Monthly Summary Briefing

HL7 EHR Work Group (EHR-WG)

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to Edmund-Scientific VA support-contract
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OCTOBER 31, 2013-Final   Edmond Scientific
Executive Summary

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

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

• An objective of the EHR Interoperability WG team is to create a clear, complete, concise, correct and consistent EHR-S FIM r3.0 in Sparx Systems Enterprise Architect tool; where, it addresses the structural issues identified by the VA negative r2.0 ballot.

• A second objective of the EHR Interoperability WG is producing a Meaningful Use profile for r2.0.

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

NOTE: EHR-S FIM is NOT intended to imply a specific architecture or workflow!
# EHR WG Meeting Participation

<table>
<thead>
<tr>
<th>Meeting</th>
<th>Time (ET)</th>
<th>Relevance</th>
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</thead>
<tbody>
<tr>
<td>EHR-S FM Plenary</td>
<td>Every Tuesday 3:00 PM Eastern Phone: 770-657-9270, PC 510269# LiveMeeting</td>
<td>All things EHR, liaison with other WGs, ballot reconciliation, and development of WG documentation</td>
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<tr>
<td>EHR Interoperability</td>
<td>Every Tuesday 2:00 PM Eastern Phone: 770-657-9270, PC 510269# GoTo Meeting</td>
<td>Directly addressing EHR-S r2.0 Interoperability concern- and-needs</td>
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<tr>
<td>Resource Management and Evidentiary Support</td>
<td>Every Monday 12:00 Noon Eastern Phone: 650-479-3208 WebEx Code: 923-467-215, PC1519</td>
<td>Directly addressing EHR-S r2.0 RMES concerns and needs</td>
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<tr>
<td>Standards Gap Analysis</td>
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EHR-S FM r2.0
Dimensions and Stakeholders

Care Provision
1. CP.1 Manage Clinical History
2. CP.2 Render Externally Sourced Information
3. CP.3 Manage Clinical Documentation
4. CP.4 Manage Orders
5. CP.5 Manage Results
6. CP.6 Manage Treatment Administration
7. CP.7 Manage Future Care
8. CP.8 Manage Patient Education & Communication
9. CP.9 Manage Care Coordination & Reporting

Care Provision Support
1. CPS.1 Record Management
2. CPS.2 Support Externally Sourced Information
3. CPS.3 Support Clinical Documentation
4. CPS.4 Support Orders
5. CPS.5 Support for Results
6. CPS.6 Support Treatment Administration
7. CPS.7 Support Future Care
8. CPS.8 Support Patient Education & Communication
9. CPS.9 Support Care Coordination & Reporting

Population Health Support
1. POP.1 Support for Health Maintenance, Preventive Care and Wellness
2. POP.2 Support for Epidemiological Investigations of Clinical Health Within a Population
3. POP.3 Support for Notification and Response
4. POP.4 Support for Monitoring Response Notifications Regarding a Specific Patient’s Health
5. POP.5 Donor Management Support
6. POP.6 Measurement, Analysis, Research and Reports
7. POP.7 Public Health Related Updates
8. POP.8 De-Identified Data Request Management
9. POP.9 Support Consistent Healthcare Management of Patient Groups or Populations
10. POP.10 Manage Population Health Study-Related Identifiers

Administration Support
1. AS.1 Manage Provider Information
2. AS.2 Manage Patient Demographics, Location and Synchronization
3. AS.3 Manage Personal Health Record Interaction
4. AS.4 Manage Communication
5. AS.5 Manage Clinical Workflow Tasking
6. AS.6 Manage Resource Availability
7. AS.7 Support Encounter/Episode of Care Management
8. AS.8 Manage Information Access for Supplemental Use
9. AS.9 Manage Administrative Transaction Processing

Trust Infrastructure
1. TI.1 Security
2. TI.2 Audit
3. TI.3 Registry and Directory Services
4. TI.4 Standard Terminology and Terminology Services
5. TI.5 Standards-Based Interoperability
6. TI.6 Business Rules Management
7. TI.7 Workflow Management
8. TI.8 Database Backup and Recovery
9. TI.9 System Management Operations and Performance

Record Infrastructure
1. RI.1 Record Lifecycle and Lifespan
2. RI.2 Record Synchronization
3. RI.3 Record Archive and Restore
EHR-S FIM
Reference Information-Architecture
by Stephen Hufnagel PhD; where,
RIM is the HL7 reference Information Model, FHIR is Fast Health Interoperability Resource
**EHR-S FIM Anatomy Conceptual Model (Level 1)**

**ISSUE:** Currently, *Managers* do not consistently correspond to *Data Entities*.

[Diagram of EHR-S FIM Anatomy Conceptual Model (Level 1)]
ISSUE: Consistency of CC Verb-Hierarchy, EHR-S Managers, Record Lifecycle Events.

ISSUE
How do Lifecycle Events correspond to
- EHR-S FM Verb-Hierarchy
- EHR-S FIM Managers and their-operations
## EHR-S FM Action Verb Hierarchy
Vs. EHR-S FIM Manager Operations
VS. Record Lifecycle Events

**ISSUE:** Consistency of CC Verb-Hierarchy, EHR-S Managers, Record Lifecycle Events.

### Manage (Data)

<table>
<thead>
<tr>
<th>Capture</th>
<th>Maintain</th>
<th>Render</th>
<th>Exchange</th>
<th>Determine</th>
<th>Manage-Data-Visibility</th>
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<tbody>
<tr>
<td>Auto-Populate</td>
<td>Store Update Remove</td>
<td>Extract Present Transmit</td>
<td>Export Import Receive Transmit</td>
<td>Analyze Decide</td>
<td>De-Identify Hide Mask Re-Identify Unhide Unmask</td>
</tr>
<tr>
<td>Enter</td>
<td>Archive</td>
<td>Attest Update Delete</td>
<td>Import</td>
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<tr>
<td>Import</td>
<td>Decrypt</td>
<td>Annotate</td>
<td>Present</td>
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<tr>
<td>Receive</td>
<td>Encrypt</td>
<td>Extract</td>
<td>Transmit</td>
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<tr>
<td>Archive</td>
<td>Retrieve</td>
<td>Update</td>
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<tr>
<td>Backup</td>
<td>Retrieve</td>
<td>Remove</td>
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<tr>
<td>Attest</td>
<td>Retrieve</td>
<td>Save</td>
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<tr>
<td>Edit</td>
<td>Retrieve</td>
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<tr>
<td>Harmonize</td>
<td>Extract</td>
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<tr>
<td>Integrate</td>
<td>Present</td>
<td></td>
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<tr>
<td>Link</td>
<td>Transmit</td>
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<tr>
<td>Tag</td>
<td>Receive</td>
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<td>Delete</td>
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<tr>
<td>Purge</td>
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![Record Entry Lifecycle Event Type Enumeration](image)
INTERIM CONCLUSION

• We have looked at medication management, orders management and Immunization management.

• The EHR-S Conceptual Information Model (CIM) for CP.6.2 Immunization Management is generally applicable for all of the Care Provisioning (CP) section of the EHR-S FM; where,
  • minor CIM additions and modifications will likely occur as we analyze the rest of the CP section; but,
  • The Conceptual Manager Model remain to be substantially developed
EHR-S-FIM Physiology
"Function" (Conceptual Model)
CP.6.2 Immunization Management

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

- **Event**
- **EHR-S Manager**
- **Record Manager**
- **Treatment**
- **Medication Administration**
- **Immunization Administration**

- **EHR-S**
- **Patient**
- **Encounter**
- **Provider**
- **List**
- **Treatment History**
- **Immunization History**
- **Order Set**
- **Order**
- **Order for Medication**
- **Order for Immunization**
- **Observation History**
- **Observation**
- **Immunization Schedule**
- **Allergy, Intolerance and Adverse Reaction**

- **CP.6.2 Manage Immunization Administration**
- **CP.1.2 Manage Allergies ...**
- **other EHR or related systems**

- depends on

-link

-is-a

-has-a
EHR-S-FIM Physiology "Function" (Traceability Model)
CP.6.2 Immunization Management

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

Event

link

EHR-S Manager

Record Manager

Treatment

Medication Administration

Immunization Administration

has-a

Treatment History

is-a

EHR-S

List

Observation History

Observation

Immunization Schedule

Allergy, Intolerance and Adverse Reaction

CP.6.2#01 CP.6.2#02 CP.6.2#03 CP.6.2#04 CP.6.2#05 CP.6.2#06 CP.6.2#07 CP.6.2#08 CP.6.2#09 CP.6.2#10 CP.6.2#11 CP.6.2#12 CP.6.2#13 CP.6.2#14 CP.6.2#15 CP.6.2#16 CP.6.2#17 CP.6.2#18 CP.6.2#19 CP.6.2#20 CP.6.2#21 CP.6.2#22 CP.6.2#23
EHR-S FIM Physiology
"Function" (Logical Model)
CP.6.2 Immunization Management

**Medication Administration**
- date of discontinuation
- date of end
- date of review
- date of start
- dispensing information
- dose
- formulation
- instructions
- interaction checking done :boolean
- interactions indicated
- justification
- medication administration information
- name
- order date
- pharmacist change information
- potential interaction
- prescriber
- route
- SIG
- source
- type

**Immunization Administration**
+ date (recommended booster)
+ immunization type
+ series (immunization)
- dose
- educational information received :boolean
- encounter
- future booster
- healthcare organization
- immunization order
- immunization provider
- justification-immunization refusal
- lot
- manufacturer
- ordered immunization due date
- receipt of immunization preference
- receiving entity (educational information)
- refusal of vaccine type
- route of administration
- time (administration)
- type

**Event**
- Audit Log :link
- circumstances
- date & time (entry)
- date & time (occurrence)
- date & time (report)
- date & time (review)
- description
- duration
+ Initiator :link
- initiator-role
- initiator location
- mechanism
+ Record Entry :link* (bag)
- status
- trigger
- type (bag)
+ Type Related Information :link*
EHR-S FIM Physiology
"Function" (Logical Model)
CP.6.2 Immunization Management

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

- differential diagnosis
- disposition
- follow up activities
- follow up needed :boolean
- follow up results
- type

Encounter

List
- define sort restrictions()
- define sort criteria()
- filter()
- link to problem-treatment()
- manage()
- manage reason for change()
- sort()

Observation

Immunization Schedule
+ manage()

Immunization History
+ render()
- harmonize()
- capture()
- exchange()
- update()

Treatment History

Observation History

Allergy, Intolerance and Adverse Reaction
- data of review
+ Patient :link*
- reaction type
- severity
- type
1. 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.

2. 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.

3. 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.

4. The system **SHOULD** provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific immunization.

5. 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).

6. 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.

7. The system **SHALL** provide the ability to maintain the immunization schedule.

8. 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.

9. The system **SHALL** conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).

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.

11. The system **SHOULD** exchange immunization histories with public health immunization registries according to scope of practice, organizational policy and/or jurisdictional law.
ISSUE: Consistency of Conformance Criteria (CC) across related functions, such as Medication-and-Immunization and Orders-and-Results Management.

12. The system SHOULD harmonize Immunization histories with a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law.

13. The system SHOULD capture and render immunization histories from a public health immunization registry.

14. The system SHALL conform to function CP.1.6 (Manage Immunization List).

15. The system SHOULD provide the ability to update immunization histories at the time of capturing an immunization administration.

16. The system SHALL provide the ability to render the immunization order as written (i.e., exact clinician order language) when rendering administration information.

17. "The system SHALL provide the ability to determine due and overdue ordered immunizations and render a notification."

18. The system SHALL provide the ability to render a patient educational information regarding the administration (e.g., Vaccine Information Statement (VIS)).

19. The system SHALL provide the ability to capture that patient educational information (e.g., VIS) was provided at the time of immunization administration.

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.

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.

22. The system SHOULD provide the ability to capture and maintain immunization refusal reasons as discrete data.

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.
EHR-S FIM Physiology
"Function"
CP.6.2 Immunization Management

Resultant Description (Scenario):

• The System Manager can
  • Capture, Auto-populate,
  • Maintain, Render,
  • Transmit, Exchange,
  • Harmonize, Update,
  • Determine

• The applicable data modules are
  • Immunization Administrations
  • Events, Schedules, Plans and Educational Materials
INTERIM CONCLUSION

• Based on medication management, orders management and Immunization management functions we see a consistency-advantage in immunization-applicable data-elements

• A high level EHR-S Information Model is emerging as a set of
  • Patients, Providers, External Partners, Encounters, EMRs, Care Plans, Lists, Managers, Docs and Notes;

• A high level EHR-S Manager Model is emerging to
  • Capture, Auto-populate, Maintain, Render, Transmit, Exchange, Harmonize, Update, Determine
EHR-S FIM Physiology
"Function" (Conceptual View)
RI.1.1.1 Originate and Retain Record Entry

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

- manage()

other EHR or related systems

+ audit()
+ auto-populate()
+ capture()
+ determine()
+ exchange()
+ harmonize()
+ maintain()
+ render()
+ transmit()
+ update()
EHR-S FIM Physiology
"Function" (Conceptual Traceability View)
RI.1.1.1 Originate and Retain Record Entry

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

other EHR or related systems

Event
link

EHR-S
link

Record Entry
manage

Signature
depends on
0..*
link
other EHR or related systems
link

EHR-S Manager
link

Record Manager
manage

RI.1.1.1#07
RI.1.1.1#06
RI.1.1.1#03
RI.1.1.1#01
RI.1.1.1#12
RI.1.1.1#02
RI.1.1.1#04
RI.1.1.1#05
RI.1.1.1#09
RI.1.1.1#10
RI.1.1.1#11
1. RI.1.1.1#01 The system **SHALL** provide the ability to capture (originate) a Record Entry instance corresponding to an Action instance and context.

2. RI.1.1.1#02 The system **SHALL** capture a unique instance identifier for each Record Entry.

3. RI.1.1.1#03 The system **SHALL** conform to function TI.2.1.1.1 (Originate/Retain Record Entry Audit Trigger), including specified metadata.

4. RI.1.1.1#04 The system **SHALL** capture the signature event (e.g., digital signature) of the origination entry Author, binding signature to Record Entry content.

5. RI.1.1.1#05 The system **SHALL** provide the ability to capture both structured and unstructured content in Record Entries.

6. RI.1.1.1#06 The system **SHALL** provide the ability to capture Record Entries from information recorded during system downtime.

7. RI.1.1.1#07 The system **SHOULD** provide the ability to integrate Record Entries from Information recorded during system downtime.

8. RI.1.1.1#08 The system **SHALL** provide the ability to capture date/time an Action was taken or data was collected if different than date/time of the Record Entry.

9. RI.1.1.1#09 The system **SHOULD** capture metadata that identifies the source of non-originated Record Entry (e.g., templated, copied, duplicated, or boilerplate information).

10. RI.1.1.1#10 The system **MAY** provide the ability to tag unstructured Record Entry content to organize it according to need, for example, in a time-related fashion or by application-specific groups (such as photographs, handwritten notes, or auditory sounds).

11. RI.1.1.1#11 The system **MAY** capture and maintain a Record Entry encoded as a standards-based data object (e.g., HL7 Continuity of Care or other HL7 CDA R2 Document).

12. RI.1.1.1#12 The system **MAY** capture and maintain a standards-based data object to mirror (be duplicate and synchronous with) internal Record Entry representation.
EHR-S FIM Physiology
"Function"
RI.1.1.1 Originate and Retain Record Entry

Resultant Description (Scenario):

• The EHR-S System Manager can
  • Capture, Create, Copy,
  • Record, Transcribe, Identify,
  • Link, Tag, Encode, Mirror, Integrate

• The applicable data modules are
  • Record-Entry
    • structured or unstructured-data link-to associated
      • Event-Metadata and Signature
INTERIM CONCLUSION

we have only looked at the RI.1.1.1 function; yet,

• we see that the emergence of common Record-Entries, Events, Record Entries and a Record Entry Manager

• which can Capture, Create, Copy, Record, Transcribe, Identify, Link, Tag, Encode, Mirror, Integrate

• structured-data or unstructured-data and link-to

• associated Event-Metadata and Signature.
ISSUE: EHR-S FM r2.0 traceability to UML Model Elements, FHIR & FHIM is essential to guarantee a clear, complete, concise, correct and consistent EHR-S FIM r3.0

- **Workbook 1**: Class attributes & operations mapped to EHR-S FM r2.0 Functions and LOCAL CCs
- **Workbook 2**: Class attributes & operations mapped to EHR-S FIM r3.0 Functions and GLOBAL CCs
- **Workbook 3**: EHR-S FM r2.0 Functions and CCs mapped to EHR-S FIM r3.0 Functions and CCs
- **Workbook 4**: EHR-S FM r2.0 Functions and LOCAL Conformance Criteria (CC)
- **Workbook 5**: EHR-S FIM R3.0 Functions and UNIVERSAL Conformance Criteria (CC)
- **Workbook 6**: EHR-S FIM UML-Model mapped to FHIR (optional)
- **Workbook 7**: EHR-S FIM UML-Model mapped to FHIM (Federal Health Information Model) (optional)
- **Workbook 8**: FHIR mapped to FHIM (Federal Health Information Model) (optional)
- **Workbook 9**: Master Data Dictionary (DD) (If we use FHIR or FHIM, they already have an DD)

**ISSUE**: Can the Traceability-Matrices and DD be efficiently done directly in Sparx EA?
ISSUE: EHR-S FM r2.0 Implied Information Model is Ad-Hoc; where, FHIR & FIM Information Model & Data Dictionary are Configuration Managed.

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

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

- **FHIR Infrastructure**
  - Support: List, Media, Other, DocumentReference, (Binary)
  - Audit: Provenance, SecurityEvent
  - Exchange: Document, Message, OperationOutcome, Query
  - Conformance: Conformance, ValueSet, Profile
FHIR
Order Resource
http://www.hl7.org/implement/standards/fhir/
FHIR
Medication Prescription
http://www.hl7.org/implement/standards/fhir/
FHIR
Medication Administration
http://www.hl7.org/implement/standards/fhir/