**: Device, Location, Substance, Group
  - **Workflow Management**: Encounter, Alert, Supply, Order, OrderResponse
  - **Financial**: Coverage

- **FHIR Clinical**
  - **General**: AdverseReaction, AllergyIntolerance, CarePlan, FamilyHistory, Condition, Procedure, Questionnaire
  - **Medications**: Medication, MedicationPrescription, MedicationAdministration, MedicationDispense, MedicationStatement, Immunization, ImmunizationProfile
  - **Diagnostic**: Observation, DiagnosticReport, DiagnosticOrder, ImagingStudy, Specimen
  - **Device Interaction**: DeviceCapabilities, DeviceLog, DeviceObservation

- **FHIR Infrastructure**
  - **Support**: List, Media, Other, DocumentReference, (Binary)
  - **Audit**: Provenance, SecurityEvent
  - **Exchange**: Document, Message, OperationOutcome, Query
  - **Conformance**: Conformance, ValueSet, Profile
The 2016 EHR-S FIM release-3 objective is for an analyst-or-architect to use the EA-tool to
1. Create a use case from a prescribed lexicon of Entities, Events, Modifiers and Actions; where,
2. the lexicon is mapped to applicable EHR System Functions; where,
3. the EA-tool can generate an Interoperability-Specification (IS) containing
   - UML EHR-S-FIM/FHIR/FHIM profile, based-on the use-case
   - including FHIR-XML (International)
   - including FHIR-FHIM-XML (US Realm) with appropriate terminology value-set binding;
   - Where, other realm models could be added to the EA-tool by interested stakeholders
   - profiles can be further refined to support local needs.

EHR-S-FIM is EHR System Function-and-Information model
FHIR is Fast Healthcare Interoperability Resource
FHIM is US Federal Health Information Model
Prototype
Allergy, Intolerance & Adverse-Reaction
FHIR Design-Specification

Name: FHIR Specification for Allergy, Intolerance and Adverse Reaction
Author: Steve Hufnagel
Version: Prototype
Created: 11/5/2013 4:25:17 AM
Updated: 11/8/2013 4:49:33 PM

class FHIR Specification for Allergy, Intolerance and Adverse Reaction

- + data of review
- + Patient :link*
- + reaction type
- + severity
- + type
- + source
- + manage()

- + identifier :Identifier [0..1]
- + criticality :code [0..1]
- + sensitivityType :code
- + recordedDate :dateTime [0..1]
- + status :code
- + subject :Resource(Patient)
- + recorder :Resource(Practitioner|Patient)
- + reaction :Resource(AdverseReaction)* [0..1]
- + sensitivityTest :Resource(Observation)* [0..1]

- + identifier [0..*] (bag)
- + reactionDate :dateTime [0..1]
- + subject :link*
- + didNotOccurFlag :boolean
- + recorder :link* [0..1]

- + code :CodeableConcept
- + severity :ReactionSeverity [0..1]

- + exposure.exposureDate :dateTime [0..1]
- + exposure.exposureType :code [0..1]
- + exposure.causalityExpectation :code [0..1]
- + exposure.substance :Resource(Substance)* [0..1]
- + AllergyIntolerance.sensitivityType :code
- + recordedDate :dateTime [0..1]
- + status :code
- + subject :Resource(Patient)
- + recorder :Resource(Practitioner|Patient)
- + substance :Resource(Substance)*
- + reaction :Resource(AdverseReaction)* [0..1]
Contents

FY2014Q1-Prototype Report
EHR-S FIM Release-3:2016 Preparation

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Prototype
FHIM-Detailed Allergy & Intolerance Specification

Note that participation classes are used when we need date/time or comments, otherwise, we point directly to Individual Provider. This why there are "authors" from Comment Event, etc., but Intolerance Condition uses the Author Participation.
Prototype
FHIM Detailed Adverse-Reaction Specification

class FHIM Adverse-Event Reporting Domain

Name: FHIM Adverse-Event Reporting Domain
Author: Steve Hufnagel
Version: Prototype
Created: 11/7/2013 12:42:32 PM
Updated: 11/8/2013 4:54:03 PM

Details shown on separate diagram.
INTERIM CONCLUSION

EHR-S FIM, FHIR and FHIM complement each other; where,
• EHR-S FIM defines Requirements; where,
  • EHR-S FIM needs data-specifications and Dictionary and
  • FHIR & FHIM provide data-specifications and Dictionary
• FHIR defines the International Data-Specifications (“The 80% set”)
• FHIM can define the US-FHA FHIR-Profile
• Joint Configuration Management is essential for FIM/FHIR/FHIM consistent

A FIM-FHIR-FHIM populated UML-Tool (e.g., EA or RSA) can manage
• Requirements from EHR-S FIM
• International Data-Specifications from FHIR
• US-Realm Data-Specifications-Profile from FHIM