

ISO 21089 – Health Informatics – Trusted End-to-End Information Flows

Presentation to S&I DPROV Community

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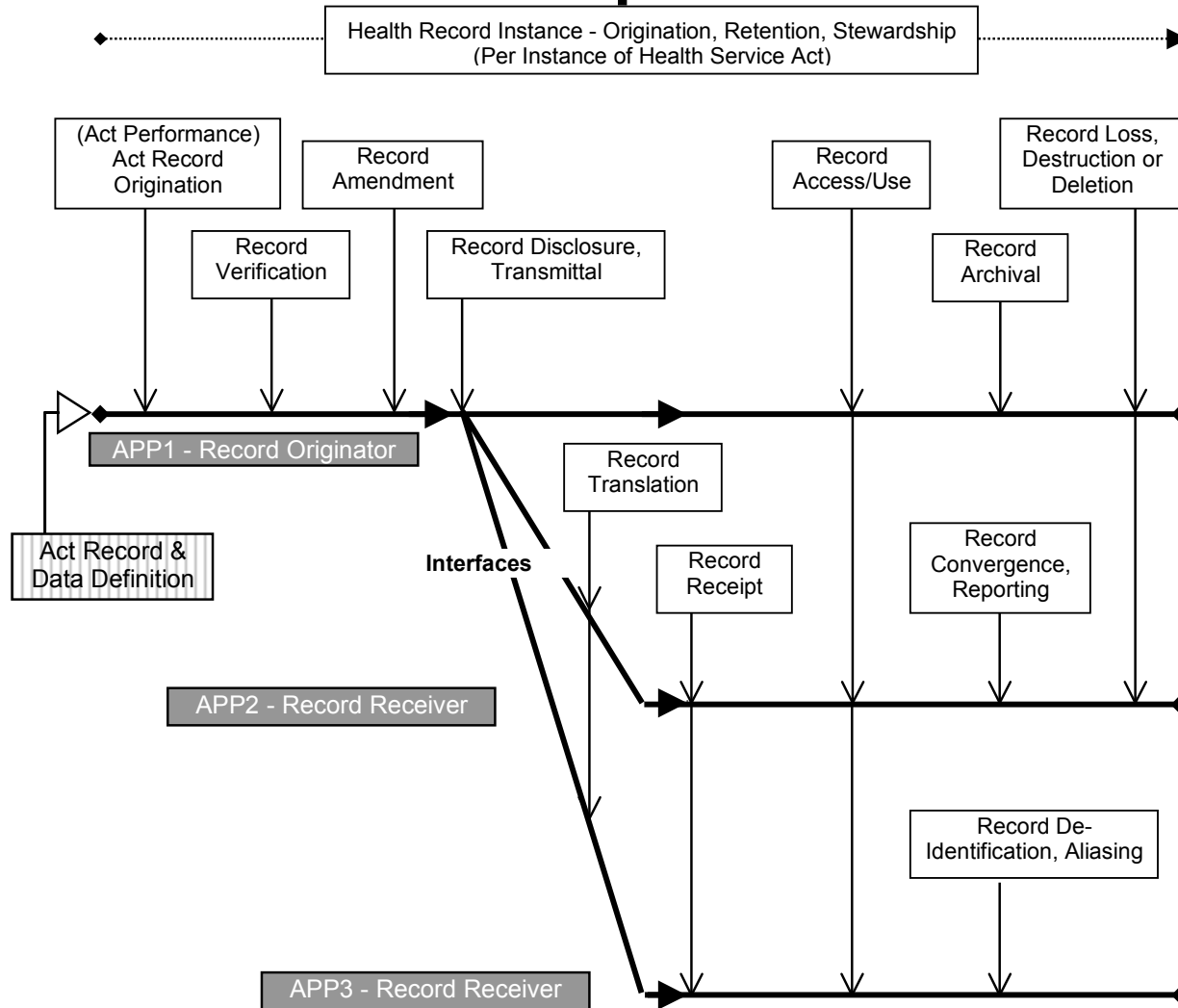
Lifespan and Lifecycle Events

- First HIT Standard to focus on health data/record:
 - Lifespan – point of origination to point of destruction/deletion
 - Lifecycle events occurring at various points in the lifespan

Data/Record Lifespan and Lifecycle

- First balloted/published in 2004
 - Acts/Actions documented in Act Record (original term)
- Currently in revision
 - Approved ISO TC215 New Work Item in September 2014
 - Acts/Actions documented in Record Entry(ies) (new term)

Data/Record Lifespan and Lifecycle



Companion Standards

- Derivations of Record Lifespan/Lifecycle include:
 - 2007 – HL7 EHR Interoperability Model DSTU
 - 2008 – HL7 CDA R2 Implementation Guide for EHR Interoperability DSTU
 - 2008 – HL7 EHR Lifecycle Model DSTU
 - 2009 – HL7 Records Management/Evidentiary Support Functional Profile (of EHR-S FM R1.1)
 - 2014 – ISO/HL7 10781 EHR-S FM R2
 - 2014 – ISO/HL7 16527 PHR-S FM R1
 - 2014 – ISO 19669 – Re-usable Component Strategy for Use Case Development (based on S&I Simplification)
 - 2014 – Record Lifecycle Events using HL7 Fast Health Interoperability Resources (FHIR)

Dimensions of End-to-End Flow

Record Lifespan

1. Within Single System


- Starting at point of origination, in Source System, OR
- 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

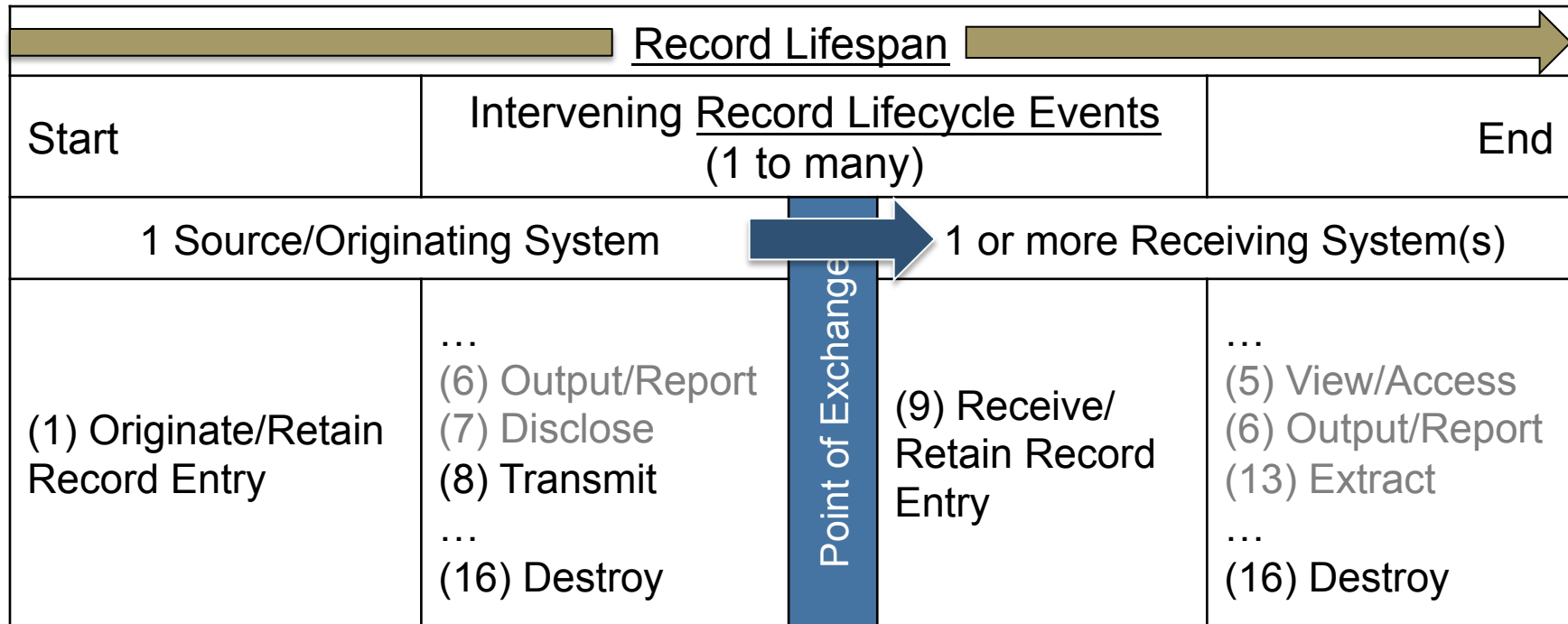
Record Lifespan – End-to-End

Within Single System

Record Lifespan 		
Start	Intervening Record Lifecycle Events (0 to many)	End
<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) Pseudo-nymize (12) Re-Identify (13) Extract	(16) Destroy
<u>Receiving System</u> (9) Receive/Retain Record Entry	(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

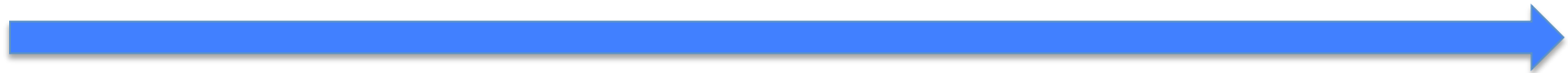
Record Lifespan – End-to-End

Across Multiple Systems



Repeated at each point of exchange to each Receiving System...

Traceability

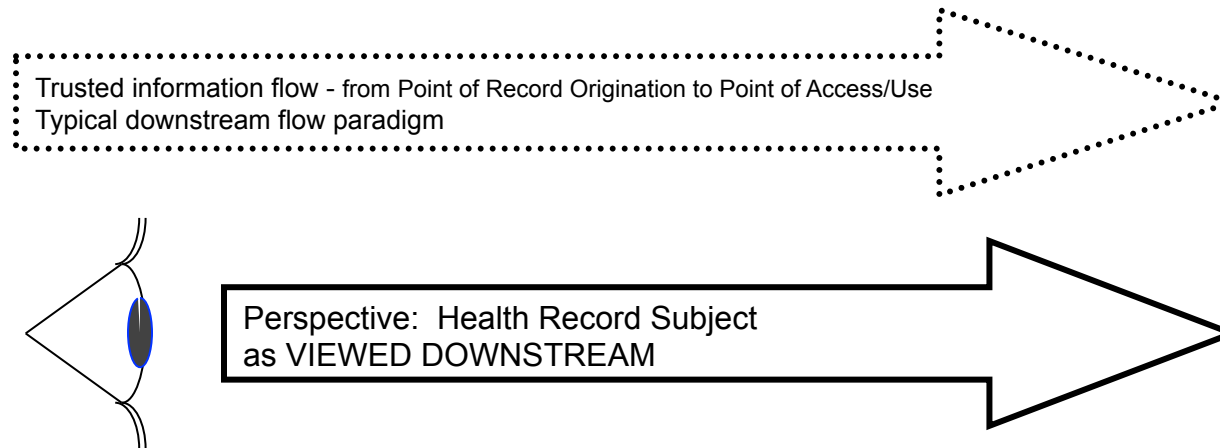


- Forward Traceability
 - Source perspective
 - Point to point downstream: to whence it goes



- Backward Traceability
 - User perspective
 - Point to point upstream: from whence it came

Downstream Information Flow and Trust Perspective Health Record Subject



As the health record subject (e.g., patient, health plan member)...

How might I be assured (trust) the persistent integrity and authenticity of my health record and its content?

How might I be assured that access/use of my health record is based on "need to know" principles?

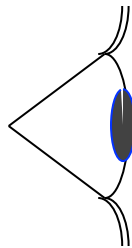
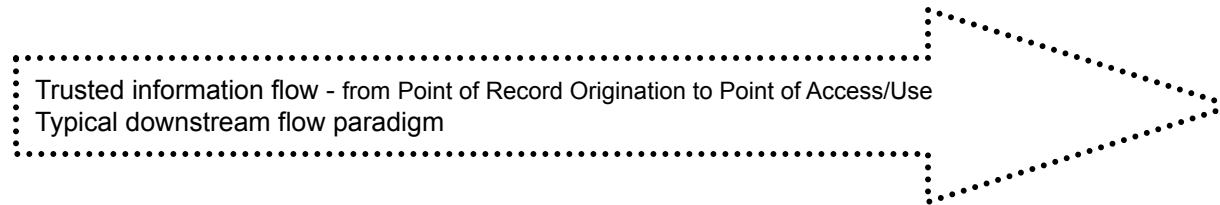
How might I be assured that routine access/use of my health record is according to my consent agreement? Other disclosures according to my specific authorization?

With regard to my health record, how might I be assured (trust) that accountable actions by accountable parties are ascribed, authenticated and traceable, including key points in the record lifecycle:

- Record origination, amendment, verification, translation?
- Record access/use?
- Record disclosure and transmittal?
- Record receipt, retention and stewardship?
- Record de-identification or aliasing?
- Record archival, destruction?

Downstream Information Flow and Trust Perspective

Health Record Author/Originator



Perspective: Accountable Party for health record content
as VIEWED DOWNSTREAM

**As an accountable provider of health(care) services (as ascribed in the health record)...
As an accountable author, scribe and/or verifier of health record content...**

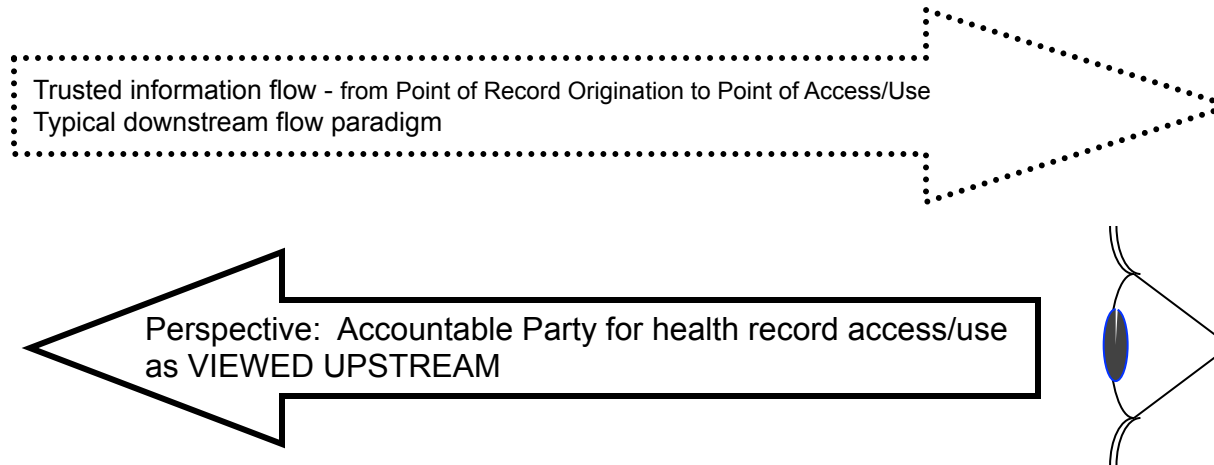
How might I be assured (trust) the persistent integrity and authenticity of health record content ascribed to me?

With regard to health record content ascribed to me, how might I be assured (trust) that subsequent accountable actions by accountable parties are ascribed, authenticated and traceable, including key points in the record lifecycle:

- Record origination, amendment, verification, translation?
- Record access/use?
- Record disclosure and transmittal?
- Record receipt, retention and stewardship?
- Record de-identification or aliasing?
- Record archival, loss or destruction?

Upstream Information Flow and Trust Perspective

Health Record User



As an accountable user of health record content...

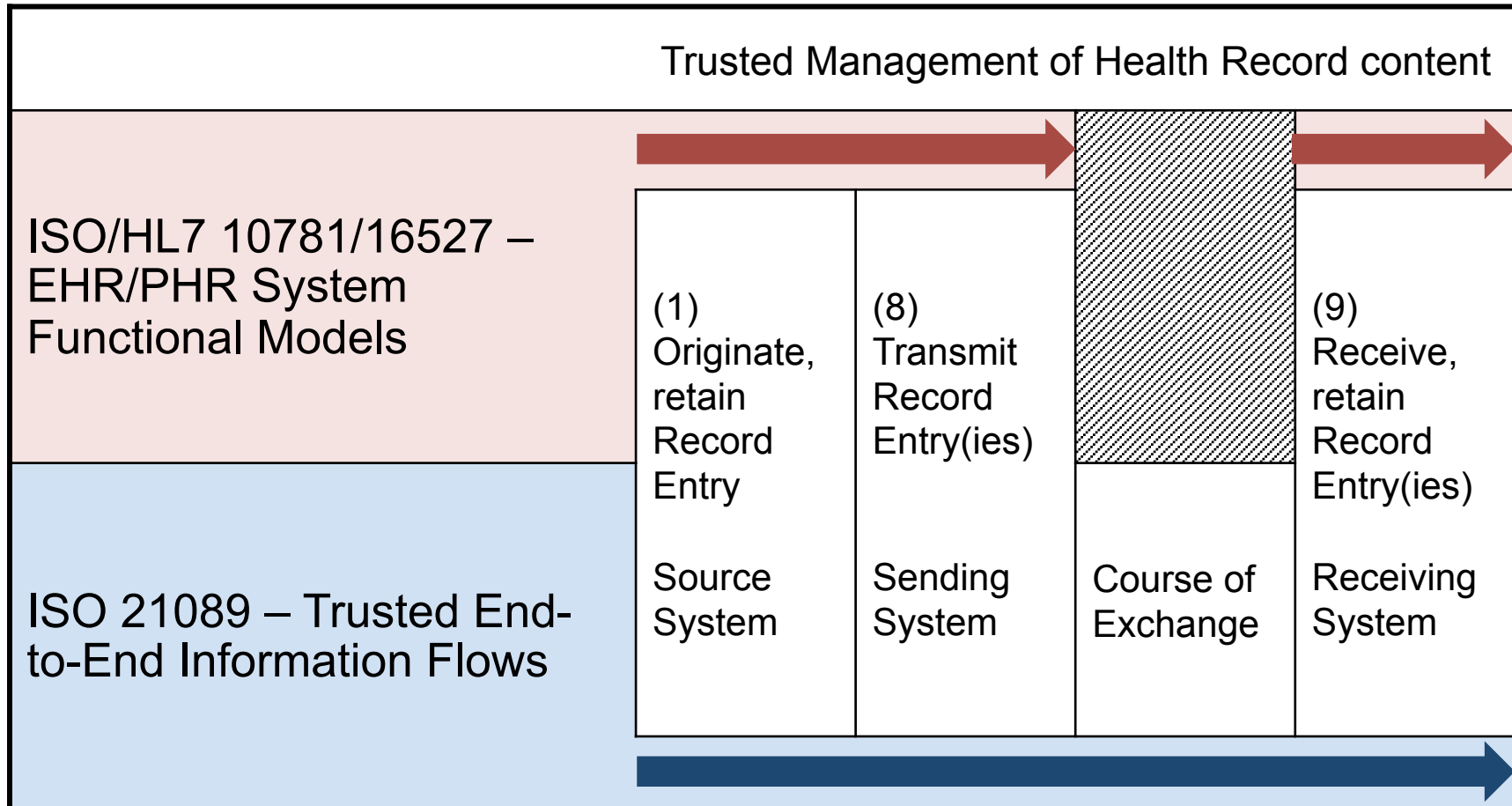
How might I be assured (trust) the persistent integrity and authenticity of health record content which I access and use?

With regard to health record content, how might I be assured (trust) that accountable actions by accountable parties are ascribed, authenticated and traceable, including key points in the record lifecycle:

- Record origination, amendment, verification, translation?
- Record access/use?
- Record disclosure and transmittal?
- Record receipt, retention and stewardship?
- Record de-identification or aliasing?
- Record archival, loss or destruction?

Complementary ISO/HL7 Standards

Scope




(#) Lifecycle Event

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			

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				

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

	<u>Prior Event</u> Added...	<u>During Interval between Events</u> Retains (at rest): Indivisibly+Immutablely	PRE	<u>At New Event</u> Adds...	POST
Basic	1 SecurityEvent instance	1 or more SecurityEvent instances >> One per each prior Record Lifecycle Event	→	1 SecurityEvent instance	Becomes Prior Event
w/Provenance	1 Provenance instance	1 or more Provenance instances >> One per each prior Record Lifecycle Provenance Event	→	1 Provenance instance	
	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)	

Contact/Links

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

Health Record Trust Stakeholders

- Individuals
 - Health record subjects, subjects of care
 - Patients, health plan members
 - Health(care) professionals, caregivers, record authors, scribes, verifiers, record users
- Organizations
 - Providers, health plans, employers...
- Business units
 - Departments, services, specialties...

ISO 21089 – Trusted End-to-End Information Flows

Trust Stakeholders

Trust Stakeholders for health record content, including individually identifiable information Stakeholder	Individual	Organization	Business Unit	Subject of Record	Accountable Source, Author of Record Content	Accountable Verifier of Record Content	Accountable Scribe/Proxy of Record Content	Accountable User of Record Content	Accountable Record Steward	Accountable Provider of Health Services as Ascribed in Record
Subject of Care, Health Plan Member	X			Yes	Yes	A/A	N/A	A/A	No	No
Next of Kin, Emergency Contact	X			Yes	No	No	No	No	No	No
Healthcare Professional, Caregiver	X			Yes	Yes	Yes	Yes	Yes	Yes	Yes
Care Assistant	X			Yes	Yes	Yes	Yes	Yes	Yes	Yes
Transcriptionist	X			Yes	No	A/A	Yes	A/A	Yes	No
Department, Service, Specialty			X	Yes	N/A	N/A	N/A	Yes	Yes	Yes
Healthcare Provider	X	X		Yes	N/A	N/A	N/A	Yes	Yes	Yes
Integrated Delivery Network (IDN)		X		Yes	N/A	N/A	N/A	Yes	Yes	Yes
Payment Guarantor, Health Plan, HMO	X	X		A/A	No	No	No	Yes	Yes	No
Value Added Network, Claims Clearinghouse		X		No	No	No	No	Yes	Yes	No
Employer	X	X		A/A	No	No	No	Yes	A/A	No
Public Health Agency		X		No	No	No	No	Yes	A/A	No
Regulatory Agency		X		No	No	No	No	Yes	A/A	No
Accreditation Agency		X		No	No	No	No	Yes	A/A	No
Research	X	X		No	No	No	No	Yes	A/A	No
Professional Education	X	X		No	No	No	No	Yes	A/A	No
Others										

