Record Lifecycle Events on FHIR
W5 Analysis Project
October FHIR Connectathon Track

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http://www.hl7.org/fhir

FHIR Infrastructure Resources

Infrastructure

Support:

- Media 1
- Basic 1
- Provenance 0 ←
- AuditEvent 0 ←

Documents & Structure:

- List 0
- Composition (+ Clinical Document) 2
- DocumentReference (+ XDS) 0
- DocumentManifest 0

Exchange:

- MessageHeader 2
- OperationOutcome 5
- Subscription 1
- Bundle 3
- Binary 3
- Parameters 0

Conformance:

- ImplementationGuide 0
- Conformance 0
- StructureDefinition 3
- ValueSet 4
- ConceptMap 2
- DataElement 3
- OperationDefinition 0
- SearchParameter 0
- NamingSystem 0
- TestScript 0

Targets

- # FHIR W5 Report Analysis
  - – Current Build: http://hl7-fhir.github.io/w5.html?
- # DSTU-2 Reconciliation Deadline
  - – 31 August 2015
- # DSTU-2 Publication
  - – September 2015(?)
- # FHIR Connectathon 10
  - – 3-4 October 2015, HL7 Atlanta

Mapping to FHIR

Requirements	Are Fulfilled by…
ISO/HL7 10781 EHR-S FM R2 Record Infrastructure (RI) → 24(+7) Record Lifecycle Events	Implementable FHIR Resources
<u>Basic Lifecycle Event</u>	• AuditEvent
<u>Provenance Lifecycle Event</u> when Record Entry content is originated or updated	• AuditEvent • 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.
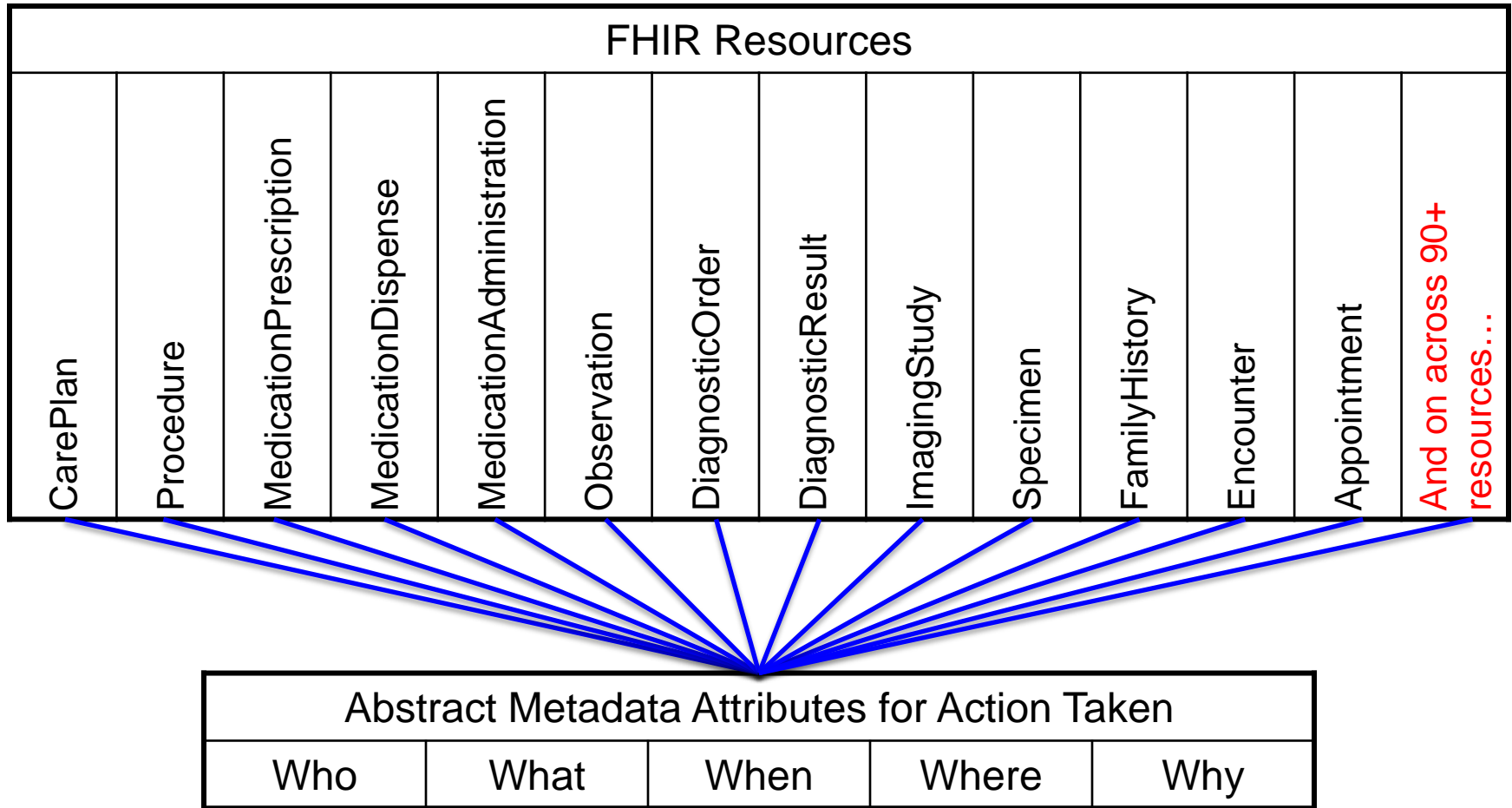
Fundamentals

- Actors take Actions
- Actors may be individuals, organizations and/or software/devices
- EHR and PHR Record Entries <u>document</u> (show <u>evidence</u> of) Actions Taken in health and healthcare
- Actions and Record Entries have separate (yet corresponding) sets of metadata
- Thus: Action W5 + Record Entry W5

Action and Record Entry

Action/Record Entry W5 Metadata

Action	Is documented/evidenced by	Record Entry
Action W5: Who/role – Action focus, subject, patient Who/role – Action performer, assistant, witness What – Action taken When – Action date/time/duration Where – Action physical location Why – Action rationale, purpose		**Record Entry W5:** Who/role – Entry target, subject, patient Who/role – Entry author, scribe, verifier, attester, witness… What – Entry Action: originate, update, verify, attest, exchange… When – Entry date/time Where – Entry device ID, network address Why – Entry rationale, purpose
Expressed across all FHIR resources		<u>Fully Expressed</u> in FHIR AuditEvent and Provenance resources when bound to other FHIR resources

Action Metadata
Abstract Attributes

FHIR Resources													
CarePlan	Procedure	MedicationPrescription	MedicationDispense	MedicationAdministration	Observation	DiagnosticOrder	DiagnosticResult	ImagingStudy	Specimen	FamilyHistory	Encounter	Appointment	And on across 90+ resources…

Abstract Metadata Attributes for Action Taken				
Who	What	When	Where	Why

Individuals have specific…

Action and Record Entry Roles

Action Roles	Record Entry Roles
• Action Focus, Subject • Action Performer • Action Witness	• Entry Target • Entry Author • Entry Recorder (Enterer) • Entry Verifier • Entry Attester • Entry Informant • Source/Copy From

Fundamentals

- EHR/PHR Record Entries:
  - Have a <u>lifespan</u>:
    - Point of origination to ultimate point of destruction/deletion
    - Point of origination to each ultimate point of retention, access/use
  - Have one or more <u>lifecycle events</u> occurring over the course of their lifespan:
    - Originate/retain, update, verify, attest, view/access and more
  - Retain relevant W5 metadata to document/evidence <u>authenticity</u> of, and <u>accountability</u> for:
    - Lifecycle events, content and data state changes
  - Enable <u>transparency</u>/<u>traceability</u>:
    - From point of origination to each point of access/use
    - Evidencing W5 metadata from each previous lifecycle event

Fundamentals

- <u>Persistent</u> FHIR Resource Instances are:
  - Captured in EHR/PHR Record Entries
    - *As native artifacts*
  - Bound with FHIR AuditEvent and Provenance Resources (as applicable) to capture:
    - Evidence of authenticity and accountability (as W5 metadata)
  - Retained on source system for legal retention period
- <u>Transient</u> FHIR Resource Instances are (typically):
  - Created for purposes of exchange
    - *As transient artifacts*
  - Retained on source/receiver system for limited time

W5 Evidence

- Show how W5 metadata is expressed (evidenced) in FHIR resources
  - Across FHIR resources
- Show how Record Entry W5 metadata is expressed (evidenced) in FHIR resources
  - AuditEvent and Provenance
- As evidence of authenticity and accountability
- Establish as Best Practice
  - Full capture of Action and Record Entry W5
  - Creation and binding of FHIR AuditEvent and Provenance (if applicable)

Action and Record Entry Metadata

Ideally…

At each Record Lifecycle/CRUDE Event…	
Action W5 metadata…	Record Entry W5 metadata…

• May be expressed in <any> resource
• Is expressed consistently across <all> resources:
  • resource.element name
  • description
  • data type
  • code/value set, if any
	• Is expressed in AuditEvent resource
	• Is also expressed in Provenance resource when resource content is originated or updated
	• If carried in <any> resource (whether or not bound to AuditEvent or Provenance), is expressed consistently

Current Build
FHIR W5 Report

- Now Referencing Current Build
- Compilation now includes all W5 metadata
  - Who, what, when, where, why
- Across
  - FHIR Clinical, Administrative, Infrastructure Domains
  - Not Finance (yet)
- Two Sections
  - Concise: FHIR Resources + Attributes
  - Full: FHIR Resources + Attributes + Data Types

W5 Worksheet

1st Tab – W5 Definition Worksheet

Col B – W5 Metadata

- Current W5 Report: Blue background
- Proposed: Orange background
- Action: Determine if W5 Metadata list complete?
- Criteria to add new W5 metadata elements:
  - Requirement from ISO/HL7 10781 EHR System Functional Model Release 2, Record Infrastructure
  - Breakout by who role: e.g., subject, performer, assistant, witness, author, attester, informant
  - Breakout by Action and Record Event
  - Concept missing, not combinable

W5 Worksheet

1st Tab – W5 Definition Worksheet

Col C – Action or Record Entry Metadata

- Action or Record Entry (or both) Metadata?

Col D – AuditEvent/Provenance Reference

- Encompassing Record Entry W5 Metadata

Col E – W5 Attribute Names

- Action: Review and disambiguate concepts…
- Same concept, different attribute name?
- Different concept, same or different attribute name?

W5 Worksheet

1st Tab – W5 Definition Worksheet

Col F – Current W5 Definition

Col G – Proposed Definition

- Action: Review and refine

2nd Tab – Element Comparison

Col A – Resource

Col B – Element

Col C – Short Description

Col D – Data Type

Col E – Code/Value Set

W5 Worksheet

3rd Tab – Record Lifecycle Events

Col A – ID

Col B – Record Lifecycle Event

4th Tab – Full Element Definition

(27 July 2015 snapshot from Current Build)

Col A – W5 column

Col B – Resource.element

Col C – Data Type

Col D – Full Description

Notes/Issues

- W5 metadata attributes are designated by resource owner WG

- Significance of empty cells:
  - No equivalent W5 Metadata Attribute? <u>or</u>
  - Not yet evaluated? <u>or</u>
  - Inadequate definition of W5 concept/term?

Notes/Issues

- Identify overlap between FHIR AuditEvent and Provenance metadata and that of other resources

- Ensure W5 synchrony at same Action Instant (point in time)?
  - As captured in FHIR instance
  - Need Synchronous Snapshot to ensure we can actually track: Who did What When, Where and Why

October FHIR Connectathon

- [October 2015 FHIR Connectathon Link](#)

- Piggyback on existing Scenarios, starting with Track 1 – Patient ID/Demographic

- Identify CRUDE points

- Add AuditEvent to all Scenarios

- Add Provenance resource to CUE Scenarios, as appropriate

Track 1 - Patient

	Scenario	CRUDE	AuditEvent	Provenance
1	Register a New Patient	C	X	X
2	Update a Patient	U	X	X
3	Retrieve Patient History	R	X	
4	Search for a Patient on Name	R	X	

Links

- RLE on FHIR Materials – HL7 EHR Interop Wiki:
  - http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG
- FHIR DSTU-2 – Record Lifecycle Event Implementation Guide
  - http://www.hl7.org/fhir/2015May/ehrs-rle.html
- FHIR W5 Report (Current Build)
  - http://hl7-fhir.github.io/w5.html?
- FHIR Connectathon 10
  - http://wiki.hl7.org/index.php?title=FHIR_Connectathon_10

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

Action and Record Entry Metadata

	Action Metadata	**Record Entry** Metadata
What	Action Taken Medication Order for Ambien 20mg PRN	Entry Origination/Retention evidenced by AuditEvent 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

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

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 …			

CRUDE Points

- W5 Metadata is captured (in FHIR resource <u>instances</u>) at CRUDE points
  - **C**apture: Originate content in new <u>instance</u>
  - **R**ead: Access/view content in existing <u>instance</u>
  - **U**pdate: Update content in existing <u>instance</u>
  - **D**elete: Purge/destroy existing <u>instance</u> and its content
  - **E**xecute: Perform operation(s) on content in existing <u>instance</u>

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 Pseudonymize	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			X	X		X	X	X		X	X	X	X				X	X			X	X	X	X	X	X	X

Duplicate U/E events – to be resolved