“Record to Rely On” Workshop
Truth (Authenticity) as Evidence for Trust (Assurance)

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Impetus

1970s to Early 80s

- Early HIT: Mini-computer era
  - Barely beyond punch cards, paper type, teletype machines
- Transitioned from FORTRAN → BASIC → PL/1 → MUMPS
- Pre EHR, internet, email, mobile devices, personal apps
- Pre DRGs – “Cost-based" reimbursement
- Learned key defense to audit disallowances was really very basic. Always:
  - Capture/document: who did what when where and why (provenance)
  - Capture/document each billed item:
    - Service provided, patient, provider, role
    - Duration: e.g., procedure time, facility/room time, ventilator time
    - Units of use: e.g., medications dispensed, supply items used, gas as metered
  - Ensure billed items are included in patient chart detail (still hardcopy)
- We found ourselves entirely audit-proof – while following the rules
- We increased operations/staff/services 4X over 10 years

Impetus

The Critic and The Challenge

- Entered HIT/EHR Standards Space in 1989
  - Joined HL7 – Mostly as a critic
  - Key Issues
    - Integrated Whole (integrated by design) vs. Best of Breed (interfaced together as only resort)
    - Homogeneous vs. Heterogeneous
    - Top Down vs. Bottom Up
    - Strongly opposed to HL7 v3 model/message scheme
  - Still focused on
    - Who did what when, where and why
  - As critic, always challenged:
    - "If you don't like it, what would you do instead?"

Standards Pathway

2000-2003

2000	Formed HL7 Electronic Health Record Work Group (EHR WG)	Co-Chairs: Ed Hammond (US), David Markwell MD (UK), Sam Heard MD (Australia)

2003	• EHR WG challenged to develop industry-first EHR System Functional Model (EHR-S FM) Standard
	• EHR-S FM developed and balloted via HL7 (ANSI-accredited) consensus process
		• Specifies EHR System Functions and Conformance Criteria (shall/should/may)
		• Sponsors:
		  • Veterans Administration
		  • HHS Assistant Secretary for Planning/Evaluation
		  • HIMSS
		  • Robert Wood Johnson Foundation

Standards Pathway

2003-2004

2003
2004
	Began consideration of:
	• How does an EHR System (*software*) manage an EHR Record (*data*)?
	  • As a persistent chronicle (evidence) of Actions taken (by Actors) in support of individual health and provision of healthcare
	  • With basic correspondence to entries in a paper chart
	• As the basis for authentic EHR recordkeeping, how does an EHR system:
	  • Capture evidence when an Actor takes accountability for taking Action(s)?
	  • In EHR Record Entries?
	• Record Entries capture Actor/Action facts, findings and observations
	  • Forming a chronology of: who did what when where and why
	• Record Entries have a lifespan with lifecycle events occurring over time

	Who	**(did) What**	**When**	**Where**	**Why**
1	Action taken...				
	Actor(s)	Took Action	At Action date/time (with duration)	At Action Location	To fulfill Action Reason or Purpose
2	Then, Action documented in EHR record entry...				
	Actor(s) as Author, Enterer	Recorded Action Details, including Facts, Findings, Observations	At Recording date/time	At Recording Location	To create EHR record entry documenting Action taken

Standards Pathway

2004-2005

Apr 2004	Balloted/Published: • ISO TR 21089 Trusted End-to-End Information Flows	• Technical Report (Informative) • Specifies Record Lifespan and 14 Lifecycle Events (RLEs)
July 2004	Balloted/Published: • HL7 EHR-S FM DSTU	Draft Standard for Trial Use

Aug 2004	(Formed) Certification Commission for Health Information Technology (CCHIT)	• Many certification criteria based on EHR-S FM Conformance Criteria
		• Original Sponsors:
		  • AHIMA
		  • HIMSS
		  • NAHIT (AHA)

2005	Formed HL7 Records Management/Evidentiary Support (RM-ES) Work Group	Led by AHIMA

Standards Pathway

2007-2011

2007	Balloted/Published: • HL7 EHR-S FM Release 1	First Normative Release
2009	Balloted/Published: • ISO/HL7 10781 EHR-S FM Release 1.1	• International Standard • Joint Ballot: HL7, ISO TC215, CEN TC251
	Balloted/Published: • HL7 RM-ES Functional Profile R1 (of EHR-S FM R1)	First set of standard functions/ conformance criteria focused on: • EHR as Legal Record

2011 on	ONC Standards & Interoperability (S&I) Framework
	• Formed: S&I Simplification Work Group
	• Developed: S&I Simplification Core Matrix
		• In close collaboration with NIST, AHRQ
		• Core Matrix includes:
		  • 21 S&I Initiatives
		  • Use Cases with 47 Scenarios
		• References 14 RLEs

Standards Pathway

2014-2015

2014	Balloted/Published: • ISO/HL7 10781 EHR-S FM R2	• Normative • Joint ballot: HL7, ISO TC215, CEN TC251, IHTSDO, CDISC, GS1 • Includes RM-ES FP • Includes 24 RLEs
	• Formed: S&I Data Provenance Initiative • Developed: • System Event Matrix	References 7 RLEs
2015	Balloted/Published: • HL7 FHIR EHR-S Record Lifecycle Event Implementation Guide (RLE IG), DSTU-2	• FHIR = Fast Health Interoperable Resources • First introduction: RLEs in FHIR • Includes 27 RLEs

Standards Pathway

2016 on

2016	Balloted/Not Yet Published: • FHIR EHR-S RLE IG, STU-3	• Latest FHIR Release • Includes 27 RLEs
	Balloted/Not Yet Published: • ISO TS 21089: Trusted End-to-End Information Flows	• Technical Specification (Normative) • Includes 27 RLEs
	Balloted/Not Yet Published: • ISO TR 19669: Reusable Component Strategy for Use Case Development	• Technical Report (Informative) • Based on S&I Simplification • References 27 RLEs
2016 2017	Consideration of Action Items resulting from ONC "Record to Rely On" Workshop	As input to development of: • RM-ES Functional Profile Release 2
	Development of International Patient Summary (IPS)	• In collaboration with ISO TC215, CEN TC25 • Will reference 6+ RLEs?

Lifecycle Events in a Basic Manual Record Use Case

	(Real World)	Collect			Use
Lifecycle Event >	N/A	Originate	Verify/Attest	Retain	Access/View (Trust Decision)
Flow >	➔	➔	➔	➔	◆
Scenario 1A - Manual Record - One Domain					
Actor >	Human	Human	Human	Human	Human
Manual Record >	Takes action(s) to support individual health and deliver healthcare: observes, measures, assesses	Writes Entry in Source Paper Record	Signs Entry in Source Paper Record	Saves/Files Source Paper Record	Views Copy
Artifact >		#1 Original	#1 Original	#1 Original	#1 Original

Lifecycle Events in a Basic Electronic Record Use Case

	(Real World)	Collect			Use
Lifecycle Event >		Originate	Verify/Attest	Retain	Access/View (Trust Decision)
Flow >	➔	➔	➔	➔	◆
Scenario 1A - Manual Record - One Domain					
Actor >	Human	Human	Human	Human	Human
Manual Record >	Takes action(s), observes, measures, assesses	Writes Entry in Source Paper Record	Signs Entry in Source Paper Record	Saves/Files Source Paper Record	Views Copy
-- Artifact >		#1 Original	#1 Original	#1 Original	#1 Original
Scenario 1B - Electronic Record - One Domain					
System >		EHR-A			
Actor >	Human	Human	Human	System	Human
Electronic Record >	Takes action(s) to support individual health and deliver healthcare: observes, measures, assesses	Documents action(s), observations, measures, assessments	Verifies action(s)/signs observations, measures, assessments	Saves EHR-A Record Entry	Views action(s) taken, observations, measures, assessments
Artifact >		#1 Data entry screen/window	#2 Verification screen/window	#3 EHR-A Record Entry	#4 Presentation screen/window
State >		Is Transient	Is Transient	Is Persistant	Is Transient

Lifecycle Events in a Electronic Record Print/Output Use Case

	(Real World)	Collect			Share	Use
Lifecycle Event >	N/A	Originate	Verify/Attest	Retain	Print/Output	Access/View (Trust Decision)
Flow >	➔	➔	➔	➔	➔	◆
Scenario 2A - Manual Record - One Domain - w/Print						
Actor >	Human	Human	Human	Human	Human	Human
Manual Record >	Takes action(s), observes, measures, assesses	Writes Entry in Source Paper Record	Signs Entry in Source Paper Record	Saves/Files Source Paper Record	Duplicates Source Paper Record via Photocopy	Views Copy
Artifact >		#1 Original	#1 Original	#1 Original	#2 Copy of Original	#2 Copy of Original
Scenario 2B - Electronic Record - One Domain - w/Print						
System >		EHR-A				
Actor >	Human	Human	Human	System	System	Human
Electronic Record >	Takes action(s) to support individual health and deliver healthcare: observes, measures, assesses	Documents action(s), observations, measures, assessments	Verifies action(s)/signs observations, measures, assessments	Saves EHR-A Record Entry	Renders Hard/Soft Copy	Views action(s) taken, observations, measures, assessments
Artifact >		#1 Data entry screen/window	#2 Verification screen/window	#3 EHR-A Record Entry	#4 Hard or Soft Copy	#5 Presentation screen/window
State >		Is Transient	Is Transient	Is Persistant	Is Transient?	Is Transient

Lifecycle Events in an Electronic Record Exchange Use Case

	(Real World)	Collect			Share			Use
Lifecycle Event >	N/A	Originate	Verify/Attest	Retain	Transmit	Receive	Retain	Access/View (Trust Decision)
Flow >	→	→	→	→	→	→	→	◆
Scenario 3A - Manual Record - 1+ Domains								
Actor >	Human	Human	Human	Human	Human	Human	Human	Human
Manual Record >	Takes action(s), observes, measures, assesses	Writes Entry in Source Paper Record	Signs Entry in Source Paper Record	Saves/Files Source Paper Record	Transmits Copy of Source Paper Record via Fax	Receives Fax or Photocopy	Saves/Files Fax or Photocopy	Views Copy
Artifact >		#1 Original	#1 Original	#1 Original	#2 Copy of Original	#2 Copy of Original	#2 Copy of Original	#2 Copy of Original
Scenario 3B - Electronic Record - 1+ Domains								
System >		EHR-A				EHR-B		
Actor >	Human	Human	Human	System	System	System	System	Human
Electronic Record >	Takes action(s) to support individual health and deliver healthcare: observes, measures, assesses	Documents action(s), observations, measures, assessments	Verifies action(s)/signs observations, measures, assessments	Saves EHR-A Record Entry	Sends Exchange Artifact	Receives Exchange Artifact	Saves EHR-B Record Entry	Views action(s) taken, observations, measures, assessments
Artifact >		#1 Data entry screen/window	#2 Verification screen/window	#3 EHR-A Record Entry	#4 Exchange Artifact (message, document, resource)		#5 EHR-B Record Entry	#6 Presentation screen/window
State >		Is Transient	Is Transient	Is Persistant	Is Transient?		Is Persistant	Is Transient

Crosswalk – Common Events – ISO/HL7 Standards and ONC MU 2015 Edition (in GREEN) – DRAFT 27 June 2016				
#	Record Entry Lifecycle Event	**As specified in ISO/HL7 Standards ➔** Occurs when Record Entry(ies) ➔	•ISO/HL7 10781 EHR-S Functional Model Release 2 (2015) •ISO 21089 Trusted End-to-End Information Flows (2016 DTS) •HL7 FHIR Record Lifecycle Event Implementation Guide (part of FHIR DSTU-2, September 2015)	**ONC MU 2015 Edition** Ref: ASTM 2147 Audit Events VDT= View/Download/Transmit	Audit Event
1	Originate/Retain	Content is originated and retained – often during the course of an Action itself – to document the Action and its context		Additions (retain)	Y
2	Update/Amend	Content is modified (from its original or previously retained state) – typically upon conclusion of an Action – to correct, update or complete content		Changes (retain)	Y
3	Translate/ Transform	Content is amended to include translation of content – typically to transform a) coded data from one coding/classification scheme to another, or alternatively b) one human language to another		—	—
4	Attest	Content is attested for accuracy + completeness – typically during/after conclusion of an Action		—	—
5	Access/View	Content is viewed or accessed		Access + VDT	Y
6	Output/Report	Content is output or reported		Print, Copy + VDT	Y
7	Disclose	Content is disclosed according to organizational policy and/or jurisdictional law		Disclose	N
8	Transmit	Content is transmitted – typically to an external entity or system		Transmit + VDT	N
9	Receive/Retain	Content is received and retained – typically from an external entity or system		Receive (retain)	Y
10	De-Identify	Content is transformed into de-identified version		—	—
11	Pseudonymize	Content is transformed into an pseudonymized version		—	—
12	Re-Identify	Content is re-identified from a previously pseudonymized version		—	—
13	Extract	Content is extracted to render subsets, derivations, summaries or aggregations		Queries + VDT	Y
14	Archive	Are archived – typically to off-line (less readily available) storage media		—	—
15	Restore	Are restored from archive		—	—
16	Destroy/Delete	Are destroyed, deleted or identified as missing		Deletion	Y
17	Deprecate	Are deprecated if found to be improperly identified or otherwise invalid		—	—
18	Re-Activate	Are made active again after being previously Destroyed/Deleted or Deprecated		—	—
19	Merge	Are merged together		—	—
20	Unmerge	Are unmerged from previous merge		—	—
21	Link	Are linked together		—	—
22	Unlink	Are unlinked from previous linkage		—	—
23	Add Legal Hold	Are marked (and held in an unaltered state) for purposes of a legal hold (typically as the result of court or legal action)		—	—
24	Remove Legal Hold	Are released from legal hold (previously marked and held in unaltered state)		—	—
25	Verify	Content is verified for accuracy, completeness		—	—
26	Encrypt	Content is encoded in a cipher or code		• Transmit/disclose • Retain (to datastore) • Close user session (on mobile device)	N Y N
27	Decrypt	Content is decoded from a cipher or code		• Access/view (from datastore) • Receive (retain) • Open user session (on mobile device)	Y Y N

ONC MU 2015 Edition = Analysis of Regulatory Language and Test Procedures

EHR as “Record to Rely On”

Standards Focus

- For 30 Years of HL7
  - v2/v3 messages, CDA/CCDA documents, RIM, CIMI...
  - Now even FHIR resources
  - Emphasis is on Exchange Artifacts and Computability
  - At point of exchange
- What If Our Emphasis had been on
  - Authenticity and Trustworthiness First?
  - Then Computability (as a derivative)?
  - EHR as Legal Record? From point of capture/origin?
  - Correspondence to Management and Curation of Traditional Paper Record and its Entries
- Where Would We Be Now?
- So, Maybe I Remain a Critic!

Contact

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Slides that Follow...

Reference Materials and Links

- ISO/HL7 10781 EHR-S Functional Model (and Profiles)
  - Key Trust Objectives
- ISO 21089 Trusted End-to-End Information Flows
  - Health Record Trust Constituency
  - Truth and Trust Objectives, Traceability
- Complementary Scope: ISO 10781/21089
- EHR Record Lifespan: Inter/Intra System
  - Sample Health Data/Record Flow
- HL7 RM-ES Proposal to ONC
- S&I Simplification
- S&I Data Provenance – System Event Matrix
- HL7 FHIR (STU-3) Record Lifecycle Event Implementation Guide
- HL7/CEN International Patient Summary – Work in Progress
- Health Data/Record Transformation Challenges and Risks
- And more Citations, References and Links...

ISO/HL7 Functional Models and Profiles

EHR-S FM/FPs and RM-ES FP

- HL7 EHR System Functional Model Release 2
  - http://www.hl7.org/implement/standards/product_brief.cfm?product_id=269
- List of EHR-S FM Functional Profiles including Release 2 Status
  - http://wiki.hl7.org/images/a/a1/EHRS_FM-Functional_Profiles-20161023.pdf
- HL7 EHR System Records Management/Evidentiary Support Functional Profile, Release 1 (2009)
  - http://www.hl7.org/implement/standards/product_brief.cfm?product_id=86

EHR-S FM – Key Trust Objectives

Accountability, Authenticity, Integrity

Accountability (of Actors)	Authenticity and Integrity

• Individuals
  • Actors supporting individual health and provision of healthcare services
  • Actors as authors, scribes, source of record entry content
• Organizations
  • Actors as business/clinical record keepers
• Systems
  • Software functions
  • Record management architecture
  • Vendors, software developers
	Providing evidence of:
	• Identity:
	  • Individuals, organizations, systems
	• Authentication: of EHR entry content
	• Source of truth, trust anchor
	• Provenance:
	  • Who, what, when, where, why
	• Traceability:
	  • End-to-end
	  • Source to use (forward)
	  • Use to source (backward)
	• Revision history

EHR-S FM – Key Trust Objectives

Record Protection & Management

Record Protection	Record Management

• Authorization
  • Permission, consent
  • By user and device
• Authentication
  • User, device, use
• Access control
  • User, role, context-based
• Immutability, non-alteration
• Encryption
• Audit:
  • Logging and reporting
  • System and record events
	• EHR Record Entry = Unit of Record Management
	• Record Lifespan, in two dimensions:
	  • Point of Origination to Point of Use
	  • Point of Origination to Point of Deletion
	• EHR Record Lifecycle Events and related “Ceremonies”
	  • Create/originate, attest/sign, update/amend, read/access, transform/translate...
	  • Revision history
	• Standard Output Format:
	  • EHR Record Rendering for Investigation/Evidentiary Purposes

Health Record Trust Constituency

- Individuals
  - Subjects of care, Subjects of health records
    - Humans as patients, health plan members
  - Health(care) professionals, caregivers, record authors, scribes, verifiers, record users…
- Organizations
  - Providers, payers/health plans, public health agencies, employers, researchers, legal/accreditation…
- Business units
  - Departments, services, specialties…

ISO 21089 – Trusted End-to-End Information Flows

Trust Constituency

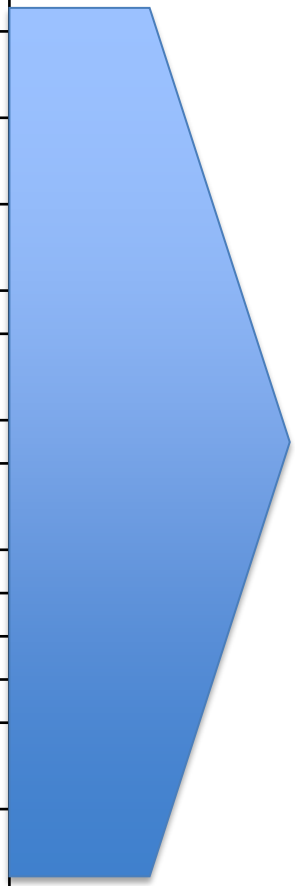
Trust Constituency: for health record content, including individually identifiable information **↓Constituents, Acting as →**	Individual	Organization	Business Unit	Subject of Record	Accountable Source, Author of Record Conte	Accountable	Accountable Verifier, Attester of Record Content	Accountable User of Record Content	Accountable Record Steward	Accountable Provider or 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, Careqiver	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, Accountable Care Organization	--	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	--	--	--	A/A	A/A	A/A	A/A	A/A	A/A	A/A

N/A = Not applicable A/A = As applicable

ISO 21089 – Trusted End-to-End Information Flows

Truth and Trust

Truth	as evidence for	Trust
✔ Identity is evident		
✔ Actions are evident: e.g., actions taken to support individual health and provide healthcare		
✔ Who took what action when, where and why is evident		
✔ Action facts, findings and observations are evident		
✔ Source, origination and provenance is evident		
✔ Attestation (signature) is evident (confirming accuracy/completeness)		
✔ Signature/content binding is evident		
✔ Who authored what when, where and why is evident		
✔ Content is un-altered		
✔ Context is evident		
✔ Completeness (or not) is evident		
✔ Update(s) to original content are evident		
✔ Chain of Trust is evident ✔ From source to use		
✔ Transformation(s) are evident (e.g., to/from exchange artifacts)		
✔ Original "Source of Truth" is evident		



Establishing:

- Belief (believability)
- Safety
- As a conscious human conclusion (conviction)
- Based on – and manifest in – evidence presented
- Always traceable to the "source of truth"

Resolving to:

- Certainty: sureness
- Reliance: placing trust in

ISO 21089 – Trusted End-to-End Information Flows

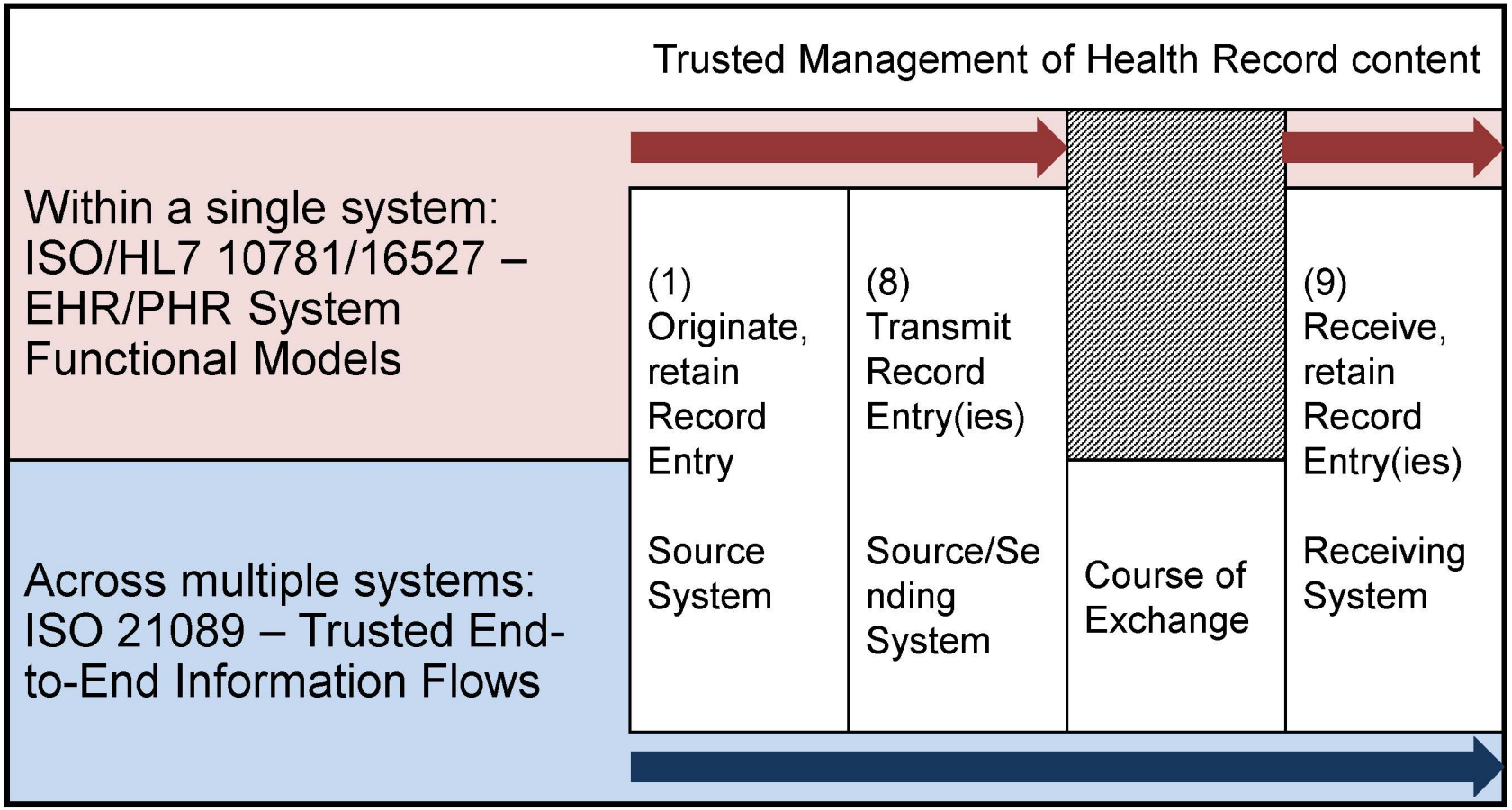
Traceability

- Forward Traceability
  - Source perspective: point of origination/retention
  - Point to point downstream: to whence it goes

- Backward Traceability
  - User perspective: point of access/use
  - Point to point upstream: from whence it came

Complementary ISO/HL7 Standards

Scope



(#) Record Lifecycle Event

Dimensions of End-to-End Flow – Inter/Intra System

EHR Record Lifespan

Within Single System

- Starts at point of origination, in Source System; or
- Starts at point of receipt, in Receiving System
- Ends at point of destruction/deletion

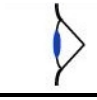
Across Multiple Systems

- Starts at point of origination, in Source System
- Traverses one or more Points of Exchange
- Ends at point of destruction/deletion, in each System

Health Data/Record Chain of Trust from Point of Collection to each ultimate Point of Use to Support the Affirmative Trust Decision for Primary Clinical Use

Function	Flow	Point of Health Data/Record	(For primary clinical use)	Audit Event	Provenance Event	Original Content
	Source System					

COLLECT	↓	Collection (Capture, Origination)
		• Source of Truth
		• Anchor Point for Chain of Trust
			• Clinical facts, findings and observations are captured
			• Clinical context is captured
			• Provenance is captured:
			  • Who, what, when, where, why
			• Identities are established:
			  • Patient: subject of care
			  • Provider: organization, individual
			  • Author of data/record content
				X	X	Is captured

	↓	Retention	Of Source Record Entry	X		Is retained
	↓	Attestation	• Application of Signature • Bound to data/record content	X	X	Is attested/ signed
SHARE	↓	Transformation	From Source Record Entry to Exchange Artifact: e.g., HL7 message or document	X	X	Is carried
	↓	Transmission	Of Exchange Artifact	X		Is carried
	Receiving System					
	↓	Receipt	Of Exchange Artifact	X		Is carried
	↓	Transformation	From Exchange Artifact to Receiver Record Entry	X	X	Is carried
	↓	Retention	Of Receiver Record Entry	X		Is retained
USE	↓	Access, view • Trust Decision	By End User 	X		Is accessed, viewed

EHR as Legal Record

- "Statement from the Defense"
  - Chad Brouillard JD
  - http://wiki.hl7.org/images/3/32/Statement_from_the_Defense.pdf
- HL7 EHR/RM-ES
  - EHR as Legal Record Project Proposal
  - http://wiki.hl7.org/images/e/eb/EHR-WG-Legal_Record-ONC_Proposal-20160226.pdf
- Statement of Benefits and Savings
  - http://wiki.hl7.org/images/6/6f/EHR-WG-Legal-Record-Benefits-Savings-20160517a.pdf
- Common Events Crosswalk
  - ISO/HL7 10781 EHR-S FM to ONC MU 2015 Edition
  - http://wiki.hl7.org/images/6/61/EHR-WG-Legal-Record-Crosswalk_Lifecycle_Events-20160627a.pdf

Actor in Role, Target & Frequency

Actor	Role/Participation	Target	Frequency
Individuals	As subject of... As performer of... As observer/witness of...	Action taken	Per occurrence
Individuals	As subject of... As author/originator of... As scribe/enterer of... As verifier of... As attester of...	EHR record entry content	Per occurrence
Software – systems, devices	As source of...	EHR record entry content	Per occurrence
Organizations	As performer of...	Action taken	Per occurrence
Organizations	As steward of...	Persistent EHR-based clinical/business record	Continuously, uninterrupted
→ **Audit/Legal**	As inquirers, reviewers of...		Periodically
→ **Providers** → **Providers**	As implementer of...	EHR system software	At setup
	As configurator of...	EHR system parameters	Periodically
→ **Vendors**	As developer/proprietor of...	EHR system software	Ongoing

RM-ES Proposal to ONC

Evidentiary Scope

Evidentiary Scope of EHR System and Applicability of Key Characteristics – Based on Purpose of Use (of EHR record content)	Use: Primary	Use: **Evidentiary**	Use: Secondary
Showing accountability of Actors for Actions...			
Actors taking Conscious Actions: individuals, organizations	X	**X**	--
Actors taking Programmed Actions: software and devices	X	**X**	--
Ensuring evidence of...			
Identity: individuals (patients and professionals), organizations, software and devices	X	**X**	--
Authentication: of EHR record entry content	X	**X**	--
Source of truth – trust anchor – at point of record entry creation/origination	X	**X**	--
Provenance: of EHR record entry content creation/update	X	**X**	--
Traceability: end-to-end			
a) Forward: source to use, across zero or more points of exchange	X	**X**	--
b) Backward: use to source, across zero or more points of exchange	X	**X**	--
Audit			
a) Audit triggers	X	**X**	--
b) Audit log (trail)	X	**X**	--
Ensuring protection of EHR records and record content...			
Authorization, permission, consent	X	**X**	--
Access (control) a) Actor (user)/use authentication	X	**X**	--
Indelibility, non-alteration of record content	X	**X**	--
Encryption			
a) Data at rest	X	**X**	--
b) Data in motion	X	**X**	--
Continuously managing EHR records and record content...			
Unit of record management = record entry	X		--
Record lifespan			
a) Point of origination to point of use (within/across systems)	X	**X**	--
b) Point of origination to point of deletion (within systems)	X	**X**	--
Record lifecycle events (occurring during record lifespan)			
a) Creation/origination/retention	X	**X**	--
b) Verification	X	**X**	--
c) Attestation/signature	X	**X**	--
d) Update/amendment	X	**X**	--
e) Read/access/view	X	**X**	--
f) Transformation/translation	X	**X**	--
g) Outbound exchange: extraction, output, disclosure, transmittal	X	**X**	--
h) Inbound exchange: receipt/retention	X	**X**	--
i) De-identification, pseudonymization	X	**X**	--
k) Deprecation	X	**X**	--
l) Archival	X	**X**	--
m) Deletion, destruction	X	**X**	--
n) Encryption, decryption	X	**X**	--
o) Place/remove legal hold	--	**X**	--
User ceremonies (whilst acting as source/author in EHR record lifecycle events a-e)	X	**X**	--
Revision history	X	**X**	--

S&I Simplification

- S&I Simplification Wiki
  - http://wiki.siframework.org/Cross+Initiative+-+S%26I+Simplification+WG
- S&I Simplification Core Matrix, v3.4
  - http://wiki.hl7.org/images/7/77/ONC-SI-Simplification-Core-Matrix-v3-4-20151228.xlsx
- Includes:
  - 21 S&I Initiative Use Cases
  - 47 Stepwise Scenarios
  - With Events and Actions linked to EHR and PHR System functions (ISO/HL7 10781/16527)

Simplification Core Matrix

S&I Simplification - Analysis Status - 28 December 2015 - Core Matrix Version 3.4 DRAFT
Incorporation of Use Case Initiatives in S&I Simplification Core Matrix

Initiative	Initial Analysis Phase - Core Matrix					FHIM	AHRQ	Consensus Core Matrix
	Analysis Type	Common Requirements	Common Actors, Systems, Roles	Scenarios, Event Steps	Common Actions	Common Data Objects, Elements	US Health Information Knowledgebase	
Transitions of Care (TOC)	Retro	COMPLETE	COMPLETE	COMPLETE	COMPLETE	FHIM Mapping in Progress	REGISTERED	v1
Lab Results Interface (LRI)								
Longitudinal Coordination of Care (LCC) 1								v2.1
Care Plan Interoperability (LCC 2)							Awaiting Tooling	v4
Lab Orders Interface (LOI)							REGISTERED	v2.1
Provider Directory (PD) - Digital Certificate								
PD - Electronic Address								
esMD 1 - Electronic Submission of Medical Documentation, Provider Profiles Authentication								
esMD 2 - Structured Content of Electronic Medical Documentation Request (eMDR)								
esMD 3 - Author of Record Level 1	Concurrent						Awaiting Tooling	v3
esMD 3 - Author of Record Level 2	Retro							
esMD 3 - Author of Record Level 3	TBD	Future						
Query Health (QH)	Retro	COMPLETE	COMPLETE	COMPLETE	COMPLETE	FHIM Mapping in Progress	REGISTERED	v2.1
Data Segmentation for Privacy (DS4P)								
Public Health Reporting (PHRI)								
HeD 1 - Health eDecisions - Clinical Decision Support (CDS) Artifact Sharing							Awaiting Tooling	v3
HeD 2 - CDS Guidance Service								
Structured Data Capture								
EU/US eHealth Initiative	Concurrent							
DAF 1 - Data Access Framework - Local	Retro							
DAF 2 - Targeted Access								
Data Provenance	Concurrent							v4
RESTful Health Exchange (RHEx)	TBD	TBD						TBD
Automated Blue Button								
Electronic Certificate		N/A				In Progress	REGISTERED	N/A

DPROV System Event Matrix

- S&I Data Provenance Initiative (DPROV) – System Event Matrix – Patient Summary Data Flow Example
  - http://wiki.hl7.org/images/b/b9/ONC-SI-DPROV-System_Event_Matrix-20151130.pdf
- Includes:
  - Source/sender-side Extract Event: Assemble (by software) or Compose (by human)
  - Receiver-side Extract Event: Disassemble (by software) or Decompose (by human)

Record Lifecycle Events on (HL7) FHIR

RLE Implementation Guide

- HL7 Fast Health Interoperable Resources (FHIR)
  - http://hl7.org/fhir
- Record Lifecycle Event Implementation Guide (RLE IG) (part of HL7 FHIR STU-3, September 2016)
  - http://hl7.org/fhir/2016Sep/ehrsrle/ehrsrle.html
- FHIR STU-3 Implementer's Safety Checklist (see #9)
  - http://hl7.org/fhir/2016Sep/safety.html
- FHIR RLE STU-3 AuditEvent Profile
  - http://hl7.org/fhir/2016Sep/ehrsrle/auditevent-ehrsrle.html
- FHIR RLE STU-3 Provenance Profile
  - http://hl7.org/fhir/2016Sep/ehrsrle/provenance-ehrsrle.html

International Patient Summary

- Joint HL7/CEN Project
- International Patient Summary (INTERPAS/IPS) Data Integrity Functional Requirements Applicable to EHR, PHR or other system
  - http://wiki.hl7.org/images/3/3f/International_Patient_Summary-Data_Integrity-Functional_Requirements-20161023.pdf

Primary and Secondary Use

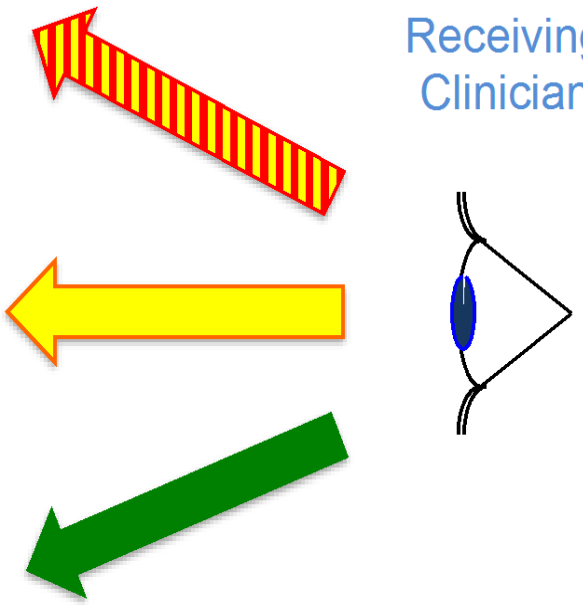
The Transformation Challenge

Use	Purpose	Health Record Content Exchange			Post Exchange Fit for Use?
		Source	→ → →	Receiver	
Primary (clinical)	• Care, care coordination • Treatment • Diagnosis • Decision making • Interventions …	Without Transformation (maintaining fidelity to source)			**YES**
		With Transformation(s)			**Often NO**
Secondary (everything else)	• Billing: claim, payment, substantiation • Operations • Public Health • Research • Legal Proceedings • Oversight, Accreditation …	With Transformation(s)			**Typically YES**

Transformation Challenges Trust

Too Great a Risk?

Transforms	Primary Use – Clinician View
1, 2, 3, 4…	1 2 3 4 Blind Transforms View Last (Sum) Result Use with Extreme Caution!
	1 2 3 4 Visible Transforms View each Result Be Aware!
0	View Unaltered Source Health Record Content **Be Assured!**



Transformation Challenges Trust

Too Great a Risk?

Examples	Source Clinical Content is/has…	Likely Disjunction	
Mismatched	Incorrectly matched • Including Patient or Provider identity	Error	
	Structured content mapped to/from unstructured content	Error or	Alteration
	Disjoint data types: e.g., integer vs. decimal	Error or	Alteration
	Codes/values mapped one to many	Error or	Alteration
Incomplete or missing	No corresponding target data element	Omission	
	No corresponding code/value in target code/ value set	Omission or	Alteration
Less Precise	Source codes/values mapped many to one	Error or	Alteration
	Less digits/characters, rounding/truncation	Error or	Alteration
Skewed	As the effect of multiple transforms • 1 off + 1 off + 1 off + 1 off	Error or	Alteration

References

EHR as Legal Record

- Healthcare IT News, 13 October 2016:
  - “Electronic health records platforms are leaving doctors exposed by making it hard to demonstrate what they did and why.”
  - “Some providers are even settling malpractice suits and not because of guilt.”
  - “Hospitals cannot ignore the issue anymore.”
  - http://www.healthcareitnews.com/news/legal-records-lurking-ehrs-add-new-wrinkle-malpractice-lawsuits

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EHR as Legal Record

- Healthcare IT News, 4 February 2016:
  - “Amid surge in malpractice lawsuits, EHRs often targeted in litigation.”
  - “Providers often wind up defending their electronic health records, rather than what got them sued in the first place.”
  - http://www.healthcareitnews.com/news/amid-surge-malpractice-lawsuits-ehrs-often-targeted-litigation-attorney-says

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EHR as Legal Record

- Healthcare IT News, 13 April 2015:
  - “EMRs can be costly in malpractice suits”
  - http://www.healthcareitnews.com/news/emrs-can-be-costly-malpractice-suits
- Healthcare IT News, 28 September 2010:
  - “At AHIMA, defining 'The Legal EHR’”
  - http://www.healthcareitnews.com/news/ahima-defining-legal-ehr