<u>EHRS-FM R2 – Record Infrastructure</u> Record Entry Lifecycle Event Metadata on FHIR

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http://www.hl7.org/fhir

FHIR Resource Index

As of 22 September 2014

Clinical

General:

- AdverseReaction
- AllergyIntolerance
- Condition (aka Problem)
- CarePlan
- ReferralRequest
- Procedure
- Contraindication
- RiskAssessment

Administrative Attribution:

- Patient
- RelatedPerson
- Practitioner
- Organization

Infrastructure Support:

- List
- Media
- Other
- Provenance
- SecurityEvent
- (Binary)

Medications:

- Medication
- MedicationPrescription
- MedicationAdministration
- MedicationDispense
- MedicationStatement
- NutritionOrder
- Immunization
- ImmunizationRecommendation

Entities:

- Device
- Location
- Substance
- Group

Documents:

- Composition
- DocumentReference
- DocumentManifest

Diagnostics:

- Observation
- DiagnosticReport
- DiagnosticOrder
- ImagingStudy
- Specimen
- DeviceObservationReport

Workflow Management:

- Encounter
- Alert
- Supply
- Order
- OrderResponse

Exchange:

- MessageHeader
- OperationOutcome
- Query
- Subscription

Data Collection:

- Questionnaire
- QuestionnaireAnswers
- FamilyHistory

Scheduling:

- Appointment
- Appointment Response
- Availability
- Slot

Conformance:

- Conformance
- Profile
- DataElement
- OperationDefinition
- ValueSet
- Namespace
- ConceptMap

Lifecycle Events on FHIR **Targets**

- 30 September 2014
 - RecordLifecycleEvent FHIR Profile Proposal
 - <u>http://wiki.hl7.org/index.php?title=RecordLifecycleEvent_FHIR_Profile_Proposal</u>
- 7 December 2014
 - Submit DRAFT Proposal
 - Ready for Comment Only Ballot
- Spring 2015
 - FHIR DSTU 2 Ballot

Now Underway Mapping to FHIR

| Requirements | Are Fulfilled by |
|---|---|
| ISO/HL7 10781 EHR-S FM R2 Record Infrastructure (RI) \rightarrow 24(+3) Record Lifecycle Events | Implementable FHIR Resources |
| Basic Lifecycle Event | SecurityEvent |
| Provenance Lifecycle Event when Record Entry content is originated or updated | SecurityEvent Provenance Other new/updated resource(s) → corresponding to Action Taken |

↑ Resources may also be indivisibly and immutably bound by one or more digital signatures in a Record Entry.

EHR-S FM Record Lifecycle Pre/Post Events 1-9

| Pre Event State | Resource @ Event | Post Event State | | | | |
|------------------------------|----------------------------|----------------------------|--------------------------------------|-------------------------|---------------------|---------------------|
| | SecurityEvent + Provenance | Added Event Evidence | Retained Pre Edition Unaltered | Added New Edition | Signed as Author | Signed as System |
| [none] | 1 Originate/Retain | Х | | Х | Opt | Х |
| | 2 Amend | Х | X | Х | Opt | Х |
| | 3 Translate | Х | X | Х | | Х |
| [Record Entry as persisted, | 4 Attest | Х | X | | Х | Х |
| indivisible and | 5 Access/View | Х | | | | |
| immutable since | 6 Output/Report | Х | | | | Х |
| previous Lifecycle Event] | 7 Disclose | Х | | | | Х |
| | 8 Transmit | Х | | | | Х |
| | 9 Receive/Retain | Х | Х | | | |

11 December 2014

EHR-S FM Record Lifecycle Pre/Post Events 10-18

| Pre Event State | Resource @ Event | Post Event State | | | | |
|---------------------------------|-------------------------------|------------------|--------------------------------------|-------------------------|---------------------|---------------------|
| | SecurityEvent + Provenance | | Retained Pre Edition Unaltered | Added New Edition | Signed as Author | Signed as System |
| | 10 De-Identify | Х | Х | Х | | Х |
| | 11 Pseudonymize | Х | | | | |
| [Record Entry as | 12 Re-Identify | Х | | | | |
| persisted, | 13 Extract | Х | Х | Х | | Х |
| indivisible and immutable since | 14 Archive | Х | | | | |
| previous Lifecycle | 15 Restore | Х | | | | |
| Event] | 16 Destroy/Delete | Х | | [no | ne] | |
| | 17 Deprecate | Х | | | | |
| | 18 Re-Activate | Х | | | | |

11 December 2014

EHR-S FM Record Lifecycle Pre/Post Events 19-27

| Pre Event State | Resource @ Event | Post Event State | | | | |
|---------------------------------|------------------------|----------------------------|--------------------------------------|-------------------------|---------------------|---------------------|
| SecurityEvent + Provenance | | Added Event Evidence | Retained Pre Edition Unaltered | Added New Edition | Signed as Author | Signed as System |
| | 19 Merge | Х | Х | Х | | |
| | 20 Unmerge | Х | | | | |
| [Record Entry as persisted, | 21 Link | Х | | | | |
| | 22 Unlink | Х | | | | |
| indivisible and immutable since | 23 Add Legal Hold | Х | | | | |
| previous Lifecycle | 24 Remove Legal Hold | Х | | | | |
| Event] | 25 Verify (new event) | Х | | | | |
| | 26 Encrypt (new event) | Х | Х | ? | | |
| | 27 Decrypt (new event) | Х | Х | ? | | |

11 December 2014

Pre/Post Entry Content and...

Record Entry Lifecycle

Lifecycle Starts: at Point of Origination/Creation as New Event

| | Prior Event Added | During Interval between Events Retains (at rest): Indivisibly+Immutably | PRE | At New Event Adds | POST |
|--------------|---|--|----------|---|---------|
| Basic | 1 SecurityEvent instance | 1 or more SecurityEvent instances >> One per each prior Record Lifecycle Event | → | 1 SecurityEvent instance | Event |
| Jance | 1 Provenance instance | 1 or more Provenance instances >> One per each prior Record Lifecycle Provenance Event | ÷ | 1 Provenance instance | Prior |
| w/Provenance | 1 or more other resource instance(s) | 1 or more other FHIR resource instances > Corresponding to Action(s) Taken > As documented in Record Entry(ies) | → | 1 or more other resource instance(s) | Becomes |
| | | | | | |

From ISO/HL7 10781 EHR-S FM – Sample Conformance Criteria Originate/Retain Record Entry

With Event Evidence (RI.1.1.1.1) → At Lifecycle Event Occurrence (RI.1.1.1)

- **1** The system SHALL provide the ability to capture (originate) a Record Entry instance corresponding to an Action instance and context.
- 2 The system SHALL capture a unique instance identifier for each Record Entry.
- 3 The system SHALL capture the signature event (e.g., digital signature) of the origination entry Author, binding signature to Record Entry content.
- **4.** The system SHALL provide the ability to capture both structured and unstructured content in Record Entries.
- 5. The system SHALL provide the ability to capture Record Entries from information recorded during system downtime.
- 6. The system SHOULD provide the ability to integrate Record Entries from Information recorded during system downtime.
- 7 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.
- 8 The system SHOULD capture metadata that identifies the source of non-originated Record Entry (e.g., templated, copied, duplicated, or boilerplate information).
- 9. 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), or by order of relative importance.
- **10** The system MAY capture and maintain a Record Entry encoded as a standards-based data object (e.g., HL7 Continuity of Care, other HL7 CDA R2 Document, ISO 13606 artifact).
- **11.** The system MAY capture and maintain a standards-based data object to mirror (be duplicate and synchronous with) internal Record Entry representation.
 - Fulfilled by FHIR Resource Implementation
 - Lifecycle Event Metadata (who, what, when, where, why)

- 1. The system SHALL audit each occurrence when a Record Entry is originated and retained.
- **2.** The system SHALL capture identity of the organization where Record Entry content is originated.
- **3.** The system SHALL capture identity of the patient who is subject of Record Entry content.
- **4.** The system SHALL capture identity of the individual(s) who performed the Action documented in Record Entry content.
- 5. The system SHALL capture identity of the user who entered/authored Record Entry content.
- **6.** The system SHALL capture identity of the system application which originated Record Entry content.
- 7. IF the source of Record Entry content is a device THEN the system SHALL capture identity of the device.
- 8. The system SHALL capture the Action as evidenced by Record Entry content.
- **9.** The system SHALL capture the type of Record Event trigger (i.e., originate/retain).
- **10.** The system SHALL capture date and time of Action occurrence as evidenced by Record Entry content.
- **11.** The system SHALL capture date and time Record Entry content is originated.
- **12.** The system MAY capture the duration of the Action evidenced by Record Entry content.
- **13.** The system MAY capture the physical location of the Action evidenced by Record Entry content.
- **14.** The system SHOULD capture identity of the location (i.e., network address) where Record Entry content is originated.
- **15.** The system MAY capture the rationale for the Action evidenced by Record Entry content.
- **16.** The system MAY capture the rationale for originating Record Entry content.
- **17.** IF Record Entry content includes templates (boilerplate information) or copied (duplicated) information THEN the system SHOULD capture the source of such content.

11 December 2014

EHR Record Lifecycle Event Metadata on FHIR

Individuals have specific...

Action and Record Entry Roles

| Action Roles | Record Entry Roles |
|---|---|
| Subject Performer Witness | Record Target Author Recorder (Enterer?) Verifier Attester Informant Source/Copy From |

Example – Medication Order

Action and Record Entry Metadata

| | Action Metadata | Record Entry Metadata |
|-----|--|---|
| | Action Subject (Patient) Johnny Walker Role: Subject | Entry Subject (Patient) Johnny Walker Role: Record Target |
| | Action Organization Bay City Medical Center | |
| Who | Action Practitioner/ Performer Doctor Sally Smith Role: Performer | Entry Source – Author or Scribe Nurse Janice Jones Role: Recorder |
| | | Entry Source – System/Device Erstwhile EHR/Device XX123456 |

Example – Medication Order

Action and Record Entry Metadata

| | Action Metadata | Record Entry Metadata |
|-------|---|--|
| What | Action Taken Medication Order for Ambien 20mg PRN | Entry Origination/Retention evidenced by SecurityEvent Provenance + FHIR Resources related to Medication Order MedicationPrescription, et al |
| When | Action Date/Time 22 Aug 2014 @ 1800 | Entry Date/Time 22 Aug 2014 @ 1810 |
| When | Action Duration 3 Minutes | |
| Where | Action Physical Location Ward/Room B/12 | Entry Location – IP Address 255.255.255.1 |
| Why | Action Reason/Purpose To Induce Sleep | Entry Reason/Purpose <none entered=""></none> |

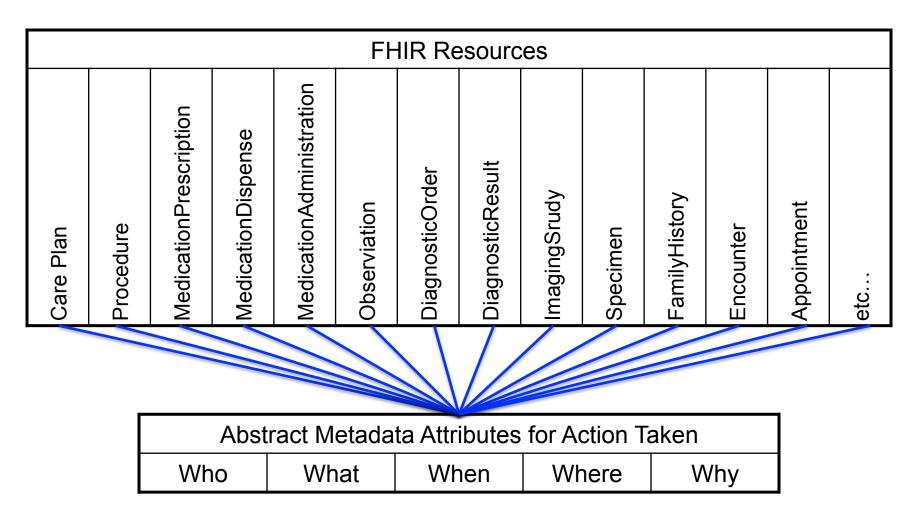
EHR-S FM Record Infrastructure (RI) – Lifecycle Events Plus... More Evidentiary Metadata

| | Lifecycle Event → | Originate Retain | Amend | Attest | Translate |
|--------|--|---------------------|-------|--------|-----------|
| ES. | Record Entry Unique ID | Х | | | |
| RM-ES. | Record Entry Content: Data, Document, Artifact ID(s) | Х | Х | | |
| by | Digital Signature(s) – Individual(s) | | | Х | |
| Vetted | Digital Signature – Acting System/Device | Any/All | | | |
| Ve | Corresponding/linked Record Entry(ies) | Х | Х | | |
| | Pointer to Pre-Event Entry, if any: pre update/translation | | Х | | Х |
| | Pointer to Post-Event Entry, if any: post update/translation | | Х | | Х |
| | Amendment and/or Translation Sequence | | Х | | Х |
| | Identity and version of Translation Tool(s), if any | | | | Х |

EHR-S FM Record Infrastructure (RI) – Lifecycle Events Plus... More Evidentiary Metadata

| | Lifecycle Event → | Originate Retain | Amend | Attest | Disclose Transmit |
|-----------|--|--|---|--|----------------------|
| by RM-ES. | Source of Copied Content: if copy/paste, template or boilerplate | | Х | | |
| oy R | Event is Known Disclosure Indicator | | | | X |
| Vetted | Permissions associated with Record Entry Content | | | | X |
| Vet | Entries in Event Transaction, if multiple | Acc Tra Rec Ext Arc Des | of Entr cesse nsmit ceived racted stroye /Off L | d/Viev ted d d /Rest ed/Del | ored |

A Potential Solution for Action Metadata Abstract Attributes



Analysis, Comments and Proposals Upcoming Slides...

- From the perspective of each Lifecycle Event:
 - Basic Metadata:
 Who, What, When, Where, Why
 - Plus... More Evidentiary Metadata

<u>Lifecycle Event Metadata</u>

| Lifecycle Event Metadata | FHIR Resource | Resource Attribute(s) |
|-----------------------------|-----------------------------------|---|
| | Provenance | signature : string 0* |
| Organization | Provenance.Agent : 0* | role : Coding 11 « ProvenanceAgentRole+ » type : Coding 11 « ProvenanceAgentType+ » reference : uri 11 |
| | Provenance | signature : string 0* |
| Patient | Provenance.Agent : 0* | role : code 11 « ProvenanceEntityRole » type : Coding 11 « ProvenanceEntityType+ » reference : uri 11 |
| | SecurityEvent.Participant : 1* | role : CodeableConcept 0* « DICOMRoleId+ » reference : Resource(Organization Practitioner Patient Device) 01 requester : Boolean 11 |
| Action - Performer | TBD | |

Distinguish Action from Record Metadata. [See Medication Order Example] Action-Performer not resolved. Need to add RelatedPerson to Practitioner|Patient|Device choice (per Lloyd)?

Lifecycle Event Metadata Who, con't

| Lifecycle Event Metadata | FHIR Resource | Resource Attribute(s) |
|-----------------------------|-----------------------------------|--|
| | Provenance | signature : string 0* |
| Record - Author/ | Provenance.Agent : 0* | role : Coding 11 « ProvenanceAgentRole+ » type : Coding 11 « ProvenanceAgentType+ » reference : uri 11 |
| User | SecurityEvent.Participant : 1* | role : CodeableConcept 0* « DICOMRoleId+ » reference : Resource(Practitioner Patient Device) 01 userId : string 01 requester : Boolean 11 |
| | Provenance | signature : string 0* |
| Record - | Provenance.Agent : 0* | role : Coding 11 « ProvenanceAgentRole+ » type : Coding 11 « ProvenanceAgentType+ » reference : uri 11 |
| System/Device | SecurityEvent.Participant : 1* | role : CodeableConcept 0* « DICOMRoleId+ » reference : Resource(Practitioner Patient Device) 01 userId : string 01 requester : Boolean 11 |

Note: Provenance.Agent.reference may resolve to a uri or Resource Provenance.signature 0..* instead of 0..1

<u>Lifecycle Event Metadata</u> What

| Lifecycle Event Metadata | FHIR Resource | Resource Attribute(s) | |
|-----------------------------|---------------------------|--|--|
| Action - Taken | TBD | | |
| | SecurityEvent.Event : 11 | type : CodeableConcept 11 « SecurityEventType+ » subtype : CodeableConcept 0* « SecurityEventSubType+ » action : code 01 « SecurityEventAction » <i>policy</i> : uri 0* | |
| Record - Lifecyle Event | SecurityEvent.Object : 0* | identifier : Identifier 01 reference : Resource(Any) 01 type : code 01 « SecurityEventObjectType » role : code 01 « SecurityEventObjectRole » lifecycle : code 01 « SecurityEventObjectLifecycle » | |

Action Taken not resolved. Add policy attribute to SecurityEvent.Event [See Medication Order Example <corresponding set of Med Order resources>]

<u>Lifecycle Event Metadata</u> When

| Lifecycle Event Metadata | FHIR Resource | Resource Attribute(s) |
|---------------------------------------|--------------------------|-----------------------|
| Action - Date/ Time | твр | |
| Record - Date/ | Provenance | recorded : instant 11 |
| Time | SecurityEvent.Event : 11 | dateTime : instant 11 |
| Action - Duration/ Elapsed Time | твр | |

Action Date/Time and Duration not resolved.

Lifecycle Event Metadata Where

| Inelauala | | Resource Attribute(s) |
|-------------------------------|---------------------------------------|--|
| Action - Physical Location | ТВД | |
| Record - | Provenance | location : Resource(Location) 01 |
| Network Address | SecurityEvent.Participant.Net work | identifier : string 01 type : code 01 « SecurityEventParticipantNetworkType » |

Action Physical Location not resolved. Add "location" to SecurityEvent.Event?

Lifecycle Event Metadata Why

| Lifecycle Event Metadata | FHIR Resource | Resource Attribute(s) |
|---|--------------------------|-----------------------------|
| Action - Reason, Rationale, Purpose | TBD | |
| Record - | D | reason : CodeableConcept 01 |
| Reason, Rationale, | Provenance | policy : uri 0* |
| Purnose | SecurityEvent.Event : 11 | reason : CodeableConcept 01 |

Action Reason not resolved Reason or purpose of use (DICOM) Add "reason" to SecurityEvent.Event?

Lifecycle Event Metadata Evidentiary

| Lifecycle Event Metadata | FHIR Resource | Resource Attribute(s) |
|--|---|--|
| Digital Signature(s) | Provenance | signature : string 0* |
| Record Entry ID | SecurityEvent.Object : 0* | identifier : Identifier 01 reference : Resource(Any) 01 |
| Record Entry Content ID(s): data, docs, artifacts | SecurityEvent.Object : 0*, one for each Content item | identifier : Identifier 01 reference : Resource(Any) 01 |
| Corresponding/ linked Record Entry(ies) | SecurityEvent.Object : 0*, one for each linked Record Entry | identifier : Identifier 01 reference : Resource(Any) 01 |
| Amendment/ Translation Sequence | SecurityEvent.Object : 0* | lifecycle : code 01 « SecurityEventObjectLifecycle » |
| Pointer to Pre Event Entry, if chained | SecurityEvent.Object : 0*, one to previous instance | identifier : Identifier 01 reference : Resource(Any) 01 |

Shouldn't signature be 0..* (System/Device + Individual)?

<u>Lifecycle Event Metadata</u> Evidentiary, con't

| Lifecycle Event Metadata | FHIR Resource | Resource Attribute(s) | |
|---|---|---|--|
| | SecurityEvent.Object : 0*, one for each source | identifier : Identifier 01 reference : Resource(Any) 01 type : code 01 « SecurityEventObjectType » role : code 01 « SecurityEventObjectRole » | |
| Event is known Disclosure | SecurityEvent.Object : 0* | ifecycle : code 01 « SecurityEventObjectLifecycle », where lifecycle = disclosure" | |
| | SecurityEvent.Participant : 1*, one for each participant | role : CodeableConcept 0* « DICOMRoleId+ » [for role-based] reference : Resource(<u>Practitioner</u> Patient Device) 01 userId : string 01 [for user-based permissions] | |
| | SecurityEvent.Object : 0* | sensitivity : code 01 «SecurityEvent.object.sensitivity » | |
| | SecurityEvent.Object : 0*, one for each Record Entry | identifier : Identifier 01 reference : Resource(Any) 01 type : code 01 « SecurityEventObjectType » | |
| Identifier/Version of Translation Tools | SecurityEvent.Participant : 1*, one for each tool | role : CodeableConcept 0* « DICOMRoleId+ » reference : Resource(Practitioner Patient Device) 01 userId : string 01 | |

For SecurityEvent.Participant, role and identifier support role and user-based authorization/access control.

Analysis, Comments and Proposals Upcoming Slides...

- From the perspective of FHIR Provenance and SecurityEvent resources:
 - Targeted Resource Attributes, some with Code/Value Sets
 - Resource Notes, Comments and Proposals

FHIR Resource Provenance

| Resource | Resource Attribute | Description | Value Set |
|------------|-----------------------------|---|-----------|
| Provenance | L | Who, What, When for a set of | |
| | | resources | |
| | target : Resource(Any) 1* | Target resources (usually version specific) | |
| | period : Period 01 | When the activity occurred | |
| | recorded : instant 11 | When the activity was recorded/updated | |
| | | Where the activity occurred, if relevant | |
| | reason : CodeableConcept 01 | Reason activity is occurring | TBD |
| | | Policy or plan the activity was defined by | |

FHIR Resource Provenance.Agent

| Resource | Resource Attribute | Description | Value Set |
|----------------------|---|---|--|
| Provenance. Agent | → | Person, organization, records, etc. involved in creating resource | |
| | role : Coding 11 « ProvenanceAgentRole+ » | | <confirm> Enterer, performer, author, verifier, attester, informant, source, cc, application, daemon</confirm> |
| | type : Coding 11 « ProvenanceAgentType+ » | | <confirm> Practitioner, organization, software, record, document</confirm> |
| | reference : uri 11 | | |

Provenance.Agent.reference may resolve to a uri or Resource (like others) Review value sets for "role" and "type" [RM-ES]

FHIR Resource SecurityEvent.Event

| Resource | Resource Attribute | Description | Value Set |
|-------------------------|---|--|--|
| SecurityEve nt.Event | → | What was done | |
| | type : CodeableConcept 11 « SecurityEventType+ » | Type/identifier of event | <confirm> Rest + DICOM codeset</confirm> |
| | subtype : CodeableConcept 0* « SecurityEventSubType+ » | More specific type/id for the event | <confirm> Read, vread, update, delete, validate, create, history-instance, history-type, history-system, search-type, search-system, transaction + DICOM codeset</confirm> |
| | action : code 01 « SecurityEventAction » | | <confirm> C) Create; R) Read/view/print; U) Update; D) Delete; E) Execute.</confirm> |
| | dateTime : instant 11 | Time when the event occurred on source | |
| | reason : CodeableConcept 01 | TBD | TBD |
| | policy : uri 0* | Policy or plan the activity was defined by | |

Review value sets for "type", "subtype" and "action". Add "reason", "policy" attributes with value set for "reason".

FHIR Resource SecurityEvent.Source

| Resource | Attribute | Description | Value Set |
|--------------------------|---|---|--|
| SecurityEve nt.Source | 7 | Application systems and processes | |
| | | Logical source location within the enterprise | |
| | identifier | The id of source where event originated | |
| | type : CodeableConcept 11 « SecurityEventSourceType+ » | The type of source where event originated | <confirm> 1) User Device; 2) Data Interface; 3) Web Server; 4) Application Server; 5) Database Server; 6) Security Server; 7) Network Device; 8) Network Router; 9) Other.</confirm> |

[This sub-resource not currently referenced by Lifecycle Event metadata.] Review value set for "type" [RM-ES].

FHIR Resource SecurityEvent.Object

| Resource | Resource Attribute | Description | Value Set |
|--------------------------|--|---|--|
| SecurityEve nt.Object | → | Specific instances of data or objects accessed | |
| | identifier : Identifier 01 | Specific instance of object (e.g. versioned) | |
| | reference : Resource(Any) 01 | Specific instance of resource (e.g. versioned) | |
| | type : code 01 « SecurityEventObjectType » | Object type being audited | <confirm> 1) Person; 2) System Object; 3) Organization; 4) Other.</confirm> |
| | role : code 01 « SecurityEventObjectRole » | Functional application role of Object | <confirm> 1) patient; 2) location; 3) report; 4) resource; 5) master file; 6) user; 7) list; 8) doctor; 9) subscriber; 10) guarantor; 11) security user entity; 12) security user group; 13) security resource; 14) security granularity definition; 15) practitioner; 16) data destination; 17) data reposition; 18) schedule; 19) customer; 20) job; 21) job stream; 22) table; 23) routing criteria; 24) query.</confirm> |

For "type", need "EHR record entry" as specific value. Review value sets for "type" and "role" [RM-ES].

FHIR Resource SecurityEvent.Object, con't

| Resource | Resource Attribute | Description | Value Set |
|----------|--|--|--|
| | lifecycle : code 01 « SecurityEventObjectLifecycle » | Life-cycle stage for the object | <confirm> 1 OriginationCreation; 2) Import/ Copy from original; 3) Amendment; 4) Verification; 5) Translation; 6) Access/Use; 7) De-identification; 8) Aggregation, summarization, derivation; 9) Report; 10) Export/ Copy to target; 11) Disclosure; 12) Receipt of disclosure; 13) Archiving; 14) Logical deletion; 15) Permanent erasure/Physical destruction</confirm> |
| | sensitivity : code 01 «SecurityEvent.object.sensitivity » | Policy-defined sensitivity for the object | <confirm> L) Low; M) Moderate; N) Normal; R) Restricted; U) Unrestricted; V) Very restricted.</confirm> |
| | description : string 01 | Instance-specific descriptor for Object | |

SecurityEvent.Object.lifecycle must reference RI.1.1.1-27. Review value sets for "lifecycle" and "sensitivity" [RM-ES].

FHIR Resource SecurityEvent.Participant

| Resource | Resource Attribute | Description | Value Set | | | | |
|------------------------------|--|---|-----------|--|--|--|--|
| SecurityEve nt.Participan | | A person, a hardware device or software process | | | | | |
| t | | User roles (e.g. local RBAC codes) | | | | | |
| | reference : Resource(Practitioner Patient Device) 01 | Direct reference to resource | | | | | |
| | userId : string 01 | Unique identifier for the user | | | | | |
| | requester : Boolean 11 | Whether user is initiator | | | | | |
| | <i>location :</i> Resource(Location) 01 | TBD | | | | | |

Review value set for "role".

FHIR Resource SecurityEvent.Participant.Network

| Resource | Resource Attribute | Description | Value Set |
|------------------------------|--------------------------|--|---------------------|
| SecurityEve nt.Participan | | Logical network location for application activity | |
| t.Network | identifier : string 0, 1 | Identifier for the network access point of a user device | |
| | | The type of network access point | <confirm></confirm> |

Review value set for "type" [RM-ES].

Basics

Record Entry and FHIR Resources

- An EHR System manages a persistent EHR comprising Record Entries for
 - One or more provider organizations,
 - One or more individual practitioners, and
 - Many patients
- An EHR comprises
 - Many Record Entry instances
- A Record Entry instance may comprise
 - One or more FHIR Resource instance(s)
 - With signature bindings

Project Focus/Success Criteria

FHIR Enabled Lifecycle Events

| Project Focus | Success Criteria |
|---|--|
| Binds (joins) FHIR Resource Instance(s) together in Record Entry Instance: Including applicable Clinical, Administrative, Infrastructure Resources Based on Action(s) Taken | Complete specification of baseline Set of FHIR Resources applicable at each Record Lifecycle Event (1-27) and captured in the resulting Record Entry Instance Allowing additional Resources to be bound in a Record Entry Instance, per Clinical, Administrative and/or other context |
| Includes Pre- and Post-LifecycleEvent Entry Statese.g., before/after amendment or translation | Complete specification of how both pre- and post-lifecycle event states (of FHIR Resources) are captured and preserved in one or more Record Entries |

Project Focus/Success Criteria

FHIR Enabled Lifecycle Events

| Project Focus | Success Criteria |
|---|--|
| Includes Action/Event Metadata | Complete specification of Action/Event Metadata (in FHIR Resources) per Record Entry |
| Includes Attestation and Content Binding • With/without Digital Signature | Complete specification of: Attestation and/or Digital Signature bound to Record Entry content |

EHR Record Lifecycle/Lifespan

Dimensions of End-to-End Flow

Record Lifespan

- 1. Within Single System
 - <u>Starting</u> at point of origination, in Source System
 - <u>Starting</u> at point of receipt, in Receiving System
 - <u>Ending</u> at point of deletion
- 2. Across Multiple Systems
 - <u>Starting</u> at point of origination, in Source System
 - <u>Traversing</u> one or more Points of Exchange
 - Ending at point of deletion, in each System

Record Lifespan – End-to-End Within Single System

| Record Lifespan | | | | | | | | |
|--|--|--------------|--|--|--|--|--|--|
| Start | Intervening Record Lifecycle Events (0 to many) | End | | | | | | |
| <u>Source System</u> (1) Originate/ Retain Record Entry | (2) Amend (3) Translate (25,4) Verify, Attest (5) View/Access (6) Output/Report (7) Disclose (8) Transmit (10) De-Identify (11) Decude pumize | (16) Destroy | | | | | | |
| <u>Receiving System</u> (9) Receive/Retain Record Entry | (11) Pseudo-nymize (12) Re-Identify (13) Extract (14,15) Archive, Restore (17,18) Deprecate/Retract, Re-Activate (19,20) Merge, Unmerge (21,22) Link, Unlink (23,24) Place, Remove Legal Hold (26,27) Encrypt, Decrypt | (16) Destroy | | | | | | |

Record Lifespan – End-to-End Across Multiple Systems

| Record Lifespan | | | | | | | | | | | |
|--------------------------------------|--|-------------------|--|--------------|--|--|--|--|--|--|--|
| Start | Intervening <u>Record Lifecycle Events</u> (1 to many) End | | | | | | | | | | |
| Source/Send | ing System | | Receiving Sy | vstem | | | | | | | |
| (1) Originate/Retain Record Entry | (6) Output/Report (7) Disclose (8) Transmit | Point of Exchange | (9) Receive/Retain (5) View/Access (6) Output/Report (13) Extract | (16) Destroy | | | | | | | |

Repeated at each point of exchange...

Current/Emerging Projects Related to...

EHR-S FM Record Infrastructure

- EHR Record Lifecycle Event Metadata using HL7 Fast Health Interoperable Resources (FHIR) – this project
- S&I Data Provenance
- S&I esMD
- S&I Simplification
 - S&I Use Case Requirements Analysis
 - Use Case Authoring Tool (UCAT) Development
- HL7 Functional Model Framework
 - Next Releases of EHR-S FM (R3), PHR-S FM (R2), Lab FM (?)
- HL7 Vocabulary Harmonization: EHR, Security, CBCC WGs
- Functional Profile Development: RM-ES R2, MU FP, PH FPs
- ISO 21089 Revision, Trusted End-to-End Information Flows
- ISO 13606 Revision, EHR Communication

| ISO/HL7 Standard or S&I Activity → Record Lifecycle Event ↓ (EHR-S FM RI.1.1.x) | ISO TC215 – Stds. Infrastructure Frame | ISO 21089:2004 Trusted End to End Published TR | ISO 21089:2014 Trusted End to End In development | ISO/HL7 10781 EHRS FM R2:2014 Published | ISO/HL7 16527 PHRS FM R2 In development | ISO 19669 – Re- Usable Use Case In development | ISO 13606 – EHR Communication In Revision | HL7 EHR Lifecycle Model DSTU:2008 Published | HL7 RM-ES FP R2 In Development | HL7 Record Lifecycle on FHIR In Development | US S&I Simplification | US S&I Data Provenance |
|---|---|--|--|---|---|--|---|---|-----------------------------------|---|-----------------------|---------------------------|
| 1 Originate/Retain Record Entry | X | X | X | X | X | x | | х | X | Х | Х | |
| 2 Amend Record Entry | X | X | X | X | X | X | | X | x | X | X | |
| 3 Translate Record Entry | X | X | X | X | X | X | | X | X | X | X | |
| 4 Attest Record Entry | X | | X | X | X | X | | X | X | X | X | |
| 5 View/Access Record Entry | X | X | X | X | X | X | | Х | X | X | Х | |
| 6 Output/Depart Depard Entry | V | X | X | X | X | Х | Х | Х | X | X | Х | |
| 7 Disclose Record Entry | X | X | X | X | X | Х | Х | Х | X | Х | Х | |
| 8 Transmit Record Entry | | X | X | X | X | X | х | Х | X | х | Х | |
| 9 Receive/Retain Record Entry | X | X | X | Х | X | х | X | х | X | х | Х | |
| 10 De-Identify Record Entry | X | X | X | X | X | Х | | Х | X | X | Х | |
| 11 Pseudo-nymize Record Entry | X | X | X | X | X | x | | Х | X | X | Х | |
| 12 Re-Identify Record Entry | X | X | X | X | X | Х | | Х | X | X | Х | |
| 13 Extract Record Entry | X | X | X | X | Х | Х | | Х | X | X | Х | |
| 14 Archive Record Entry | X | X | X | X | Х | Х | | Х | X | Х | Х | 1BD |
| 15 Restore Record Entry | X | | X | X | X | X | | Х | X | X | Х | |
| 16 Destroy Record Entry | X | X | X | X | X | Х | | Х | X | X | Х | |
| 17 Deprecate/Retract Record Entry | X | | X | X | X | X | | | X | X | Х | |
| 18 Re-Activate Record Entry | X | | X | X | Х | Х | | | X | Х | Х | |
| 19 Merge Record Entry | X | | X | X | X | X | | | X | X | Х | |
| 20 Unmerge Record Entry | X | | X | X | X | Х | | | X | Х | Х | |
| 21 Link Record Entry | X | | X | X | X | Х | | | X | X | Х | |
| 22 Unlink Record Entry | X | | X | X | Х | Х | | | X | X | Х | |
| 23 Place Legal Hold on Record Entry | X | 1 | X | X | N/A | Х | | | X | Х | Х | |
| 24 Remove Legal Hold on Record Entr | | | X | X | | X | | | X | X | Х | |
| 25 Verify Record Entry Content | X | X | X | | X | X | | Х | X | X | Х | |
| 26 Encrypt Record Entry | X | - | X | | X | X | | | X | X | X | |
| 27 Decrypt Record Entry | X | | X | | X | X | | | X | X | X | |
| Applicable Lifecycle Events | ▶ 27 | 15 | 27 | 24 | 25 | 27 | 4 | 16 | 27 | 27 | 27 | ? |

ISO/HL7 10781 EHR System Functional Model Release 2 CRUDE per Record Lifecycle

| | ISO/HL7 10781 EHRS FM R2 – Record Lifecycle Events | | | | | | | | | | | New | | | | | | | | | | | | | | | |
|----------|--|---------|-------------|---------------|---------------|---|------------|------------|------------------|----------------|-----------------|----------------|------------|------------|------------|------------|--------------|----------------|----------|------------|---------|-----------|-----------------|-----------------|---|------------|------------|
| | 1 Originate/retain | 2 Amend | 3 Translate | 4 Attest/sign | 5 Access/view | | 7 Disclose | 8 Transmit | 9 Receive/retain | 10 De-identify | 11 Pseudomynize | 12 Re-identify | 13 Extract | 14 Archive | 15 Restore | 16 Destroy | 17 Deprecate | 18 Re-activate | 19 Merge | 20 Unmerge | 21 Link | 22 Unlink | 23 + Legal Hold | 24 – Legal Hold | 1 | 26 Encrypt | 27 Decrypt |
| Create | X | | | Х | | | | | Х | | | | | | | | | | | | | | | | | | |
| Read | | | | | X | | | | | | | | | | | | | | | | | | | | | | |
| Update | | Х | Х | Х | | | | | | Х | Х | Х | Х | Х | Х | | Х | Х | Х | Х | Х | X | Х | Х | X | Х | X |
| Delete | | | | | | | | | | | | | | | | X | | | | | | | | | | | |
| Execute | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pre | | | Х | Х | | | | | | Х | Х | | Х | | | | | | | | | | | | | X | |
| Exchange | | | | | | X | Х | Х | Х | | | | | | | | | | | | | | | | | | |
| Post | | | Х | | | | | | | Х | Х | Х | Х | | | | | | | | | | | | | | Х |

Longer Term...

Project Segments/Leads

| | | Leads |
|---|---|---|
| 1 | ISO/HL7 10781 EHR-S FM R2 RI – Record Infrastructure RM-ES – Records Management/ Evidentiary Support | Gary Dickinson, Reed Gelzer, MD, Lloyd McKenzie, John Moehrke, Diana Warner |
| 2 | TI – Trust Infrastructure | TBD |
| 3 | CP – Care Provision | TBD |
| 4 | CPS – Care Provision Support | TBD |
| 5 | AS – Administrative Support | TBD |
| 6 | POP – Population Health Support | TBD |
| 7 | ISO/HL7 16527 PHR-S FM R1 PH – Personal Health S – Supportive II – Information Infrastructure | John Ritter, et al. |

EHR-S FM Record Lifecycle Events on FHIR Links

• HL7 EHR Interop Wiki:

<u>http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG</u>