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 ISO/HL7 10781 r3:2017 EHR-S FIM; where, EHR-S Function-and-Information Model Release-3 is planned for ‘2017 ballot. This report demonstrates 1-function of 150-functions remaining to be done over the next three years.

Our vision is to restructure the ’2014 EHR-S FM Release-2 into clear, complete, concise, correct, consistent and easy-to-use functions and conformance criteria within the ’2017 UML-modeled EHR-S FIM Release-3 Easy-Button tool; where, the EHR-S FIM Enterprise Architect (EA) platform is capable of managing specific-profiles (e.g., personal health record, behavioral health, long-term care, emergency department, inpatient, outpatient or individual system); where, profile reports or web-sites can be automatically-generated, which include:

1. Constraints according-to patient-preference, situation, scope-of-practice, organizational-policy and jurisdictional-law
2. Functional use-case entities, system-actions information-exchanges, conformance-criteria scenarios
3. Interoperability-specifications, including selectable implementation paradigms
4. Requirements lifecycle-traceability and configuration-baselines.
5. Implementation-paradigm profile-additions; such as, those for messages, CDA documents, web-services, interface behavioral-specifications and realm-specific data-models with terminology-bindings can be added to produce a fully-qualified exchange-architecture, of system Information-Exchanges (IEs) and implementable-and-testable Interoperability-Specifications (ISs); where, this document contains a small HL7-International Fast Healthcare Interoperability Resource (FHIR) and US-realm Federal Healthcare Information Model (FHIM) example of profile-additions.

Our Linguistic-kiss Methodology hierarchically-constrains the UML-modeled EHR-S lexicon-of entities, actions and information-flows into function document-sections and sub-sections modeled-as use-case paragraphs of user-story scenario-sentences; where, these scenario-sentences are also known as conformance-criteria (CCs). 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, situation, scope-of-practice, organizational-policy and jurisdictional-law.
Our "Easy-Button tool" is an EHR-informatics knowledge-repository and 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 ISs, profiles, 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 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 "Easy-Button" 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 supports the use of other tools, such as IBM's Rational Software/System Architect.

The estimated cost to bring the EHR-S FIM "Easy-Button" vision to fruition is 3-FTEs allocated for 2-years; where, 6-total FTEs = 2-weeks per-function * 150 functions = 5-hours per conformance criterion (CC) * 2500 CC. And, adding specific implementation-paradigm capabilities requires additional resources.
** Call-for-Participation **

**EHR Workgroups-AND-Projects Logistics**

- **HL7 List Server Registration:** [http://www.hl7.org/myhl7/managelistervs.cfm](http://www.hl7.org/myhl7/managelistervs.cfm)
- **HL7 Workgroup Call-Schedule:** [http://www.hl7.org/concalls/default.aspx](http://www.hl7.org/concalls/default.aspx)

- **EHR CCD to Blue Button Tool Project** defined the conversion of an HL7 Continuity of Care Document (CCD) to the Blue Button format via an XSLT style sheet tool.
  Project contact: Lenel James and Keith Boone. List Service: EHRTeamCCD@lists.hl7.org

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

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

- **PHR Project WG** provides a reference list of functions that may be present in a Personal Health Record System (PHR-S).
  Project contact: John Ritter; johnritter1@verizon.net

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

- **EHR Interoperability WG** has two active projects
  - **EHR-S FM Meaningful Use profile**
  - **EHR-S FM Release-3** preparation is restructuring release-2; where, the benefit of this formally-specified EA tool-based Concept-of-Operation and Reference Model is a clear, complete, concise, correct and consistent EHR-S and PHR-S Function-and-Information Model, profiles and resultant Interoperability-Specifications (ISs); where, ISs include appropriate implementation-paradigm specifications (V2 or V3 messaging, CDA, FHIR profiles, web-services, RLUS Data Services).
### Plan-of-Actions & Milestones Dashboard

<table>
<thead>
<tr>
<th>POA&amp;M Task</th>
<th>#</th>
<th>Start</th>
<th>Done</th>
<th>POC</th>
<th>Status-Risks-Mitigations</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONOPS</td>
<td>12-2013</td>
<td>12-2013</td>
<td>SH, GD</td>
<td>Potential for minor changes in the future</td>
<td></td>
</tr>
<tr>
<td>Reference Model</td>
<td>06-2013</td>
<td>12-2013</td>
<td>SH, GD</td>
<td>Potential for minor changes in the future</td>
<td></td>
</tr>
<tr>
<td>manage operation-type</td>
<td>05-2013</td>
<td>EHRWG</td>
<td></td>
<td>Verb-Hierarchy was part of r2 ballot</td>
<td></td>
</tr>
<tr>
<td>Record-Entry data-types</td>
<td>01-2012</td>
<td>active</td>
<td>SH, GD</td>
<td>Data-Model to be refined for each function</td>
<td></td>
</tr>
<tr>
<td>HL7 IP for EHR-S FIM</td>
<td>01-2014</td>
<td>active</td>
<td>EHRWG</td>
<td>ISSUE: Board approval needed</td>
<td></td>
</tr>
<tr>
<td><a href="http://www.HL7.org/EHR">www.HL7.org/EHR</a></td>
<td>12-2013</td>
<td>active</td>
<td>EHRWG</td>
<td>ISSUE: PSS approval needed</td>
<td></td>
</tr>
<tr>
<td>Implementation Paradigm Integration</td>
<td>01-2014</td>
<td>1-2017</td>
<td>EHRWG</td>
<td>ISSUE: Integrated or linked models?</td>
<td></td>
</tr>
<tr>
<td>V2 and V3 messaging, CCDA, RLUS API</td>
<td>01-2014</td>
<td>1-2017</td>
<td>EHRWG</td>
<td>RECOMMENDATION: linked</td>
<td></td>
</tr>
<tr>
<td>FHIR</td>
<td>01-2014</td>
<td>1-2017</td>
<td>EHRWG</td>
<td>ISSUE: shared governance (CCB &amp; CM)?</td>
<td></td>
</tr>
<tr>
<td>FHIM</td>
<td>01-2014</td>
<td>1-2017</td>
<td>EHRWG</td>
<td>ISSUE: shared governance (CCB &amp; CM)?</td>
<td></td>
</tr>
<tr>
<td>EHR-S FIM r3 Resources</td>
<td>6</td>
<td>01-2014</td>
<td>1-2017</td>
<td>EHRWG</td>
<td>ISSUE: 6 FTEs for EHR-S &amp; PHR-S FIM r3</td>
</tr>
<tr>
<td>EHR-S and PHR-S FM Modelling</td>
<td>143</td>
<td>1-2014</td>
<td>1-2017</td>
<td>Interop</td>
<td>3 FTEs = 1 week-per-function (143)</td>
</tr>
<tr>
<td>Other work (Pub., FHIR, FHIM, V2/3 msg.)</td>
<td>pending</td>
<td>1-2017</td>
<td>EHRWG</td>
<td>1 FTE</td>
<td></td>
</tr>
<tr>
<td>EHR-S specific work</td>
<td>pending</td>
<td>1-2017</td>
<td>EHRWG</td>
<td>1 FTE</td>
<td></td>
</tr>
<tr>
<td>PHR-S specific work</td>
<td>pending</td>
<td>1-2017</td>
<td>EHRWG</td>
<td>1 FTE</td>
<td></td>
</tr>
<tr>
<td>Care Provision</td>
<td>37</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP.1 Manage Clinical History</td>
<td>9</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP.2 Render Externally Sourced Information</td>
<td>2</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP.3 Manage Clinical Documentation</td>
<td>6</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP.4 Manage Orders</td>
<td>7</td>
<td>01-2012</td>
<td>inactive</td>
<td>SH, GD</td>
<td>√ 2012 prototype → Todo wrt RM</td>
</tr>
<tr>
<td>POA&amp;M Task</td>
<td>#</td>
<td>Start</td>
<td>Done</td>
<td>POC</td>
<td>Status-Risks-Mitigations</td>
</tr>
<tr>
<td>----------------------------</td>
<td>----</td>
<td>-------------</td>
<td>-------</td>
<td>--------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>CP.5 Manage Results</td>
<td>2</td>
<td>01-2012</td>
<td>inactive</td>
<td>SH, GD</td>
<td>√ 2012 prototype → Todo wrt RM</td>
</tr>
<tr>
<td>CP.6 Manage Treatment Administration</td>
<td>3</td>
<td>01-2012</td>
<td>SH, GD</td>
<td></td>
<td>√ 2012 prototype → Todo wrt RM</td>
</tr>
<tr>
<td>CP.6.1 Medication Management</td>
<td></td>
<td>01-2013</td>
<td>inactive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP.6.2 Immunization Management</td>
<td></td>
<td>10-2013</td>
<td>active</td>
<td></td>
<td>√ Use case done, CCs in progress</td>
</tr>
<tr>
<td>CP.7 Manage Future Care</td>
<td>3</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP.8 Manage Patient Education &amp; Communication</td>
<td>2</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CP.9 Manage Care Coordination &amp; Reporting</td>
<td>3</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Care Provision Support</td>
<td>b/</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS.1 Record Management</td>
<td>14</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS.2 Support Externally Sourced Information</td>
<td>9</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS.3 Support Clinical Documentation</td>
<td>13</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS.4 Support Orders</td>
<td>10</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS.5 Support for Results</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS.6 Support Treatment Administration</td>
<td>5</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS.7 Support Future Care</td>
<td>2</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS.8 Support Patient Education &amp; Communication</td>
<td>7</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPS.9 Support Care Coordination &amp; Reporting</td>
<td>6</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Population Health Support</td>
<td>17</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.1 Support for Health Maintenance, Preventive Care and Wellness</td>
<td>3</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.2 Support for Epidemiological Investigations of Clinical Health Within a</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POA&amp;M Task</td>
<td>#</td>
<td>Start</td>
<td>Done</td>
<td>POC</td>
<td>Status-Risks-Mitigations</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>---</td>
<td>-------</td>
<td>------</td>
<td>-----</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Population</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.3 Support for Notification and Response</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.4 Support for Monitoring Response Notifications Regarding a Specific Patient's Health</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.5 Donor Management Support</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.6 Measurement, Analysis, Research and Reports</td>
<td>6</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.7 Public Health Related Updates</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.8 De-Identified Data Request Management</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.9 Support Consistent Healthcare Management of Patient Groups or Populations</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POP.10 Manage Population Health Study-Related Identifiers</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Administration Support</td>
<td>22</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.1 Manage Provider Information</td>
<td>8</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.2 Manage Patient Demographics, Location and Synchronization</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.3 Manage Personal Health Record Interaction</td>
<td>3</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.4 Manage Communication</td>
<td>5</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.5 Manage Clinical Workflow Tasking</td>
<td>5</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.6 Manage Resource Availability</td>
<td>7</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.7 Support Encounter/Episode of Care Management</td>
<td>6</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AS.8 Manage Information Access for Supplemental Use</td>
<td>6</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POA&amp;M Task</td>
<td>#</td>
<td>Start</td>
<td>Done</td>
<td>POC</td>
<td>Status-Risks-Mitigations</td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
<td>----</td>
<td>----------</td>
<td>-------</td>
<td>-----------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>AS.9 Manage Administrative Transaction Processing</td>
<td>6</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trust Infrastructure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1.1 Security</td>
<td>25</td>
<td>01-2012</td>
<td>Inactive</td>
<td>GD, SH</td>
<td>√ 2012 prototype → Todo w/r RM</td>
</tr>
<tr>
<td>T1.2 Audit</td>
<td>1</td>
<td>01-2012</td>
<td>Inactive</td>
<td>GD, SH</td>
<td>√ 2012 prototype → Todo w/r RM</td>
</tr>
<tr>
<td>T1.3 Registry and Directory Services</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1.4 Standard Terminology and Terminology Services</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1.5 Standards-Based Interoperability</td>
<td>6</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1.6 Business Rules Management</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1.7 Workflow Management</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1.8 Database Backup and Recovery</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1.9 System Management Operations and Performance</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Record Infrastructure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RI.1 Record Lifecycle and Lifespan</td>
<td>25</td>
<td></td>
<td>Inactive</td>
<td>GD, SH</td>
<td>√ 2012 prototype → Todo w/r RM</td>
</tr>
<tr>
<td>RI.1.1.2 Record Entry Create</td>
<td></td>
<td>12-2012</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RI.2 Record Synchronization</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RI.3 Record Archive and Restore</td>
<td>1</td>
<td>pending</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Legend
1) Capitalized and Underlined nouns-and-adjecitves 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)

Table of Contents
EHR-S FIM r3 CP.6.2 Immunization Management Report .......................................10
Introduction ......................................................................................................................11
EHR-S and PHR-S Reference Model ...............................................................13
EHR-S FIM CP.6.2 Requirements, Use-Cases, Information Models & Scenarios .17
EHR-S FIM-FHIR Interoperability Example .........................................................50
EHR-S FIM-FHIR-FHIM Interoperability Example ..............................................51
EHR-S FIM r3 Easy-Button Tool Overview ..........................................................56
EHR-S FIM r3 CP.6.2 Immunization Management Report

**Type:** Package

**Package:** 2013 Prototype

**Detail:** Created on 11/4/2013, Last modified on 1/1/2014

**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.

**January '2012 Project Scope Statement #688** EHR-S FIM Release 3.0 purpose:

- add core information models for each EHR-S FM function
  1) make the EHR-S FM easier to use for analysts and engineers
  2) verify and validate EHR-S FM Release 2.0

- Service Aware Interoperability Framework (SAIF) DSTU demonstration

- Add Conceptual Information Model & Logical Data Model to EHR-S Functions

- Incorporate S&I Framework simplification methodology

- EHR-S function correspond to a set of Use Cases (UC) & scenarios.

- New Use Cases and scenarios composed from reusable use-case and scenario elements

- EHR-S FM should associate information models to functions

- Maintain domain profile traceability

**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

**Issues:**

1. HL7 IP license vs. need for convenient access to EHR-S FIM versions-and-profiles.
3. FHIR WG Coordination to integrate EHR-S FIM-FHIR into a joint Sparx Enterprise Architect (EA) model
4. FHIM Team Coordination to integrate EHR-S FIM-FHIR-FHIM into a joint Sparx Enterprise Architect (EA) model
5. Concurrently maintaining release-2 baseline traceability to release-2 profiles and release-3.
6. Maintaining consistency across profiles and releases.
7. Maintaining traceability and consistency with FHIR, FHIM, IHE and implementation paradigms.
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 (CONTs)ys" standard
**Figure: 2 HL7 Service Aware Interoperability Framework (SAIF)**

**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:** EHR-S FIM r3 CP.6.2 Immunization Management Report

**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)**
- System Identifier (EHR or PHR) <followed-by>
- System Function (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-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.

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."

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.

How do we distinguish duplicate activities within Conformance Criteria scenarios? Does it matter? Should "include relationship" be replaced with "generalization relationship"?

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>>.
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,
d) 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
Figure: 7 EHR-S FIM CP.6.2 Manage Immunization Administration

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

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 GUl
- 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.
3 the plan for a certain vaccine will soon be send 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 wide spread 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
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-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
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.
An objective of the EHR Interoperability WG team, under the System Function and Information Model (EHR-S FIM r3.0) HL7-project, is to create a clear, complete, concise, correct and consistent EHR-S FIM r3.0 from EHR-S FIM r2.0, which is HL7 ballot-publishable from Sparx Systems Enterprise Architect tool. EHR-S FIM r3 is targeted for 3-to-5 years from now; because, joint ISO-HL7 ballots are very challenging to manage and sufficient-time is needed to address the structural issues identified by the VA negative ballot.

- integrate Fast Healthcare Interoperability Resource (FHIR)
- integrate 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

INTERIM CONCLUSION
FHIR implementation specifications complement EHR-S FIM requirements.

- EHR-S FIM and FHIR complement each other
- EHR-S FIM needs data element specifications and Data Dictionary
  FHIR provides data element specifications and Data Dictionary
  But, Configuration Management is essential to keep the models consistent
- Maybe, EHR WG should CM the FHIR UML model.
Figure: 12 CP.6.2 Immunization-Administration Logical Information Model (LIM)
Figure: 13 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: 16 CP.6.2#04 SHOULD provide the ability to capture allergy/adverse reaction

**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.
class CP.6.2#05 SHALL conform to function CP.3.2 (Manage Patient Clinical Measurements)

Release-2 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).

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

Figure: 17 CP.6.2#05 SHALL conform to function CP.3.2 (Manage Patient Clinical Measurements)
Figure: 18 CP.6.2#06 SHOULD provide the ability to link standard codes

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.
Figure: 19 CP.6.2#07 SHALL provide the ability to maintain the immunization schedule

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.
Figure: 20 CP.6.2#08 SHALL provide the ability to render a patient’s immunization history upon request for appropriate authorities

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.
class CP.6.2#09 SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List)

Name: CP.6.2#09 SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List)
Author: EHR Interoperability WG
Version: 2013 Release-3 Prototype
Created: 12/23/2013 2:56:35 PM
Updated: 12/31/2013 10:20:13 AM

Release-3 CP.6.2#09 The system SHALL manage Record Entries; where, it SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).

Figure: 21 CP.6.2#09 SHALL conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List)

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: 22 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.
**Figure: 23 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.
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.
class CP.6.2#13 SHOULD capture and render immunization histories from a public health immunization registry

Name: CP.6.2#13 SHOULD capture and render immunization histories from a public health immunization registry
Author: EHR Interoperability WG
Version: 2013 Release-3 Prototype
Created: 12/23/2013 4:19:15 PM
Updated: 12/31/2013 10:21:22 AM

«post-condition»
constrained according-to patient-preference, situation, scope-of practice, organizational-policy and jurisdictional-law.

«invariant-condition»
The System SHOULD manage Record-Entries; where, it can capture and render Immunization Histories from a Public-Health Immunization Registry.

The system SHOULD manage Record-Entries; where, it can capture and render Immunization Histories from a Public-Health Immunization Registry.

Release-2 CP.6.2#13 The system SHOULD manage Record-Entries; where, it can 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.
Figure: 26 CP.6.2#14 SHALL conform to function CP.1.6 (Manage Immunization List)

Release-2 CP.6.2#14 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.
Release-2 CP.6.2#15 The system SHOULD provide the ability to manage Record Entries, where, it can update Immunization Histories invoked-by the capture of Immunization Administration.

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

**Figure: 27 CP.6.2#15 SHOULD provide the ability to update immunization histories**
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.
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.
**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.
**Release-3 CP.6.2#19** During an encounter, the system SHALL provide the ability to manage Record Entries; where, it can capture a Record associated with an Immunization Administration documenting that Patient Educational Information (e.g., VIS) was provided. NOTE: #19 = #20

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

**Release-3 CP.6.2#22** During an encounter, the system SHOULD provide the ability to manage Record Entries; where, it can capture and maintain Immunization Administration Patient-Preference immunizationRefusal justification, as discrete data.

---

**Figure: 34 CP.6.2#22 SHOULD provide the ability to capture and maintain immunization refusal reasons as discrete data**
Figure: 35 CP.6.2#23 SHOULD provide the ability to capture patient preferences

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.
EHR-S FIM-FHIR Interoperability Example

Type: Package
Package: EHR-S FIM r3 CP.6.2 Immunization Management Report
Detail: Created on 12/28/2013, Last modified on 12/31/2013

This diagram illustrates how FHIR can be used to add implementation design-specification 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.
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 value set, and to define the members of the value set.
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 (F HIM) 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 value set, and to define the members of the value set.
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 (F HIM) 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 value set, and to define the members of the value set.
**EHR-S FIM r3 Easy-Button Tool Overview**

**Type:** EHR-S FIM r3 CP.6.2 Immunization Management Report  
**Package:** EHR-S FIM r3 CP.6.2 Immunization Management Report
**Detail:** Created on 12/28/2013, Last modified on 12/31/2013

The **EHR-S FIM “Easy-Button”** is resident in SparxEnterprise Architect Tool; where, an EHR-S

1. Concept-of-Operation (CONOPS) is defined-and-refined into a  
2. SystemReference-Model (RM); where,  
3. SystemFunctions are defined-by Use-Cases; where,  
   a. System-operations are verbs refined into a “manage verb-hierarchy” aka operation-type model,  
   b. System-entities are subjects-and-objects refined into a Record-Entry data-type model  
   c. Terminology value-sets are bound-to discrete-data-elements within each Record-Entry.  
4. Requirements Conformance-Criteria are defined-by use-case scenarios; where,  
5. Scenarios define business-context and subject-verb-object-terminology bindings; where,  
6. Business-Context defines pre, post and invariant conditions; where,  
   a. pre-condition are triggers, followed by  
   b. applicability; where,  
      i. “The System SHOULD or SHALL or MAY”  
      ii. “provide-the-ability-to-manage Record-Entries” or “directly-manage Record-Entries,” where,  
         1. a use-case constrained manage-hierarchy verb applies and  
         2. a use-case constrained data-model noun applies; where,  
   c. post-condition Business-Rules are  
      d. “according-to scope-of-practice, organizational-policy, jurisdictional-law, and patient-preferences.”  
7. Information-Exchanges are defined-by scenarios interoperable-with implementation-paradigms, such as  
   a. HL7 International V2 and V3 message, RIM and CDA, SOA RLUS standards and related DAMS  
   b. HL7 International FHIR (Fast Healthcare Interoperability Resource) profiled-with  
   c. FHA US-Realm FHM (Federal Health Information Model) bound to  
      i. Terminology value-sets,  
      d. IHE information-exchange behavioral-protocols refined by,  
         i. SLA and DURSA (Service-level-agreement and Data-Use-and-Reciprocal-Support-Agreement) and  
         ii. KPPs (Key Performance Parameters).  
      iii. Cost estimation factors  
8. EHR-S & PHR-S Profiles are defined-by constrained Use-Cases and scenario  
10. Interoperability-Specifications are generated with the EHR-S FIM r3 “Easy-Button” reporting-tool.  
    a. Functional Use Cases  
    b. Conformance Criteria Scenarios  
    c. Information Exchange Interoperability Specifications, Test-Cases and Simulations  
       i. Conformant-with HL7 Service Aware Interoperability Framework (SAIF)  
       ii. Interoperable-with HL7 International Fast Interoperability Healthcare Resources (FHIR)  
       iii. Interoperable-with FHA US-Realm Federal Health Information Model (FHM)  
       iv. Interoperable-with Integrating the Healthcare Enterprise (IHE) profiles  
       v. Interoperable-with HL7 V2 and V3 message, RIM and CDA,  
       vi. Interoperable-with HL7 SOA RLUS standards and related DAMS

The benefit of this formally-specified Concept-of-Operation (CONOPS) and Reference Model (RM) approach is a clear, complete, concise, correct and consistent EHR-S and PHR-S Function-and-Information Model (FIM), profiles and resultant Interoperability-Specifications (ISs); where, ISs include appropriate implementation-paradigm specifications (V2 or V3 messaging, CDA, FHIR profiles, RLUS Data Services).
Figure: 40 EHR-S FIM Tool is an “Easy-Button” to Reuse EHR-Informatics Knowledge