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

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

ONC Interoperability Roadmap (2015)	Initially… (Establish)	In Real-Time… Collect	Share Send	Share Receive	Use
	• Design, Specify, Agree by Consensus • Certify HIT System Functionality • Deploy, Operationalize, Validate	*Typically, at source, e.g.,* • *Point of service* • *Point of care*	Send	Receive	**TRUST DECISION** **(Trusted and Fit for Use)**
Key Standards for Trusted Health Data/Record Management • ISO 21089 - Health Informatics - Trusted End-to-End Information Flows (2004, in revision 2015) • ISO/HL7 10781 - Health Informatics - Electronic Health Record System (EHR-S) Functional Model Release 2 (2014)	• Define Actions/Observations • Define Record Entry content documenting Actions/Observations *(EHRs and PHRs are comprised of Record Entries. A Record Entry instance documents an Action Taken (by one or more Actors) to support individual health or to provide healthcare.)*	1) Access source EHR/HIT system/datastore 2) Originate source Record Entry 3) Retain Source Record Entry	1) Transmit <u>unaltered</u> copy of source record content 2) Transform/Translate source record content into exchange artifact 3) Transmit exchange artifact	1) Receive <u>unaltered</u> 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 <u>unaltered</u> copy of source record content 3) Access copy of Receiver Record Entry content 4) **IF TRUSTED** Use content for intended purpose
EXAMPLE: Based on HL7 Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Event Implementation Guide (part of FHIR DSTU-2 2015) • Other examples might include HL7 v2 messages or CDA/CCDA documents	• Define FHIR Resources documenting Actions/Observations, including AuditEvent and Provenance FHIR Resource Implementation Typical pattern >>>	*[Where FHIR resources are implemented natively in source record entries.]* Action-related resource(s) + AuditEvent resource + Provenance resource for Source Record Entry	*[Where FHIR resources are implemented as exchange artifacts or as system APIs.]* Action-related resource(s) + AuditEvent resource + Provenance resource for Exchange Artifact	Action-related resource(s) + AuditEvent resource	*[Where FHIR resources are implemented natively in receiver record entries.]* Action-related resource(s) + AuditEvent resource + Provenance resource for Receiver Record Entry

⬇ For each ONC Driver, Policy/Technical Component and Outcome - Define Assessment Criteria for achievement of interoperability ⬇

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 data/record collection	• 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 Information	• 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 collect	• 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

Exchange artifact, e.g.: HL7 v2 message, CDA/CCDA document or FHIR resource
Background: blue = ONC Interoperability Roadmap targets; green = affirmative trust decision;
light green = exchange unaltered content; yellow = exchange transformed content

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

In Light of
Recent Developments

- Proposal for Standards Reference Portfolios ("bundles") by ISO TC215 on Health Informatics
  - Work in progress, reaffirmed 2-6 November 2015 in Bern, Switzerland
- Proposal for Standards Sets by the Joint Initiative Council (JIC)
  - JIC includes ISO TC215, CEN TC251, HL7, IHTSDO, DICOM, CDISC, GS1, IHE
  - Work in progress, reaffirmed 5 November 2015 in Bern, Switzerland
- Revision of ISO 21089, Health Informatics - Trusted End-to-End Information Flows
  - As normative ISO Technical Specification
  - Work in progress
- Publication of HL7 Fast Health Interoperable Resources (FHIR)
  - 2nd Edition Draft Standard for Trial Use, 26 September 2015
- Publication of US Office of National Coordinator Interoperability Roadmap
  - Final Version 1, 6 October 2015

In Light of
Recent Developments

- Publication of ISO/HL7 10781, Health Informatics - Electronic Health Record System Functional Model Release 2
  - As normative International Standard
  - April 2014 (HL7), August 2015 (ISO TC215)
- Merger of the Clinical Information Modeling Initiative (CIMI) w/Health Level Seven (HL7)
  - Formally at HL7 WG meeting in Atlanta, October 2015
- Development of Event-based services (APIs) by the Health Services Platform Consortia (HSPC) using FHIR resources
  - Work in progress, reaffirmed 28-30 September 2015 in Scottsdale, Arizona
- Proposal for interoperability (achievement) measures by KLAS and vendor organizations
  - Announced in October 2015

Objectives

- Focus end-to-end interoperability of health data/records resulting in
  - Affirmative trust decision
  - By each ultimate end user
- Identify key end-to-end standards
- Show example using FHIR
- Show basic use case for data/record flow: collect, share, use
- Incorporate targets from ONC Interoperability Roadmap
- Show framework to assess achievement of interoperability
  - At each step in data/record flow
  - As a pattern for development of testable Assessment Criteria

Interoperability is a function of:

- ## Truth = factual, authentic
  - The facts are evident

- ## Trust = assurance, reliance
  - I am assured, I trust, thus I rely on

- ## Trust decision
  - *(green background)*
  - By each ultimate end user of health data/records
  - Regarding fitness for their use

Interoperability is a function of:

- Source of truth, anchor point:
  - Point of data collection
  - Point of origination/retention of Record Entry in source system (e.g., EHR, PHR or other)
- Trusted management of health data/record content:
  - From point of collection/ origination/retention
  - To each ultimate point of access/ use

Interoperability is a function of:

- Traceability from:
  - Source to use (forward)
  - Use to source (backward)

- Fitness for purpose of use:
  - *(green background)*
  - Primary use: clinical care, interventions and decision making
  - Secondary (most everything else)

ONC Interoperability Roadmap
(*blue background*)

- Collect, Share, Use

- Drivers, Policy and Technical Components, Outcomes
  (Items A-P in first column)

Basic Use Case:

- **Collect** – at source
  (3rd column)

- **Share** – send/receive
  (4th and 5th columns)

- **Use** – IF TRUSTED –
  for purpose intended
  (6th column)

Interoperability Pathways (collect, share, use):

- ## Unaltered source content
  (light green background)
  - PRIMARY USE – WITH ASSURANCE

- ## Derivative content – transformed/translated
  (yellow background)
  - From source data/record
  - To exchange artifacts
  - To receiver internal representation
  - PRIMARY USE – ONLY WITH AWARENESS/CAUTION

Example: Using FHIR Resources for Implementation

- Based on FHIR DSTU-2 Record Lifecycle Event Implementation Guide

- Collect – Show FHIR resources as native to source system

- Share – Show FHIR resources as exchange artifacts

- Use – Show FHIR resources as native to receiving system

Other examples might include: HL7 v2 messages or CDA/CCDA documents

For each ONC Driver, Policy and Technical Component, Outcome

- Initially Establish

  (2nd column)

  – At time of deployment/ implementation

- Collect, share, use

  (3rd through 6th columns)

  – Continuously from system(s) startup (uninterrupted)

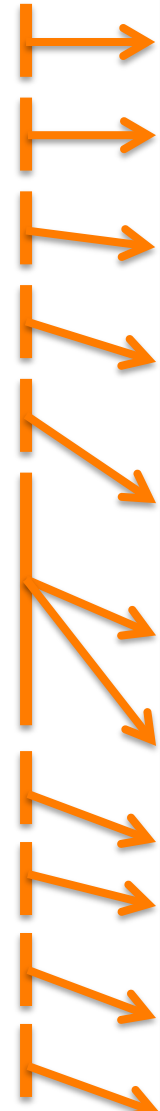 – Then in Real-Time to support health/healthcare services

Next Step: for each ONC Driver, Policy/ Technical Component and Outcome

- Define **Assessment Criteria** to measure achievement of interoperability

  - *(Items A-P, blue background)*

  - *(Then left to right cell by cell in 2nd through 6th columns)*

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ONC Interoperability Roadmap, Final Version 1.0 — https://www.healthit.gov/policy-researchers-implementers/interoperability
ISO/HL7 10781 Electronic Health Record System (EHR-S) Functional Model, Release 2 — http://www.hl7.org/implement/standards/product_brief.cfm?product_id=269
HL7 Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Event Implementation Guide (FHIR DSTU-2) — http://hl7.org/fhir/ehrs/ehrsrle.html
Validation Matrix developed by: Gary Dickinson, Director, Healthcare Standards, CentriHealth, DRAFT 8 November 2015 — gary.dickinson@ehr-standards.com

Assessment Criteria to be based on Standards for

- Network Infrastructure
- Entity Identity, Authentication
- Entity Authorization
- Permissions, Consents
- Testing and Certification
- Information Models, Vocabularies, Data Types, Syntax, Formats, Exchange Artifacts
- Security
- Transport
- Individual Matching
- Directories, Resources

Drivers
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