End-to-End Interoperability of Health Data/Records - Validation Framework to ensure Affirmative Trust Decision

Data/Record Flow - Point of Collection/Origination to each Ultimate Point of Access/Use →

ONC Interoperability Roadmap (2015)	Initially… (Establish)	Collect	Share		Use
			Send	**Receive**	**TRUST DECISION (Trusted and Fit for Use)**
	• Design, Specify • Agree by Consensus • Deploy, Operationalize, Validate	*At source, typically:* • *Point of service* • *Point of care*			
Key Standards for Trusted Health Data/Record Management • ISO 21089 - Health Informatics - Trusted End-to-End Information Flows (2018) • ISO/HL7 10781 - Health Informatics - Electronic Health Record System (EHR-S) Functional Model (2014)	• Define Actions/Observations • Define Record Entries documenting Actions/Observations *(EHRs and PHRs are comprised of Record Entries. A Record Entry instance (typically) documents an Action Taken (by one or more Actors) to support individual health or to provide healthcare.)*	1) Access source EHR/HIT 2) Originate source Record Entry 3) Retain Source Record Entry	1) Transmit unaltered copy of source record 2) Transform/Translate source record content into exchange artifact 3) Transmit exchange artifact	1) Receive unaltered copy of source record content 2) Receive exchange artifact 3) Transform/Translate into Receiver Record Entry 4) Retain Receiver Record Entry	1) Access EHR/HIT system/datastore 2) Access unaltered copy of source record content 3) Access copy of Receiver Record Entry content 4) [IF TRUSTED] Use content for intended purpose
• HL7 - Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Event Implementation Guide (part of FHIR STU-3, 2017)	• Define FHIR Resources documenting Actions/Observations, including AuditEvent and Provenance Resources	*(Source and Receiver Record Entries and/or exchange artifacts may contain FHIR resource instances)*			
FHIR Resource Implementation	(Typical pattern >>>)	Action-related resource(s) + AuditEvent resource + Provenance resource for Source Record Entry	Action-related resource(s) + AuditEvent resource + Provenance resource for Exchange Artifact	Action-related resource(s) + AuditEvent resource	Action-related resource(s) + AuditEvent resource + Provenance resource for Receiver Record Entry

Drivers

A. A Supportive Payment and Regulatory Environment	• Develop, design supportive payment and regulatory environment	• Continuously, Maintain/Ensure environment ——————→			

Policy and Technical Components

B. Shared Decision-Making, Rules of Engagement and Accountability	• Design, specify decision-making, rules of engagement and accountability	• Continuously, Maintain/Ensure decision making, rules of engagement and accountability ——————→			
C. Ubiquitous, Secure Network Infrastructure	• Design, specify ubiquitous, secure network infrastructure	• At startup, Identify/Authenticate networks, nodes and systems • Continuously, Maintain/Ensure authenticated networks, nodes and systems ——————→			
D. Verifiable Identity and Authentication of All Participants	• Design, specify infrastructure to verify identity and authentication of all participants	• In real-time, Identify/ Authenticate all participants in Action Taken and health	• In real-time, Identify/Authenticate all participants in health data/record sharing - senders and receivers, sources and enquirers		• In real-time, Identify/ Authenticate all participants in health data/record use
E. Consistent Representation of Authorization to Access Electronic Health Information	• Design, specify consistent representation of authorization to access electronic health information	• Continuously, Maintain/Ensure consistent representation of authorization to access electronic health information ——————→ • In real-time, Verify authorization to collect	• In real-time, Verify authorization to share - send and receive		• In real-time, Verify authorization to use
F. Consistent Understanding and Technical Representation of Permission to Collect, Share and Use Identifiable Electronic Health	• Design, specify consistent technical representation of permission to collect, share and use identifiable electronic health information	• Continuously, Maintain/Ensure Consistent Technical Representation of permission to collect, share and use identifiable electronic health information ——————→ • In real-time, Verify specific permission to	• In real-time, Verify specific permission to share - send and receive		• In real-time, Verify specific permission to use
G. An Industry-wide Testing and Certification Infrastructure	• Design, specify industry-wide testing and certification infrastructure	• Continuously, Maintain/Ensure industry-wide testing and certification infrastructure ——————→ • In real-time, Verify certification requirements regarding collection of health data/record content	• In real-time, Verify certification requirements regarding sharing of health data/record content - to send and receive		• In real-time, Verify certification requirements regarding use of health data/record content
H. Consistent Data Semantics	• Design, specify consistent data semantics	• Continuously, Maintain/Ensure consistent data semantics ——————→ • In real-time, Capture/ Collect health data/records w/consistent semantics	• In real-time, Share (send and receive) health data/records w/consistent semantics		• In real-time, Access/Use health data/records w/consistent semantics
I. Consistent Data Formats	• Design, specify consistent data formats	• Continuously, Maintain/Ensure consistent data formats ——————→ • In real-time, Capture/ Collect health data/records w/consistent data formats	• In real-time, Share (send and receive) data/records w/consistent data formats		• In real-time, Access/Use health data/records w/consistent data formats
J. Secure, Standard Services	• Design, specify secure standard services	• Continuously, Maintain/Ensure secure, standard services ——————→			
K. Consistent, Secure Transport Techniques	• Design, specify consistent, secure transport techniques	• Continuously, Maintain/Ensure secure transport ——————→			
L. Accurate Individual Data Matching	• Design, specify methods for accurate individual data matching	• Continuously, Maintain/Ensure methods for accurate individual data/record matching ——————→ • In real-time, Capture/ Collect health data/records with verifiably accurate individual data matching	• In real-time, Share (send and receive) health data/records with verifiably accurate individual data matching		• In real-time, Access/Use health data/records with verifiably accurate individual data matching
M. Health Care Directories and Resource Location	• Design, specify infrastructure for health care directories and resource location	• Continuously, Maintain/Ensure access to health care directories and resources ——————→			

Outcomes

N. Individuals Have Access to Longitudinal Electronic Health Information, Can Contribute to that Information, and Can Direct It to Any Electronic Location

O. Provider Workflows and Practices Include Consistent Sharing and Use of Patient Information from All Available and Relevant Sources

P. Tracking Progress and Measuring Success

TRUST DECISION - Determination of Fit(ness) for Use:
• Primary Use: clinical care, interventions, decision making
• Secondary Use: most everything else

Exchange artifact: e.g., HL7 v2 message, CDA/CCDA document or FHIR resource	
ISO/HL7 10781 Electronic Health Record System (EHR-S) Functional Model, Release 2	Link
HL7 Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Event Implementation Guide (FHIR STU-3)	Link
Graphic developed by: Gary Dickinson, Director, Healthcare Standards, CentriHealth, a subsidiary of United Health Group, 14 May 2018	