EHR-S FM R2 – Record Infrastructure

Record Entry Lifecycle Event Metadata on FHIR

Gary Dickinson

Co-Chair, HL7 EHR WG

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http://www.hl7.org/fhir

As of 23 Dec 2014

FHIR Clinical Resources

Clinical

General:

- AllergyIntolerance
- ClinicalAssessment
- Condition (aka Problem)
- ReferralRequest
- Procedure
- Contraindication
- RiskAssessment
- VisionPrescription

Data Collection & Care Plan:

- Questionnaire
- QuestionnaireAnswers
- FamilyHistory
- CarePlan
- CarePlan2
- Goal

Medication, Immunization & Nutrition:

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

Diagnostics:

- Observation
- DiagnosticReport
- DiagnosticOrder
- ImagingStudy
- ImagingObjectSelection
- Specimen

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FHIR Administrative Resources

Administrative

Attribution:

- Patient
- RelatedPerson
- Person
- Practitioner
- Organization
- HealthcareService

Entities:

- Contract
- Device
- DeviceComponent
- DeviceMetric
- Location
- Substance
- Group

Workflow Management:

- Encounter
- EpisodeOfCare
- Alert
- Communication
- CommunicationRequest
- Supply
- DeviceUseStatement

Scheduling / Ordering:

- Appointment
- Appointment Response
- Schedule
- Slot
- Order
- OrderResponse
- DeviceUseRequest
- ProcedureRequest

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FHIR Infrastructure Resources

Infrastructure

Support:

- Media
- Basic
- Other
- Provenance ←
- SecurityEvent ←

Documents & Structure:

- List
- Composition
- DocumentReference
- DocumentManifest

Exchange:

- MessageHeader
- OperationOutcome
- Subscription
- Bundle
- Binary

Conformance:

- Conformance
- Profile
- ExtensionDefinition
- DataElement
- SearchParameter
- OperationDefinition
- ValueSet
- NamingSystem
- ConceptMap

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FHIR Financial Resources

Financial

Support:

- Coverage
- EligibilityRequest
- EligibilityResponse
- EnrollmentRequest
- EnrollmentResponse
- PendedRequest
- Reversal
- StatusRequest
- StatusResponse
- SupportingDocumentation

Billing:

- ClaimResponse
- InstitutionalClaim
- OralHealthClaim
- PharmacyClaim
- ProfessionalClaim
- Readjudicate
- VisionClaim

Payment:

- PaymentNotice
- PaymentReconciliation

Other:

- ExplanationOfBenefit

Targets

- 30 September 2014
  - RecordLifecycleEvent FHIR Profile Proposal
  - http://wiki.hl7.org/index.php?title=RecordLifecycleEvent_FHIR_Profile_Proposal
- 7 December 2014
  - Complete DRAFT Proposal
  - For HL7 Comment Only Ballot: closed 12 Jan 2015
  - http://hl7-fhir.github.io/iglist.html
- 22 March 2015
  - Complete Final DRAFT Proposal
  - Ready for FHIR DSTU 2 Ballot
  - Included Lifecycle Events on FHIR comments

Now Underway

Mapping to FHIR

Requirements	Are Fulfilled by…
ISO/HL7 10781 EHR-S FM R2 Record Infrastructure (RI) → 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	X		X	Opt	X
[Record Entry as persisted, indivisible and immutable since previous Lifecycle Event]	2 Amend	X	X	X	Opt	X
	3 Translate	X	X	X		X
	4 Attest	X	X		X	X
	5 Access/View	X				
	6 Output/Report	X				X
	7 Disclose	X				X
	8 Transmit	X				X
	9 Receive/Retain	X	X			

EHR-S FM Record Lifecycle

Pre/Post Events 10-18

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
[Record Entry as persisted, indivisible and immutable since previous Lifecycle Event]	10 De-Identify	X	X	X		X
	11 Pseudonymize	X				
	12 Re-Identify	X				
	13 Extract	X	X	X		X
	14 Archive	X				
	15 Restore	X				
	16 Destroy/Delete	X	[none]			
	17 Deprecate	X				
	18 Re-Activate	X				

EHR-S FM Record Lifecycle

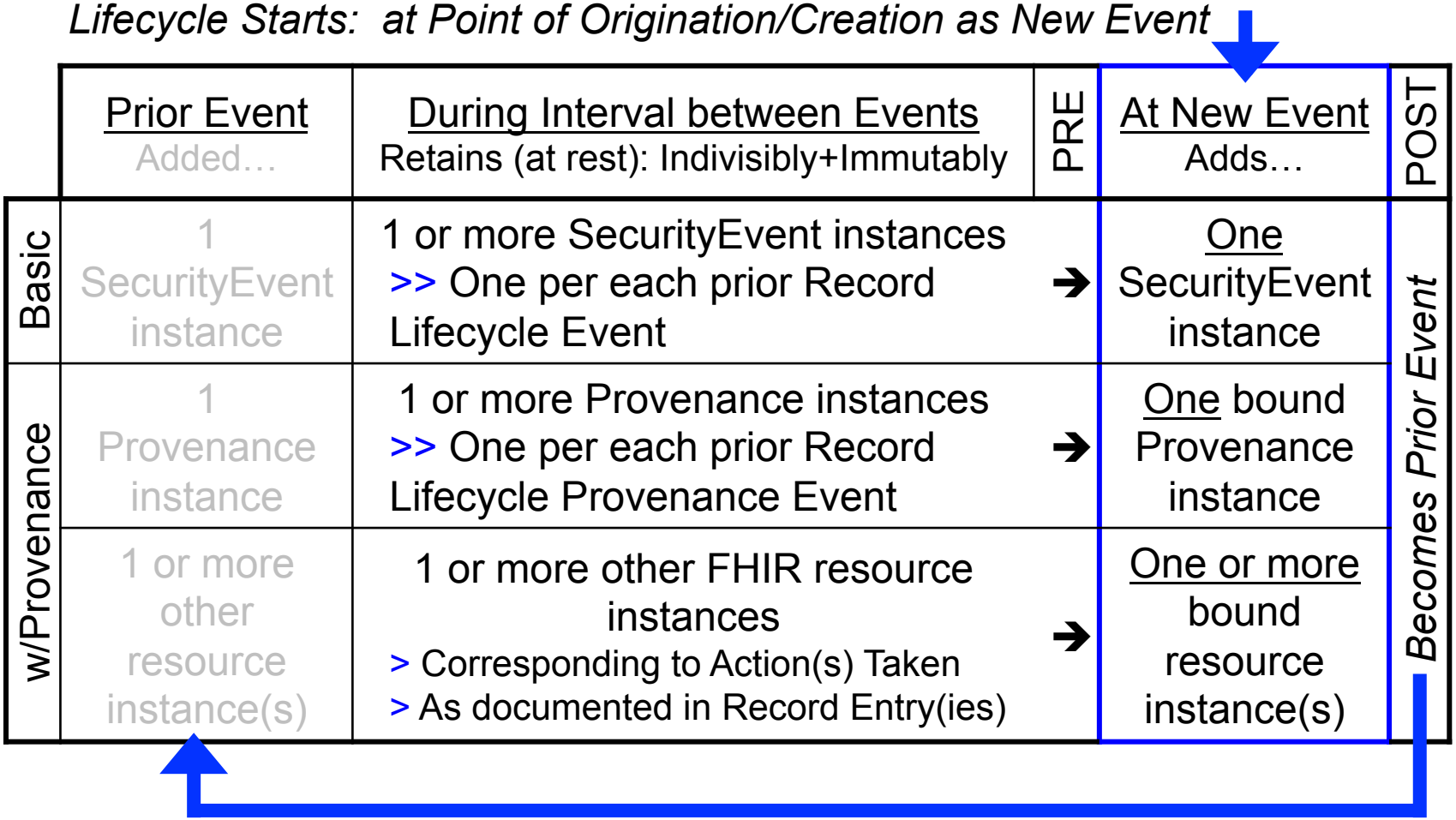
Pre/Post Events 19-27

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
[Record Entry as persisted, indivisible and immutable since previous Lifecycle Event]	19 Merge	X	X	X		
	20 Unmerge	X				
	21 Link	X				
	22 Unlink	X				
	23 Add Legal Hold	X				
	24 Remove Legal Hold	X				
	25 Verify (new event)	X				
	26 Encrypt (new event)	X	X	?		
	27 Decrypt (new event)	X	X	?		

Pre/Post Entry Content and…

Record Entry Lifecycle

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



From ISO/HL7 10781 EHR-S FM – Sample Conformance Criteria

Originate/Retain Record Entry

Vetted by RM-ES

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)
Others to consider

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.

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
Who	Action Subject (Patient) Johnny Walker Role: Subject	Entry Subject (Patient) Johnny Walker Role: Record Target
	Action Organization Bay City Medical Center	
	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
	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>

EHR-S FM Record Infrastructure (RI) – Lifecycle Events

Plus… More Evidentiary Metadata

Vetted by RM-ES

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

EHR-S FM Record Infrastructure (RI) – Lifecycle Events

Plus… More Evidentiary Metadata

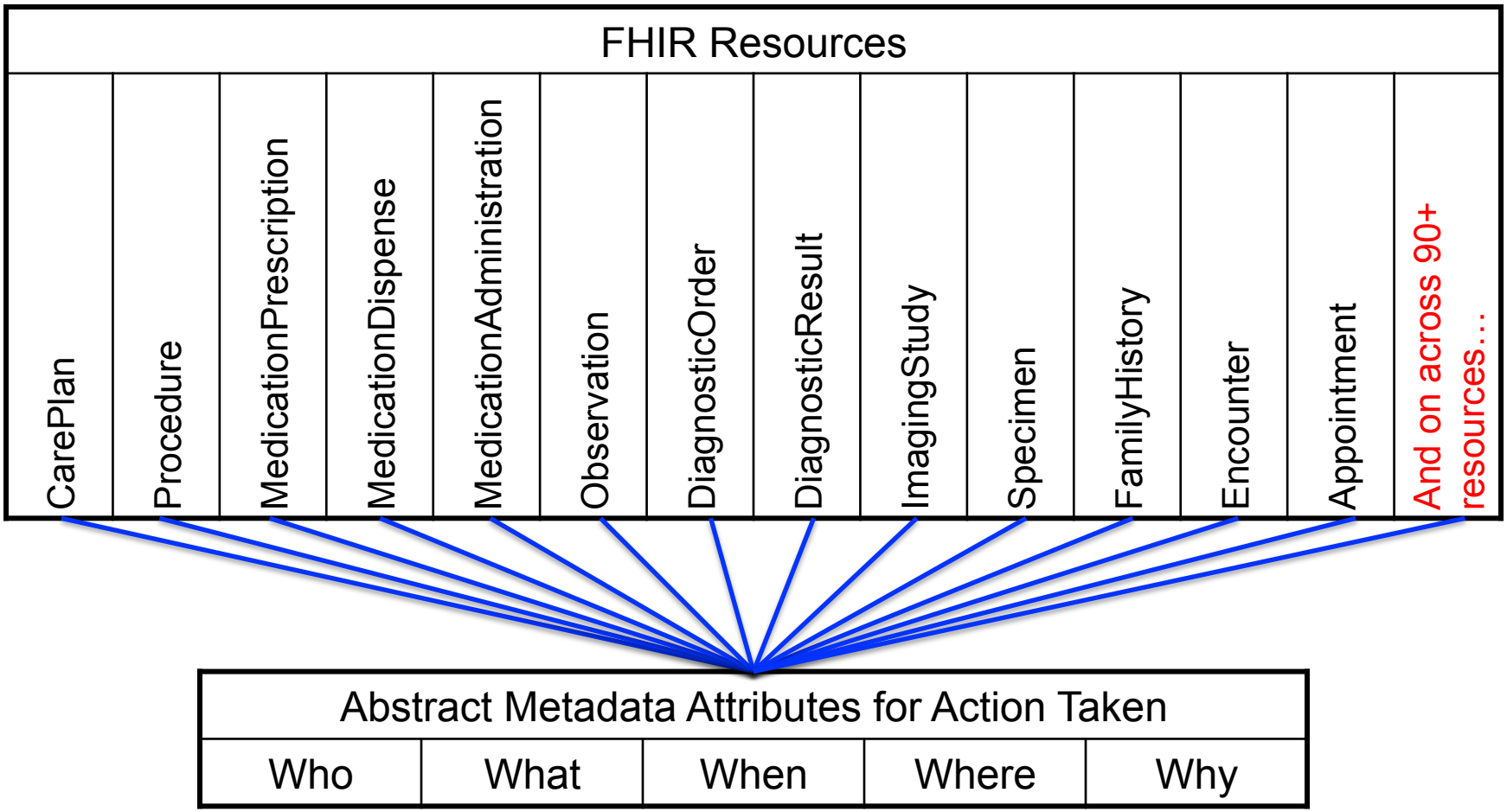
Vetted by RM-ES

Lifecycle Event →	Originate Retain	Amend	Attest	Disclose Transmit
Source of Copied Content: if copy/paste, template or boilerplate	X	X		
Event is Known Disclosure Indicator				X
Permissions associated with Record Entry Content	X	X		X
Entries in Event Transaction, if multiple	Set of Entries: • Accessed/Viewed • Transmitted • Received • Extracted • Archived/Restored • Destroyed/Deleted • On/Off Legal Hold …			

Submitted to FHIR COB

A Potential Solution for Action Metadata

Abstract Attributes



Events to FHIR Resources

- Based on ISO/HL7 10781 EHR-S FM R2 RI Metadata Requirements
- Basic
  - Who, What, When, Where, Why
- Evidentiary
  - Record Entry ID, Signature, Pre/Post Event States, Amendment Sequence…
- http://wiki.hl7.org/images/c/c2/EHRS-FM-Record_Lifecycle_Events_on_FHIR-Requirements-20150109.pdf

Select FHIR Resources, Attributes

- Select FHIR Resources and Attributes
  - http://wiki.hl7.org/images/4/41/EHRS-FM-Record_Lifecycle_Events_on_FHIR-Resource_Analysis_Worksheet-20150112.pdf
- Select FHIR Code/Value Sets
  - http://wiki.hl7.org/images/f/f7/EHRS-FM-Record_Lifecycle_Events_on_FHIR-Code_Value_Set_Analysis_Worksheet-20150112.pdf

Supporting Use Cases

- Use Case Template w/Lifecycle Events
  - http://wiki.hl7.org/images/3/34/EHRS_FM_R2-RI-Lifecycle_Event_Metadata_to_FHIR-Use_Cases-20140828.xlsx
- Patient, Provider Community Pharmacy Example Use Case
  - Julia Chan, Lead
  - Presentation: http://1drv.ms/1wwaMv9
  - Scenario Worksheet using Use Case Template: http://1drv.ms/Za7ODj

Data Provenance Examples

- Developed for S&I Data Provenance Community Initiative
- Examples with Record Lifecycle Events
  - http://wiki.hl7.org/images/7/79/ONC-Data_Provenance-User_Story_Examples-20140818.pdf

Submitted to FHIR COB

Before mid-March…

To Do's

- Resolve SecurityEvent → generic Event
- Add Reason (0..*) and Policy (0..*) attributes to SecurityEvent.Event
- Add Location (0..1) attribute to SecurityEvent.Participant
- Add multi-purpose (multi-signature role) Signature resource
- Resolve Action metadata: what, when, where, why
- Add "record lifecycle event" to code set for SecurityEvent.Object.type attribute

Submitted to FHIR COB

Before mid-March…

To Do's

- Add RelatedPerson to Practitioner|Patient| Device choice (per Lloyd)
- Resolve lifecycle code set (to include 27 Record Lifecycle Events) [submitted to COB]

Before mid-March…

To Do's

- Resolve reason (including purpose of use) code set
- Front Matter – description, scope and purpose:
  - Record Lifecycle Event Implementation Guide
  - Provenance Profile
  - SecurityEvent Profile
  - Conformance Guide

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(s) together in Record Entry Instance: • Including applicable Clinical, Administrative, Infrastructure and Financial 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 • Along with other Resources bound together in a Record Entry Instance, per Clinical, Administrative and/or other context
Provenance “Source of truth” at data capture/ origination, including: who, what, when, where, why	• Complete specification of how Provenance is bound to the “chain of trust” from point of origination to each ultimate point of access/use

Project Focus/Success Criteria

FHIR Enabled Lifecycle Events

Project Focus	Success Criteria
Includes Pre- and Post-Lifecycle Event Entry States • e.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
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 (per esMD) 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
   - Starting at point of origination, in Source System
   - Starting at point of receipt, in Receiving System
   - Ending at point of deletion
2. Across Multiple Systems
   - Starting at point of origination, in Source System
   - Traversing one or more Points of Exchange
   - Ending at point of deletion, in each System

Record Lifespan – End-to-End

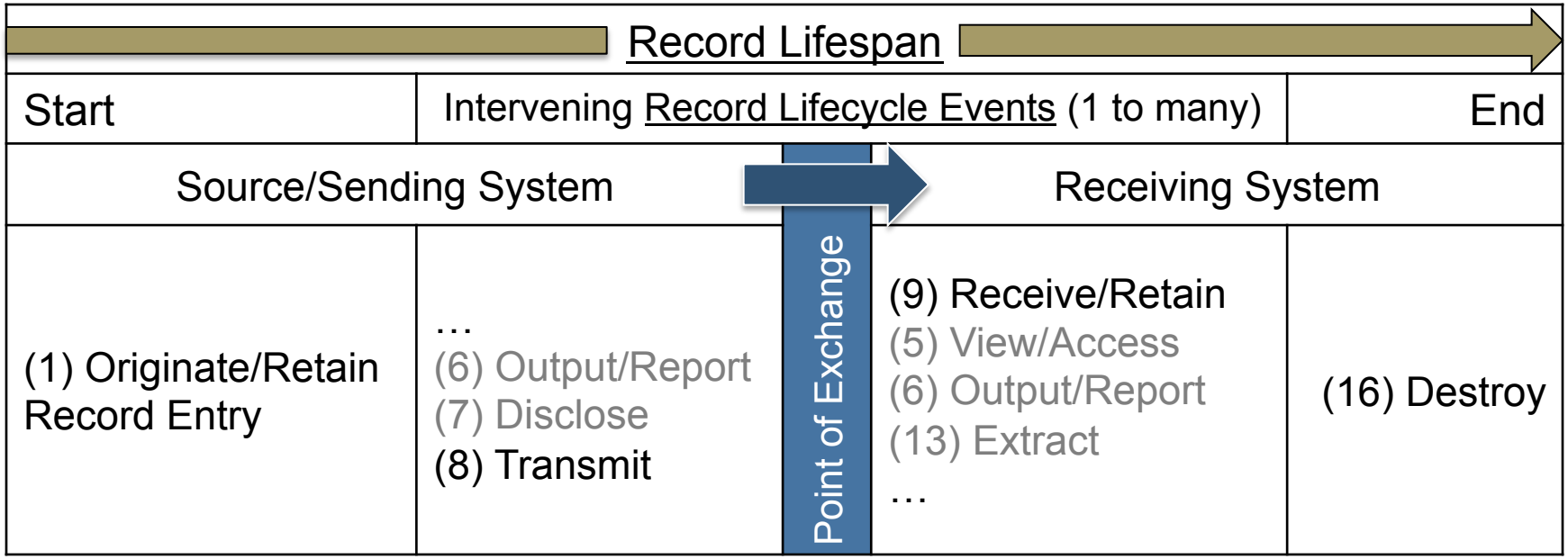
Within Single System

Record Lifespan

Start	Intervening Record Lifecycle Events (0 to many)	End
Source System (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) 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
Receiving System (9) Receive/Retain Record Entry		(16) Destroy

Record Lifespan – End-to-End

Across Multiple Systems



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 or PH 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 In development	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		X	X	X	X	TBD
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		X	X	X	X	
6	Output/Report Record Entry	X	X	X	X	X	X	X	X	X	X	X	
7	Disclose Record Entry	X	X	X	X	X	X	X	X	X	X	X	
8	Transmit Record Entry	X	X	X	X	X	X	X	X	X	X	X	
9	Receive/Retain Record Entry	X	X	X	X	X	X	X	X	X	X	X	
10	De-Identify Record Entry	X	X	X	X	X	X		X	X	X	X	
11	Pseudo-nymize Record Entry	X	X	X	X	X	X		X	X	X	X	
12	Re-Identify Record Entry	X	X	X	X	X	X		X	X	X	X	
13	Extract Record Entry	X	X	X	X	X	X		X	X	X	X	
14	Archive Record Entry	X	X	X	X	X	X		X	X	X	X	
15	Restore Record Entry	X		X	X	X	X		X	X	X	X	
16	Destroy Record Entry	X	X	X	X	X	X		X	X	X	X	
17	Deprecate/Retract Record Entry	X		X	X	X	X			X	X	X	
18	Re-Activate Record Entry	X		X	X	X	X			X	X	X	
19	Merge Record Entry	X		X	X	X	X			X	X	X	
20	Unmerge Record Entry	X		X	X	X	X			X	X	X	
21	Link Record Entry	X		X	X	X	X			X	X	X	
22	Unlink Record Entry	X		X	X	X	X			X	X	X	
23	Place Legal Hold on Record Entry	X		X	X	N/A	X			X	X	X	
24	Remove Legal Hold on Record Entry	X		X	X		X			X	X	X	
25	Verify Record Entry Content	X	X	X		X	X		X	X	X	X	
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	?

Exchange

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	6 Output/report	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	25 Verify	26 Encrypt	27 Decrypt
Create	X			X					X																		
Read					X																						
Update		X	X	X						X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X
Delete																X											
Execute																											
Pre			X	X						X	X		X													X	
Exchange						X	X	X	X																		
Post			X							X	X	X	X														X

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.

Links

- HL7 EHR Interop Wiki:
  - http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG