'2013 CP.6.2 Immunization Management
HL7 EHR-S FIM r3 Prototype-Demonstration
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EHR-Interoperability Work Group, January 2014, San Antonio, TX

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The complete-and-latest versions of EHR Interoperability WG documents are available at:

Executive Summary
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; where, the Work Group and its
projects create-and-promote appropriate-and-necessary standards.

HL7 Project Scope Statement (PSS) #688 is for EHR-S Function-and-Information Model Release-3, which
is planned for '2017 ballot (ISO/ HL7 10781 r3:2017 EHR-S FIM). This report demonstrates 1-function; where,
150-functions remain to be done over the next three-years.

Our vision is to restructure the '2014 HL7 EHR-S Functional Model (FM) Release-2 into clear, complete, concise,
correct, consistent and easy-to-use functions and conformance criteria within the UML-modeled EHR-S FIM
Release-3 Enterprise Architect (EA) platform, which is capable of managing profiles (e.g., personal health record,
behavorial health, long-term care, emergency department, inpatient, outpatient or individual-system); and where,
profile reports or web-sites can be automatically-generated, which include graphical and text
1. Function use-cases for entities, system-actions, information-exchanges; and, requirements-scenarios for each
function’s conformance-criteria, which can be constrained according-to patient-preference, situation,
scope-of-practice, organizational-policy and jurisdictional-law.
2. Requirements lifecycle-traceability throughout version-and-profile configuration-baselines.
3. Complete and traceable HL7 Service Aware Interoperability Framework (SAIF) implementation-guides, including
implementation-paradigm profiles; such as, those for messages, CDA documents, web-services; where, domain,
realm and enterprise standards, behavioral-protocols, data-models with terminology-bindings can be included to
produce a fully-qualified, semantically-interoperable exchange-architecture of system Information-Exchanges (IEs)
and their implementable, testable and certifiable Interoperability-Specifications (ISs). This prototype
document contains a partial-example for "Allergy, Intolerance and Adverse Reaction" showing HL7-International
Fast Healthcare Interoperability Resources (FHIR) and US-realm Federal Healthcare Information Model (FHIM)
classes.

Our Linguistic Methodology hierarchically-constrains the UML-modeled EHR-S lexicon-of entities, actions and
information-flows into function document-sections and sub-sections modeled-as data-flow use-cases with
paragraphs of user-story scenario-sentences; where, these scenario-sentences are also known as
conformance-criteria (CC). As an example, the Immunization-Management function’s use-case has 23 CC user-story
scenarios, which can be further constrained according-to patient-preference, context, scope-of-practice,
organizational-policy and jurisdictional-law.
Our EA platform is an EHR-informatics knowledge-repository and expert-system force-multiplier, which institutionalizes informatics-wisdom; where, it empowers users to efficiently-and-effectively reuse informatics-knowledge in EHR-related areas such as

- Business requirements, use-cases, user-story scenarios;
- Platform-independent (logical) architectural design-specifications
- Platform-specific (implementable) development, test and certification requirements-specifications and guides.

The benefit of our recommended methodology-and-technology is that high-quality and low-cost EHR-S FIM profiled web-sites and reports can be generated in hours-or-days by one-person; where formerly, weeks-or-months were required by an integrated product team. Initial results may still require subject-matter-expert verification-and-validation (V&V) to identify special-needs and gaps; where, a capability approach proposal can then be developed as-the-basis-of both strategic gap-mitigation and tactical investment-and-execution planning. The benefit of using Sparx Enterprise Architect (EA) as the underlying EHR-S FIM platform is the built-in support for enterprise-wide, full-lifecycle, model-driven, architecture-and-design solutions for visualizing, analyzing, simulating, testing and maintaining EHR-related systems, software, processes and architectures; where, EA is a collaborative team-based modeling, design, management-and-documentation tool based on UML 2.4.1. EA's Standard XML Metadata Interchange (XMI) export capability allows the use of other tools, such as IBM's Rational Software/System Architect.

The estimated resources needed to bring the EHR-S FIM vision to fruition are 3-FTEs allocated for 2-years; where, 6-total FTEs = 2-weeks per-function * 150 functions = 5-hours per conformance criteria (CC) * 2500 CC. And, adding specific implementation-paradigm capabilities will require additional resources.

**Open Issues:**

1) The estimated EHR-S FIM r3 development requirements are 6-FTEs.
2) How should EHR-S FM be harmonized with the HL7 Conformance-Testing Initiative?
3) How should EHR-S FM be harmonized with the HL7 FHIR and FHA FHIM?
   a) Same entity-names, data-dictionary, Sparx EA model, which can generate FHIR XML profiles.
   b) **ACTION:** (3-Jan-14 co-chairs) prepare brief & coordinate with Ken McCaslin, TSC chair, and John Quinn for TSC presentation on Data Standardization and EHR-S FM's organizational role in defining data-context.
4) We need a release-3 Governance/Change-Request process over the next 3-years
   a) conformance criteria are being restructured
   b) Use-case and scenario descriptions and diagrams are being added
   c) Entity data module and element names and definitions are potentially being harmonized with
      i)  ISO/EN 13940 Continuity-of-Care System-of-Concepts, FHIR & FHIM
5) Concurrently maintaining release-2 baseline traceability to release-2 profiles and release-3.
   a) Once finalized we need a Sparx EA EAP file Release-2 baseline on Gforge
   b) Similarly, as profiles are finalized, their EAP files need to be baselined on Gforge.
6) www.hl7.org/EHR home-page for EHR-S FIM development
   a) **Status** (26-Dec-13): PSS submitted to Electronic Support committee, which meets on 6-Jan-14
   b) **Plan-B** is to link to a micro-project web-site on a commercial web-site.
Legend
1) Capitalized and Underlined nouns and adjectives are Record-Entry data-types aka data-model, which should be in the EHR-S FM data dictionary; and, italicized verbs are manage sub-types aka verb-hierarchy. See www.skmtglossary.org for standard healthcare data-dictionary / glossary.
2) Blue-Bold words are recommended-additions to original text.
3) Red-Bold words are recommended-deletions from the original text.
4) Highlighted Yellow words are issues-Actions and/or important new material for the main EHR WG to review.

Acknowledgements
This work is based-on and is intended to institutionalize ideas developed within
• American Health Information Community (AHIC) Use cases
• ANSI Healthcare Information Technology Standards Panel (HITSP) Interoperability Specifications
• ONC's Standards and Interoperability (S&I) framework Use-Case Simplification initiative
• DOD and VA Integrated and now Interoperable EHR (iEHR) initiative
• DOD and VA respective EHR Modernization initiatives.
• Open Source EHR Custodial Agent (OSEHRA)
• Clinical Information Modeling Initiative (CIMI)
• Joint HL7-and-OMG Healthcare Service Specification Project (HSSP)
• HL7 International EHR Workgroup (EHR WG) and Architecture Review Board (ArB)

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Jan 2014 Immunization-Management Prototype-Report for San Antonio WG Presentation

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Introduction: This report summarizes the '2013 EHR-S FIM Release-3 prototype work done in anticipation of EHR-S-FM Release-2 ballot reconciliation; where, once release-2 is finalized and a configuration baseline has been established, then, release-3 work can truly commence.

Reference: ‘2003 Institute of Medicine (IOM) Key Capabilities of an Electronic Health Record System
- Decision Support,
- Results Management,
- Order Entry/Mgmt./CPOE,
- Administrative Processes,
- Patient Support/Education
- Health Information and Data,
- Reporting & PopHealth Mgmt.,
- Communication and Connectivity
**INTRODUCTION**: HL7 EHR-S FIM (Function–and-Information Model) release-3 PSS (Project Scope Statement) #688 was approved in January 2012; where, EHR-S and PHR-S FIM release-3 (r3) follows an agile-process to

- formally-structure EHR functional-requirements, based upon a reference model (RM), to address the structural issues identified by the release-2 ballot and

- add UML data requirements-specifications, based on release-2 functions and their conformance criteria.

- create a clear, complete, concise, correct and consistent EHR-S FIM r3.0 from EHR-S FM r2.0, which is HL7 ballot-publishable from Sparx Systems Enterprise Architect (EA) tool.

- interoperate-with Fast Healthcare Interoperability Resource (FHIR)

- interoperate-with US-realm Federal Health Information Model (FHIM)

- Harmonize with ISO/EN 13606 Health informatics - Electronic Health Record Communication standard

- Harmonize with ISO/EN 13940 "Health Informatics - System of Concepts to Support Continuity-of-Care (CONTsys) standard
**HL7 SAIF IG**: This report demonstrates the HL7 EHR-S FIM Release-3 "Easy Button" Knowledge Reuse Approach (KRA) Architecture Development Methodology (ADM) to generate Interoperability Specifications (ISs) Implementation Guides (IGs) conformant with the HL7 Service Aware Interoperability Framework (SAIF); where, SAIF organizes Interoperability Specifications (ISs) into a matrix of Computationally Independent Models (conceptual CIMs), Platform Independent Models (logical PIMs) and Platform Specific Models (implementable PSMs) views for the following SAIF (aka RM-ODP) perspectives:

1. **Enterprise/Business** (WHY - policy & business rules)
2. **Information** (WHAT - content)
3. **Computational** (HOW - behavioral)
4. **Engineering** (WHERE - engineering)
5. **Technology** (WHERE - technology)
EHR-S and PHR-S Reference Model

**Type:** Package

**Package:** Jan 2014 Immunization-Management Prototype-Report for San Antonio WG Presentation

**Detail:** Created on 11/4/2013, Last modified on 12/31/2013

Release-3 work is based on the OASIS RM definition; where, the RM

- Structures **significant-relationships among system entities** defined-by system Action-and-Information Conceptual-Models.
- is based-on a functional-use-case constrained **hierarchical-lexicon of**
  - **nouns** (Data-Entities) and **noun qualifiers** (Data-hierarchy or Sub-Types),
  - **verbs** (System-Actions) and **verb qualifiers** (Action-hierarchy or Sub-Types) with
  - **conditions** {Business Rules based on laws, policies, preferences}

- Defines Conformance-Criteria syntax-and-semantics; where,
  - Conformance Criteria (CC) are **scenario-threads** through the reference use-case.
  - Functions 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 and patterns.

**OASIS RM Definition:** 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."

**System Function (SF) Conformance Criteria (CC) SYNTAX**

**SF CC Invariant-condition (context)**

- SystemIdentifier (EHR or PHR) <followed-by>
- SystemFunction (SF) Identifier <followed-by>
- Profile Identifier <followed-by>
- SF CC Identifier (number) <followed-by>
  
  **EXAMPLE:** CP.6.2#01

**Pre-condition (verb-clause)**

- SF CC Pre-condition (trigger) <followed-by>
  
  **EXAMPLE:** During an encounter,

**SF CC Invariant-condition**

- **<After a Human-Action or System-Action> the System SHALL, SHOULD or MAY provide-the-ability-to manage Record Entries; where, it can**
- **<OR> the system SHALL, SHOULD or MAY manage Record Entries; where, it can**

**SF CC System-Action Bindings**

- Operation linked-to Data-Type; where, conditionally,
  - the System-Actions depends-on other-SF
  - Data-Type are associated-with other Data-Types
  - Information Exchange(s) are linked-to implementation specifications (e.g., FHIR, FHIM, CDA, IHE, DURSA, SLA)

**SF CC Post-Condition (expected-outcome)**

- Post-condition is a subordinate-clause.
  
  **EXAMPLE:** according-to scope-of practice, organizational-policy and jurisdictional-law.

**SF CC See Also**

- Supporting or related SFs (e.g., Infrastructure)
Methodology: We represent each function as a use case (aka Data Flow Diagram (DFD)); where, data sources, data destinations and Information Exchanges (IEs) are shown. In this way, an entire function can be simply visualized; where, this representation is independent of implementation constraints. Next, each function’s conformance criteria are analyzed as scenario execution-threads through its DFD.

But, first we present the **EHR concept-of-operations (CONOPS)**; where, the CONOPS defines the operational-context used to communicate quantitative and qualitative system characteristics to stakeholders of EHR system functions and associated information models (EHR-S FIM); where, the EHR and PHR system CONOPS describes the set of high-level operational-concepts to be refine by the set of system functions and their conformance-criteria needed to achieve a desired set of EHR system management objectives.

In the **EHR-S and PHR-S CONOPS**, 
- Patient, Clinician and EHR-S interactions are through the EHR-S GUI
- Record Entries can be an order, treatment or observation; where, Record Entries depend on the Clinician to observe the patient, write orders, treat the Patient or manage the EMR.
- Electronic Medical Record (EMR) management depends on the Patient, Clinician or their representatives to create, retrieve or update Patient data, according to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-consent.
- Conformance Criteria (CC) bind Reference Model (RM) verbs (UML class operations) to RM nouns (UML classes or entities); where, applicable System operations on applicable System data are defined by CCs (e.g., CP.6.2 Immunization Management's CCs).
- RM Adjectives are defined as UML type (generalization element) to the core RM nouns (e.g., Observation, Order, Treatment or their descendents)
- Histories are defined as lists of Observations, Treatments or Orders of various types.
- Care Plans are defined as lists of Orders

**Functions** are modeled as "manage Record-Entry" sub-type **Use-Cases**.
**Conformance Criteria** are modeled as (subject, verb, object) **Scenarios**; where,
- subjects-and-objects are Record-Entry sub-types
- verbs are manage sub-types

**Business Rules** are "according to scope of practice, organizational policy, jurisdictional law, patient preference or consent."

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Figure: 3 EHR-S & PHR-S FIM Reference Activity-Model

The **EHR-S FIM Reference Activity-Model** includes the key System-Action types, which are universally used in clinical medicine; where in the EHR-S FIM, they are <<Stereotypes>> to manage; and, they are also known as the Release-2 EHR- FM Verb Hierarchy.
ISSUE:
1. Inconsistent correspondence of Verb-Hierarchy System-Actions and Record-Infrastructure System-Actions
2. Capture needs verify, store and save verbs
3. How do we distinguish duplicate activities (e.g., transmit, record, receive) within Conformance Criteria scenarios? Does it matter?
4. Should "include relationship" be replaced with "generalization relationship"?
5. Should maintain include various forms of sharing (e.g., exchange, harmonize)

Figure: 4 EHR-S and PHR-S FIM Reference Data-Model

The EHR-S FIM Reference Data-Model includes the key-concepts, which are universally used in clinical medicine; where in the EHR-S FIM, they are the EHR Record-Entry <<Stereotypes>>.
The **EHR-S FIM Reference Conditions-Model** includes the key pre, invariant and post conditions, which are universally used in clinical medicine; where in the EHR-S FIM, they are modeled as **<<Stereotypes>>**

**ISSUE:**

**<<post-condition>>**

1) Release 2 is "according-to scope-of practice, organizational-policy and/or jurisdictional-law." Can and/or --> and
2) Do we need to include "established authorizations, patient-preference, situation" or can this be subsumed under "according-to scope-of practice, organizational-policy ..."
EHR-S FIM CP.6.2 Use-Cases, Information Models, Requirements-Scenarios

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NOTE: Interoperability Specifications (IS) for specific implementation paradigms (e.g., specific messages, services, document exchanges) and behavioral profiles (e.g., IHE) are generated separately, due to their large volume of information; where, Interoperability Specifications are defined for each Information-Exchanges (IEs) defined by EHR-S FIM Functions' scenarios; where, IEs can be bound-to implementation-paradigms, such as

a) HL7 V2 and V3 message, RIM and CDA, SOA RLUS standards and related DAMS
b) FHIR (Fast Healthcare Interoperability Resource) specifications, for the International-Realm, profiled-with
c) FHIM (Federal Health Information Model) specifications, for the US-Realm, bound to
   • Terminology value-sets,
   • IHE information-exchange behavioral-protocols refined by,
   • SLA and DURSA (Service-level-agreement and Data-Use and Reciprocal-Support Agreement) and
   • KPPs (Key Performance Parameters).
   • Cost estimation factors
**Statement:** Capture and maintain discrete data concerning immunizations given to a patient including date administered, type, manufacturer, lot number, and any allergic or adverse reactions. Facilitate the interaction with an immunization registry to allow maintenance of a patient’s immunization history.

**Description:** During an encounter, recommendations based on accepted immunization schedules are presented to the provider. Allergen and adverse reaction histories are checked prior to giving the immunization. If an immunization is administered, discrete data elements associated with the immunization including date, type, manufacturer and lot number are recorded. Any new adverse or allergic reactions are noted. If required, a report is made to the public health immunization registry or other organization (e.g. military unit commander, refugee program leadership).

**Example:** Use-Case Description
1. A Clinician reviews the patient’s EMR for Allergies and Intolerance, reviews the Patient’s Immunization-Schedule, treats (immunizes) the Patient with a Vaccine and observes Adverse-Reactions.
2. The Immunization related managers can
   - Capture, Auto-populate, Maintain, Render, Transmit, Exchange, Harmonize, Update, or Determine

**Figure: 6 EHR-S FIM CP.6.2 Manage Immunization Administration Dependencies**
1. The following data-modules:
Immunization-Administrations, Allergies, Intolerance, Adverse-Events Events, Schedules, Plans and Educational Materials

Where,
- Patient, Clinician and EHR-S interactions are through the EHR-S GUI
- Record Entries can be an order, treatment or observation; where, Record Entries depend on the Clinician to observe the patient, write orders, treat the Patient or manage the EMR.
- Electronic Medical Record (EMR) management depends on the Patient, Clinician or their representatives to create, retrieve or update Patient data, according to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent.
- Conformance Criteria (CC) bind Reference Model (RM) verbs (UML class operations) to RM nouns (UML classes or entities); where, applicable System operations on applicable System data are defined by CCs (e.g., CP.6.2 Immunization Management's CCs).
- RM Adjectives are defined as UML type (generalization element) to the core RM nouns (e.g., Observation, Order, Treatment or their descendents)
- Histories are defined as lists of Observations, Treatments or Orders of various types.
- Care Plans are defined as lists of Orders

Release-2 EHR-S FM CP.6.2 Conformance Criteria are:
- 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."
- 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.
- 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.
- CP.6.2#04 The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific immunization.
- 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).
- 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.
- CP.6.2#07 The system SHALL provide the ability to maintain the immunization schedule.
- 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.
- CP.6.2#09 The system SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).
- 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.
- 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.
- 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.
- CP.6.2#13 The system SHOULD capture and render immunization histories from a public health immunization registry.
- CP.6.2#14 The system SHALL conform to function CP.1.6 (Manage Immunization List).
- CP.6.2#15 The system SHOULD provide the ability to update immunization histories at the time of capturing an immunization administration.
• **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.

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

• **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)).

• **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.

• **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.

• **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.

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

• **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.

**ISSUE:**

From: Noam H Arzt, PhD [mailto:arzt@hln.com]
Sent: Sunday, December 29, 2013 1:25 PM
Subject: Re: REQUEST FOR FEEDBACK: Release-3 EHR-S Function and Information Model Immunization Management Prototype Use Cases, Information Models and Scenarios

Steve,

I have not been following this closely, and am not familiar with this methodology, but I do know a little about the content. I have a few suggestions for clarifying some of the information in the conformance criteria in the basic use case (p. 9 and following):

- I'm not sure if the items listed in item 1 are exhaustive or complete. At minimum, we know that public health agencies require the capture of insurance eligibility information (in particular eligibility for public vaccine programs like Vaccines for Children) at the time of encounter relative to every dose. I don't see that among the topics listed.

- With respect to immunization schedule (item 7), there are several models for doing this, including access by and EHR-S to an external clinical decision support system that would be maintained external to the EHR-S. I'm not sure I would include this type of setup in my understanding of "maintain."

- Along a similar vein, EHR-S often do more than just exchange immunization histories with a public health registry, or IIS (items 11-13). They often exchange the forecast as well. I don't see this variation captured in the conformance criteria.

There may be other things I am missing but those were the obvious ones to me.

Thanks,
Noam

From: owner-ehrinterop@lists.hl7.org [mailto:owner-ehrinterop@lists.hl7.org] On Behalf Of William Grossen
Sent: Sunday, December 29, 2013 2:28 PM

Dear Noam,

I can support your comments. However would like to suggest some adjustments.

1. All children in the Netherlands are getting the vaccines by government order. So we could change insurance into source of payment, with a vocabulary set including government, insurance, private and perhaps more.

2. Beside the external DSS there is also an external national record system from Dutch rijks Institute for Healthcare and Environmental Care RIVM which stores for every child basic personal data, vaccines history, vaccines orders and administration, side effects and as addition to the DSS the future plan for follow up vaccines according the national guideline.
the plan for a certain vaccine will soon be sent from RIVM via HL7 v3 message to the local EHR system and after administration that will be reported back.

The local EHR will have the history and complications etc as well. Any local care profession decision can be stored, including changes in the plan.

From: Rob Savage [mailto:rob.savage50@gmail.com]
Sent: Thursday, January 02, 2014 12:06 PM

I agree with Noam's comments. I would clarify one.
In the US, we record the eligibility of a person and immunization event for vaccines funded by various programs. The most widespread is the Vaccines for Children (VFC) program. An event is eligible if certain characteristics of the person are true AND if the vaccine type is eligible. For example, if the person is < 19 years old and on Medicaid, they are eligible. If they receive a vaccine eligible for VFC program (like MMR), then the event is eligible. We track the reason (Medicaid recipient). If they received a vaccine not eligible for VFC (like Yellow fever vaccine), the event is not VFC eligible. Some states also have special programs for vaccine funding when VFC does not cover them.

Funding source for a given vaccine refers to who actually paid for a given immunization. It is possible that the vaccine given was privately funded, while the recipient was VFC eligible. If funding source is important, it is captured separately from eligibility.
In this view, we represent a use case as a Data Flow Diagram (DFD); where, we focus on data flows, sources and destinations. An entire function can be described from the viewpoint of the data it processes and moves around; where, DFDs are powerful enough to show parallel activities independent of how it is actually implemented; that is, they show what takes place, rather than how an activity is accomplished. These DFDs are the basis of our detailed analyses; where each function’s conformance criteria can be considered as a scenario execution-thread through the DFD.

**Use-Case Description**

1. A Clinician reviews the patient’s EMR for Allergies and Intolerance, reviews the Patient’s Immunization-Schedule, treats (immunizes) the Patient with a Vaccine and observes Adverse-Reactions.
2. The EHR-S Immunization related managers can capture, Auto-populate, Maintain, Render, Transmit, Exchange, Harmonize, Update, or Determine

   The following data-modules:
   Immunization-Administrations, Allergies, Intolerance, Adverse-Events Events, Schedules, Plans and Educational Materials;

   - Patient, Clinician and EHR-S interactions are through the EHR-S GUI
   - Record Entries can be an order, treatment or observation; where, Record Entries depend on the Clinician to observe the patient, write orders, treat the Patient or manage the EMR.
   - Electronic Medical Record (EMR) management depends on the Patient, Clinician or their representatives to create, retrieve or update Patient data, according to scope-of-practice, organizational-policy, jurisdictional-law, patient preference-or-consent.
   - Conformance Criteria (CC) bind Reference Model (RM) verbs (UML class operations) to RM nouns (UML...
classes or entities); where, applicable System operations on applicable System data are defined by CCs (e.g., CP.6.2 Immunization Management’s CCs).

- RM Adjectives are defined as UML type (generalization element) to the core RM nouns (e.g., Observation, Order, Treatment or their descendents)
- Histories are defined as lists of Observations, Treatments or Orders of various types.
- Care Plans are defined as lists of Orders

**ISSUE** (7-Jan-14):
- Should there be an EHR-PHR exchange of Immunization Administration?
- Should there be a verify of a patient reported immunization?

![Diagram of CP.6.2 Immunization-Management Public-Health Use-Case](image)

**Figure: 8 CP.6.2 Immunization-Management Public-Health Use-Case**

**Public-Health Immunization-Management Use-Case**

**Release-2 EHR-S FM CP.6.2 Conformance Criteria are:**

- **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.
- **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.
- **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.
- **CP.6.2#13** The system SHOULD capture and render immunization histories from a public health immunization registry.
Immunization-Schedule Use-Case

Release-2 EHR-S FM CP.6.2 Conformance Criteria are:

- **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.
- **CP.6.2#07** The system **SHALL** provide the ability to **maintain** the **immunization schedule**.
ISSUE (3-Jan-14): Currently, the HL7 EHR-S FIM requirements, US-realm logical FHIM and HL7 International implementable FHIR have inconsistent data-_semantics.

DISCUSSION: Linking EHR-S FIM data-requirements with FHIM logical-classes and FHIR implementable-resources should be helpful to users; especially if, linking is done in a full lifecycle tool such as Model Driven Health Tool or Enterprise Architect, which can generate desired implementation artifacts; where, having consistent semantics (1:1 relationship among appropriate concepts and their definitions) from the high-level EHR-S FIM data-modules mapped to the corresponding FHIM data-modules and FHIR-profile data-modules will result in consistent and easier-to-use architecture, design, and test requirements specifications and implementation-artifacts. Similarly, for key data-elements, their names should have 1:1 concept-correspondence and they should have the same underlying concept definition; where, data modules-and-elements can have domain-specific name-synonyms, if they maintain the 1:1 correspondence to the common base-concept.

Recommendation (Steve Hufnagel, 4-Jan-14): The HL7 EHR and FHIR Work Groups and FHA FHIM Work Group establish a joint maintenance process to appropriately-harmonize their common data-modules, data-elements and data dictionaries for the benefit of their respective users. I am willing to lead an Immunization Management, Allergies, Intolerences and Adverse-Reaction prototype effort as an extension of the work documented in the EHR-S FIM r3 Immunization Management Prototype Report.

ACTION (4-Jan-14) Steve hufnagel coordinate with Steve Wagner, Galen Mulrooney and Sean Muir on FIM-FHIR harmonization needs and process.

ACTION (4-Jan-14) Steve Hufnagel coordinate with Grahame Grieve on FIM-FHIR harmonization needs and process and possible meeting during the 18-24 HL7 WG meeting in San Antonio.
From: Grahame Grieve  
Sent: Saturday, January 04, 2014 10:29 PM  
Subject: Re: EHR-S FM, FHIM & FHIR terminology data-module, data-element and data dictionary harmonization

My initial response is that I'm surprised that we're talking about 1:1 kind of relationships given that it's very unlikely that there's that kind of alignment at the requirements level. Even if there were, there's valid reasons why the alignment would be something other than 1:1 at the data element level.

Also, with alignment efforts, in FHIR we've found that there's 4 kinds of mapping. I call them:
- skeletal: overview of the important structural mappings to establish equivalence
- notional: field equivalence at the complex data type level with notes
- definitional: primitive attribute to attribute
- executional: all cases defined in some mapping language

These levels get progressively more useful for computing purposes, but harder to write and understand, and therefore less useful for people.

What are you trying to achieve?

From: Stephen Hufnagel  
Sent: Sunday, January 05, 2014 9:01 AM  
I find the FHIR extension rules too weak; and, I concur that 1:1 correspondence is to stringent. We need something in between. My concern is with heterogeneous structured information; where, my objective is to maintain requirements-traceability of semantically related elements, marked up with different types of structures, as they are transformed into different implementation paradigms, such as FHIR, V2 or V3 messages, documents or web services; where, the same information may be represented in different structures and worse-yet, information contained in different implementation-paradigms may be partial and inconsistent. The heterogeneity of structured information poses retrieval challenges, in particular retrieval for population-based clinical decision support; therefore, I am suggesting that the correspondence of semantically related elements in the information collections needs to be modeled in a (to-be-determined) consistent representation model. In our case, a consistent skeletal and hopefully notional representation model for EHR-S FM, FHIM and the US Realm FHIM-based extensions to FHIR. Ideally, once we have a common-sense semantic-correspondence approach, other realms and implementation paradigms can follow.

Figure: 11 CP.6.2 Immunization-Administration Logical Information Model (LIM)
**ISSUE:** Data-element attribute-Inheritance and associated requirements-traceability remains to be harmonized.

**Figure:** 12 CP.6.2#01 SHALL provide the ability to capture, maintain and render immunization administration details

**Release-2 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.

**Overarching post-condition:** System-Actions are according to scope-of practice, organizational-policy and jurisdictional-law.
Release-2 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.

**Overarching post-condition:** System-Actions are according to scope-of-practice, organizational-policy and jurisdictional-law.
Release 2 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. **Overarching post-condition:** System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

**Figure: 14 CP.6.2#03 SHALL provide the ability to determine and render required immunizations**

The system SHALL provide the ability to determine and render Required Immunizations, and their dueDates, based on widely accepted Immunization Schedules.
Release-3 CP.6.2#04 The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific immunization.

**Overarching post-condition:** System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

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**Figure: 15 CP.6.2#04 SHOULD provide the ability to capture allergy/adverse reaction**
class CP.6.2#05 SHALL conform to function CP.3.2 (Manage Patient Clinical Measurements)

Name: CP.6.2#05 SHALL conform to function CP.3.2 (Manage Patient Clinical Measurements)
Author: EHR Interoperability WG
Version: 2013 Release-3 Prototype
Created: 12/23/2013 7:09:59 AM
Updated: 1/24/2014 4:51:08 PM

| Business Rule | «pre-condition» | During an encounter, |
| Business Rule | «SHALL» | The System can provide-the-ability-to |
| Business Rule | «post-condition» | where, system-actions are constrained according to scope of practice, organizational policy and jurisdictional law. |

During an encounter, the system SHALL conforms to function CP.3.2 (Manage Patient Clinical Measurements); where, the system SHALL capture Clinical Measurements, associated-with Immunization Administration, such as vital signs. Merge 5, 9, 14 conform to other functions? Do we need capture vs. link here?

Release-2 CP.6.2#05 The system SHALL conforo to function CP.3.2 (Manage Patient Clinical Measurements) to capture other clinical data pertinent to the immunization administration (e.g., vital signs).

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

Figure: 16 CP.6.2#05 SHALL conform to function CP.3.2 (Manage Patient Clinical Measurements)
Release-2 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.

**Overarching post-condition:** System-Actions are according to scope-of practice, organizational-policy and jurisdictional-law.
Release-2 CP.6.2#07 The system SHALL provide the ability to maintain the immunization schedule.

**Overarching post-condition:** System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.
Release-2 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.

**Overarching post-condition:** System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.
Release-2 CP.6.2#09 The system SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).  

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.
**Figure: 21 CP.6.2#10 SHOULD transmit required immunization administration information to a public health immunization registry**

**Release-2 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. 

**Overarching post-condition:** System-Actions are according to scope-of-practice, organizational-policy and jurisdictional-law.
class CP.6.2#11 SHOULD exchange immunization histories with public health immunization registries

Name: CP.6.2#11 SHOULD exchange immunization histories with public health immunization registries
Author: EHR Interoperability WG
Version: 2013 Release-3 Prototype
Created: 12/23/2013 3:14:35 PM
Updated: 1/10/2014 9:02:01 PM

Figure: 22 CP.6.2#11 SHOULD exchange immunization histories with public health immunization registries

Release-2 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.

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.
Figure: 23 CP.6.2#12 SHOULD exchange immunization histories with public health immunization registries

Release-2 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.

**Overarching post-condition:** System-Actions are according to scope-of-practice, organizational-policy and jurisdictional-law.
The system SHOULD capture and render immunization histories from a public health immunization registry.

**Release-2 CP.6.2#13** The system SHOULD capture and render Immunization Histories from a Public-Health Immunization Registry.

**Overarching post-condition:** System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.
The system SHALL conform to function CP.1.6 (Manage Immunization List).

**Overarching post-condition**: System-Actions are according to scope of practice, organizational policy and jurisdictional law.
Figure: 26 CP.6.2#15 SHOULD provide the ability to update immunization histories

Release-2 CP.6.2#15 The system SHOULD provide the ability to update Immunization Histories invoked-by the capture of Immunization Administration.

Merge CP.8.2#11, #12, #13, #14, #15 history CCs? 
Merge 5, 9, 14 conform to other functions?

Release-2 CP.6.2#15 The system SHOULD provide the ability to update immunization histories at the time of capturing an immunization administration.

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.
CP.6.2#16 SHALL render Immunization-Order

Business Rule
«pre-condition»
During an encounter,

Business Rule
«SHALL»
The System can provide the ability to

Business Rule
«post-condition»
where, system-actions are constrained according to scope of practice, organizational policy and jurisdictional law.

System
«Record Entry»
Manager

Input Output
System
«flow»
+invariant-condition
+post-condition

CP.6.2 Manage Immunization Administration

Merge CP.6.2#16, #17?

Immunization
«Order»
Exact

Name: CP.6.2#16 SHALL render Immunization-Order
Author: EHR Interoperability WG
Version: 2013 Release-3 Prototype
Created: 12/23/2013 4:52:09 PM
Updated: 1/10/2014 9:00:14 PM

Release-2 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.

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.
Release-2 CP.6.2#17 The system SHALL provide the ability to determine due and overdue ordered immunizations and render a notification.

**Overarching post-condition:** System-Actions are according to scope-of practice, organizational-policy and jurisdictional-law.

Figure: 28 CP.6.2#17 SHALL determine due and overdue ordered immunizations and render a notification
**Figure: 29 CP.6.2#18 SHALL provide the ability to render a patient educational information**

**Release-2 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)).

**Overarching post-condition:** System-Actions are according to scope-of practice, organizational-policy and jurisdictional-law.
class CP.6.2#19 SHALL provide the ability to capture that patient educational information (e.g., VIS) was provided

Name: CP.6.2#19 SHALL provide the ability to capture that patient educational information (e.g., VIS) was provide
Author: EHR Interoperability WG
Version: 2013 Release-3 Prototype
Created: 12/23/2013 5:05:07 PM
Updated: 1/10/2014 8:55:39 PM

Business Rule
<pre-condition>
During an encounter,
+pre-condition
+invarant-condition
+post-condition

System
«Record Entry»
Manager

«SHALL»
The System can provide-the-ability-to

System «Record Entry» Manager

Business Rule
<post-condition>
: where, system-actions are constrained according to scope of practice, organizational policy and jurisdictional law.

System «Record Entry» Manager

Release-3 CP.6.2#20 During an encounter, the system SHALL provide the ability to capture a Record associated with an Immunization Administration documenting that Patient Educational Information (e.g., VIS) was provided.

Merge CP.6.2#18, #19, #20, #21?
#19=#20

Figure: 30 CP.6.2#19 SHALL provide the ability to capture that patient educational information (e.g., VIS) was provide

Release-2 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.

Overarching post-condition: System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.

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Figure: 31 CP.6.2#20 SHALL provide the ability to capture documentation that patient educational information was provided

Release-2 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. **Overarching post-condition:** System-Actions are according-to scope-of practice, organizational-policy and jurisdictional-law.
Release-2 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.

**Overarching post-condition:** System-Actions are according to scope-of-practice, organizational-policy and jurisdictional-law.
class CP.6.2#22 SHOULD provide the ability to capture and maintain immunization refusal reasons as discrete data

Name: CP.6.2#22 SHOULD provide the ability to capture and maintain immunization refusal reasons as discrete data
Author: EHR Interoperability WG
Version: 2013 Release-3 Prototype
Created: 12/24/2013 5:50:30 AM
Updated: 1/10/2014 8:51:00 PM

Business Rule
<pre-condition>
During an encounter,
</pre-condition>
Business Rule
<SHOULD>
The System can provide-the-ability-to
</SHOULD>
Business Rule
<post-condition>
; where, system-actions are constrained according to scope of practice, organizational policy and jurisdictional law.
</post-condition>

Release-3 CP.6.2#22 During an encounter, the system SHOULD capture and maintain Immunization Administration Patient-Preference immunizationRefusal justification, as discrete data.

Figure: 33 CP.6.2#22 SHOULD provide the ability to capture and maintain immunization refusal reasons as discrete data

Release-2 CP.6.2#22 The system SHOULD provide the ability to capture and maintain immunization refusal reasons as discrete data.
**Release-2 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.

**ISSUE:** Should CP.6.2#22 and #23 be combined?  
During an encounter, the system SHOULD provide the ability to capture and maintain patient "refused vaccine types" preferences and justification associated with the Immunization-Administration; where, the data is discrete.

**Overarching post-condition:** System-Actions are according to scope of practice, organizational policy and jurisdictional law.

**capture**

**Type:** Activity  
**Package:** EHR-S FIM CP.6.2 Use-Cases, Information Models, Requirements-Scenarios  
**Detail:** Created on 1/24/2014. Last modified on 1/24/2014.

**Constraints**
**Constraints**

- During an encounter: *(Pre-condition, Status is Proposed)*
  - The System can provide-the-ability-to: *(Invariant, Status is Approved)*
  - ; where, system-actions are constrained according to scope of practice, organizational policy and jurisdictional law: *(Pre-condition, Status is Approved)*

**Connections**

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<anonymous>

**Type:** ActivityInitial

**Package:** EHR-S FIM CP.6.2 Use-Cases, Information Models, Requirements-Scenarios

**Keywords:**

**Detail:** Created on 1/24/2014. Last modified on 1/24/2014.
**EHR-S FIM-FHIR Interoperability Example**

**Type:** Package  
**Package:** Jan 2014 Immunization-Management Prototype-Report for San Antonio WG Presentation  
**Detail:** Created on 12/28/2013, Last modified on 12/31/2013

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This diagram illustrates how FHIR can be used to add implementation design-specified fidelity to the EHR-S FIM data-requirements conformance criteria (CC) for Allergy, Intolerance and Adverse Reaction.

Fast Healthcare Interoperability Resources (FHIR, pronounced "Fire") defines a set of "Resources" that represent granular clinical concepts. The resources can be managed in isolation, or aggregated into complex documents. This flexibility offers coherent solutions for a range of interoperability problems. The simple direct definitions of the resources are based on thorough requirements gathering, formal analysis and extensive cross-mapping to other relevant standards. A workflow management layer provides support for designing, procuring, and integrating solutions. Technically, FHIR is designed for the web; the resources are based on simple XML, with an http-based RESTful protocol where each resource has predictable URL. Where possible, open internet standards are used for data representation.
The FHA, together with its federal partners, addresses Executive Order 13410 to achieve secure, interoperable health information exchanges within the federal government and its consortia. FHA serves a coordinating and convening role across the federal agencies to support alignment of health information technology (IT) investments. This has led to the Federal Health Interoperability Modeling (FHIM) Initiative, Federal Health Information Planning and Reporting (FHIPR), and other projects aimed at coordinating across federal agencies. The FHIM is a model of healthcare data developed for the FHA partner agencies. The FHIM project seeks to develop a common Logical Information Model or Computationally Independent Model (CIM).

The Federal Health Information Model is a project under a larger program called Federal Health Interoperability Modeling and Standards (FHIMS), which is an initiative of the Federal Health Architecture (FHA). Briefly, the United States federal government has established a Federal Enterprise Architecture (FEA), which provides guidance to federal agencies on how they should develop their enterprise architectures. The methodology used by FEA, the Federal Segment Architecture Methodology (FSAM) recognizes that some "lines of businesses" in which the federal government is engaged cross agency boundaries. The healthcare line of business is one such case. As a result, the FHA was established as a partnership of over 20 departments and agencies to coordinate Healthcare Information Technology (sometimes called Healthcare IT, or HIT) activities among those partners. The FHA is managed by the Office of the National Coordinator for Health IT (ONC). The FHA has served as a forum by which the partner agencies have collaborated on several important initiatives, including the Nationwide Health Information Network.
Acts, Roles, and Entities

The FHIMS program is intended to coordinate the efforts of the partner agencies with respect to information and terminology standards, including the coordination of agency efforts at relevant Standards Development Organizations (SDOs) such as Health Level Seven (HL7), the National Council for Prescription Drug Programs (NCPDP), Integrating the Healthcare Enterprise (IHE), and others. Many of the partner agencies are already active in some of these SDOs, in which case the FHIMS program can help agencies speak with a single voice at the SDOs while also reducing redundant participation. For those agencies that do not yet have a presence in a particular SDO, this program provides a mechanism for agencies to delegate issues to another agency. For example, if the Department of Veterans Affairs (VA) is active in the Organization for the Advancement of Structured Information Standards (OASIS), and the Indian Health Service (IHS) is not, the FHIMS program provides an opportunity for IHS to learn of relevant OASIS activities, and for IHS to request the VA representatives to OASIS to champion a particular issue.

Another FHIMS initiative is the Federal Health Terminology Model project, which coordinates partner agency efforts to develop healthcare terminology models (i.e., new content), and to enumerate “value sets” that can be associated with the Information Model. The Terminology Model is closely related to the Information Model, as they are each describing the same real-world concepts from two different angles. The Information Modeling team will work very closely with the Terminology Modeling team to identify those concepts which should be enumerated in a value set, to define that valueset, and to define the members of the valueset.

Figure: 37 FHIM Adverse-Event Reporting Domain


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