

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			
	Initially...	In Real-Time...			
ONC Interoperability Roadmap (2015)	(Establish)	Collect	Share		Use
	<ul style="list-style-type: none">Design, Specify, Agree by ConsensusCertify HIT System FunctionalityDeploy, Operationalize, Validate	<i>Typically, at source, e.g.,</i> <ul style="list-style-type: none">Point of servicePoint 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)	<ul style="list-style-type: none">Define Actions/ObservationsDefine Record Entry content documenting Actions/Observations <i>(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.)</i>	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	<ul style="list-style-type: none">Define FHIR Resources documenting Actions/Observations, including AuditEvent and Provenance FHIR Resource Implementation Typical pattern >>>	<i>[Where FHIR resources are implemented natively in source record entries.]</i> Action-related resource(s) + AuditEvent resource + Provenance resource for Source Record Entry	<i>[Where FHIR resources are implemented as exchange artifacts or as system APIs.]</i> Action-related resource(s) + AuditEvent resource + Provenance resource for Exchange Artifact		<i>[Where FHIR resources are implemented natively in receiver record entries.]</i> 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		

ONC Interoperability Roadmap, Final Version 1.0

ISO/HL7 10781 Electronic Health Record System (EHR-S) Functional Model, Release 2

HL7 Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Event Implementation Guide (FHIR DSTU-2)

Validation Matrix developed by: Gary Dickinson, Director, Healthcare Standards, CentriHealth, DRAFT 13 November 2015

<https://www.healthit.gov/policy-researchers-implementers/interoperability>

http://www.hl7.org/implement/standards/product_brief.cfm?product_id=269

<http://hl7.org/fhir/ehrs/ehrsrie.html>

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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**

End-to-End Interoperability of Health Data/Records - Validation Framework to ensure Affirmative Trust Decision		Basic Use Case - Data/Record Flow - Point of Collection/Origin to each Ultimate Point of Access/Use			
		In Real-Time...			
ONC Interoperability Roadmap (2015)		Collect	Share		Use
		Send	Receive	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 (2015)		1) Access source EHR/HL7 system/databases 2) Original source record entry 3) Retain Source Record Entry	1) Transform/unaltered copy of source record content 2) Transform/Translate source record content into exchange artifact 3) Transmit exchange artifact	1) Receive unaltered copy of source record content 2) Transform/Translate into exchange artifact 3) Access copy of Receiver Record Entry	1) Access EHR/HL7 system/databases 2) Access unaltered 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 Draft 8 2015) • Other examples include HL7 v2 messages or CDA/CDDA documents		• Define FHIR Resources documenting Action/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	[Where FHIR resources are implemented natively in receiver record entries] Action-related resource(s) AuditEvent resource Provenance resource for Receiver Record Entry
Drivers A. A Supportive Payment and Regulatory Environment B. Policy and Technical Components C. Ubiquitous, Secure Network Infrastructure D. Verifiable Identity and Authentication of All Participants E. Consistent Representation of Authorization to Access Electronic Health Information F. Consistent Understanding and Technical Representation of Permission to Collect, Share and Use Identifiable Electronic Health Information G. An Industry-wide Testing and Certification Infrastructure H. Consistent Data Semantics I. Consistent Data Formats J. Secure, Standard Services K. Consistent, Secure Transport Techniques L. Accurate Individual Data Matching M. Health Care Directories and Resource Location 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		• Continuously, Maintain/Ensure environment • Continuously, Maintain/Ensure decision making, rules of engagement and accountability • At startup, Identify/Authenticate networks, nodes and systems • Continuously, Maintain/Ensure authenticated networks, nodes and systems • 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, source and enquire • Continuously, Maintain/Ensure consistent representation of authorization to access electronic health information • In real-time, Verify authorization to share - send and receive • In real-time, Verify authorization to share - send and receive • Continuously, Maintain/Ensure Technical Representation of permission to collect, share and use identifiable electronic health information • In real-time, Verify specific permission to share - send permission to collect and receive • 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 • Continuously, Maintain/Ensure consistent data semantics • In real-time, Share (send and receive) health data/records w/consistent semantics • 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 • Continuously, Maintain/Ensure secure, standard services • Continuously, Maintain/Ensure secure transport • Continuously, Maintain/Ensure methods for accurate individual data/record matching • In real-time, Share (send and receive) health data/records with verifiably accurate individual data matching • Continuously, Maintain/Ensure access to health care directories and resources • Individuals Have Access to Longitudinal Electronic Health Information, Can Contribute to that Information, and Can Direct It to Any Electronic Location • Provider Workflows and Practices Include Consistent Sharing and Use of Patient Information from All Available and Relevant Sources • Tracking Progress and Measuring Success			
ONC Interoperability Roadmap, Final Version 1.0 ISO/HL7 10781 Electronic Health Record System (EHR-S) Functional Model, Release 2 HL7 Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Event Implementation Guide (FHIR DSTU-2) Validation Matrix developed by: Gary Dickinson, Director, Healthcare Standards, CentilHealth, DRAFT 8 November 2015		TRUST DECISION - Determination of Fit(ness) for Purpose of Use: Primary Use: clinical care interventions, decision making Secondary Use: most everything else https://www.health.gov.au/policy-researchers-implementers-interoperability https://www.hl7.org/implement/standards/public_html/infrastructure/uc228 https://fhir.healthcare.wa.gov.au/			

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

End-to-End Interoperability of Health Data/Records - Validation Framework to ensure Affirmative Trust Decision		Basic Use Case - Data/Record Flow - Point of Collection/Origin to each Ultimate Point of Access/Use				
Initially... (Establish)		Collect	In Real-Time... (Share)		Use	
ONC Interoperability Roadmap (2015)		<ul style="list-style-type: none">Design, Specify, Agree by ConsensusCertify HIT System FunctionalityDeploy, Operationalize, Validate	Typically, at source, e.g.: <ul style="list-style-type: none">Point of servicePoint of care	Send	Receive	TRUST DECISION (Trusted and Fit for Use)
Key Standards for Trusted Health Data/Record Management	<ul style="list-style-type: none">Define Actions/ObservationsDefine Record Entry content documenting Actions/Observations	<ul style="list-style-type: none">1) Access source EHR/PHR system/databases2) Original source Record Entry3) Retain Source Record Entry	<ul style="list-style-type: none">1) Transmit unaltered copy of source record content2) Transform/Translate source record content into exchange artifact3) Transmit exchange artifact	<ul style="list-style-type: none">1) Receive unaltered copy of source record content2) Receive exchange artifact3) Transform/Translate into Receiver Record Entry4) Retain Receiver Record Entry	<ul style="list-style-type: none">1) Access EHR/PHR system/databases2) Retrieve unaltered copy of source record content3) Access copy of Receiver Record Entry content4) If TRUSTED Use content for intended purpose	
	<ul style="list-style-type: none">ISO 21089 - Health Informatics - Trusted End-to-End Interoperability Flow (2004, 1 revision 2015)ISO/HL 12781 - Health Informatics - Electronic Health Record System (EHR-S) Functional Model Release 2 (2014)	<ul style="list-style-type: none">Define FHIR Resources documenting Actions/Observations, including AuditEvent and ProvenanceFHIR Resource Implementation Typical pattern >>>	<ul style="list-style-type: none">[Where FHIR resources are implemented natively in source record entries.]Action-related resource(s)<ul style="list-style-type: none">AuditEvent resourceProvenance resource for Source Record Entry	<ul style="list-style-type: none">[Where FHIR resources are implemented as exchange artifacts or as system APIs.]Action-related resource(s)<ul style="list-style-type: none">AuditEvent resourceAction-related resource(s)Provenance resource for Exchange Artifact	<ul style="list-style-type: none">[Where FHIR resources are implemented natively in receiver record entries.]Action-related resource(s)<ul style="list-style-type: none">AuditEvent resourceProvenance resource for Receiver Record Entry	
EXAMPLE: Based on HLT Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Event Implementation Guide (part of FHIR DSTU-2 2015) <ul style="list-style-type: none">Other examples might include HLT v2 messages or CDA/CDDA documents						
Drivers						
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				
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				
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				
H. Consistent Data Semantics	Design, specify consistent data semantics	Continuously, Maintain/Ensure consistent data semantics				
I. Consistent Data Formats	Design, specify consistent data formats	Continuously, Maintain/Ensure 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				
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.: HLT v2 message, CDA/CDDA document or FHIR resource						
Background: blue = ONC Interoperability Roadmap targets; green = affirmative trust decision; light green = exchange unaltered content; yellow = exchange transformed content						
ONC Interoperability Roadmap, Final Version 1.0						
ISOLHL 10781 Electronic Health Record System (EHR-S) Functional Model, Release 2						
HLT Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Event Implementation Guide (FHIR DSTU-2)						
Validation Matrix developed by: Gary Dickinson, Director, Healthcare Standards, CentilHealth, DRAFT 8 November 2015						
TRUST DECISION - Determination of Fitness for Purpose of Use: Primary Use: clinical care, interventions, decision making Secondary Use: most everything else						
https://www.health.gov.au/policy-researchers-implementers-interoperability https://www.hlt.org.au/interoperability/interoperability_jarvis/interoperability_jarvis http://www.dhs.gov/interoperability						

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

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			
Initially...		In Real-Time...			
ONC Interoperability Roadmap (2015)		Collect	Send	Receive	Use
Establish <ul style="list-style-type: none"> • Design, Specify, Agree by Consensus • Certify HIT System Functionality • Deploy, Operationalize, Validate 		Collect <ul style="list-style-type: none"> 1) Acquire source EHR/PHR data 2) Create source record 3) Retain Source Record Entry 	Send <ul style="list-style-type: none"> 1) Transform/Translate source record content into exchange artifact 2) Transmit exchange artifact 	Receive <ul style="list-style-type: none"> 1) Receive unaltered copy of source record content 2) Transform/Translate exchange artifact into Receiver Record Entry 3) Access copy of Receiver Record Entry 4) Retain Receiver Record Entry 	Use <ul style="list-style-type: none"> 1) Access EHR/PHR data 2) Access unaltered copy of source record content 3) Access copy of Receiver Record Entry 4) If TRUSTED Use content for intended purpose
Key Standards for Trusted Health Data/Record Management <ul style="list-style-type: none"> • Define Action/Observation • Define Record Entry • Documenting Action/Observations • EHR/PHR entries are comprised of Record Entries. A Record Entry includes an Action Taken (by one or more Actors) to support individual health or to provide healthcare. 		(Where FHIR resources are implemented natively in source record entries.) <ul style="list-style-type: none"> • Define FHIR Resources • Define FHIR Resource Implementation • FHIR Resource Implementation Typical pattern 	(Where FHIR resources are implemented as exchange artifacts or as system APIs.) <ul style="list-style-type: none"> • Action-related resource(s) • AuditEvent resource • Provenance resource for Exchange Artifact 	(Where FHIR resources are implemented natively in receiver record entries.) <ul style="list-style-type: none"> • Action-related resource(s) • AuditEvent resource • Provenance resource for Receiver Record Entry 	(Where FHIR resources are implemented natively in health data/record use.) <ul style="list-style-type: none"> • Action-related resource(s) • AuditEvent resource • Provenance resource for Receiver Record Entry
EXAMPLE: Based on HL7 Fast Health Interoperable Resources (FHIR) EHR-S Record Entry Level Implementation (subset of FHIR DSTU-2 2015). Other examples might include HL7 v2 messages or CDA/CCDA documents.					
Drivers <ul style="list-style-type: none"> A. A Supportive Payment and Regulatory Environment B. Shared Decision-Making, Rules of Engagement and Accountability C. Ubiquitous, Secure Network Infrastructure D. Verifiable Identity and Authentication of All Participants E. Consistent Representation of Authorization to Access Electronic Health Information F. Consistent Understanding and Technical Representation of Permission to Collect, Share and Use Identifiable Electronic Health Information G. An Industry-wide Testing and Certification Infrastructure H. Consistent Data Semantics I. Consistent Data Formats J. Secure, Standard Services K. Consistent, Secure Transport Techniques L. Accurate Individual Data Matching M. Health Care Directories and Resource Location 		Continuously, Maintain/Ensure environment			
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Drivers <ul style="list-style-type: none"> A. A Supportive Payment and Regulatory Environment B. Shared Decision-Making, Rules of Engagement and Accountability C. Ubiquitous, Secure Network Infrastructure D. Verifiable Identity and Authentication of All Participants E. Consistent Representation of Authorization to Access Electronic Health Information F. Consistent Understanding and Technical Representation of Permission to Collect, Share and Use Identifiable Electronic Health Information G. An Industry-wide Testing and Certification Infrastructure H. Consistent Data Semantics I. Consistent Data Formats J. Secure, Standard Services K. Consistent, Secure Transport Techniques L. Accurate Individual Data Matching M. Health Care Directories and Resource Location 		Continuously, Maintain/Ensure secure transport			
Drivers <ul style="list-style-type: none"> A. A Supportive Payment and Regulatory Environment B. Shared Decision-Making, Rules of Engagement and Accountability C. Ubiquitous, Secure Network Infrastructure D. Verifiable Identity and Authentication of All Participants E. Consistent Representation of Authorization to Access Electronic Health Information F. Consistent Understanding and Technical Representation of Permission to Collect, Share and Use Identifiable Electronic Health Information G. An Industry-wide Testing and Certification Infrastructure H. Consistent Data Semantics I. Consistent Data Formats J. Secure, Standard Services K. Consistent, Secure Transport Techniques L. Accurate Individual Data Matching M. Health Care Directories and Resource Location 		Continuously, Maintain/Ensure methods for accurate individual data/record matching			
Drivers <ul style="list-style-type: none"> A. A Supportive Payment and Regulatory Environment B. Shared Decision-Making, Rules of Engagement and Accountability C. Ubiquitous, Secure Network Infrastructure D. Verifiable Identity and Authentication of All Participants E. Consistent Representation of Authorization to Access Electronic Health Information F. Consistent Understanding and Technical Representation of Permission to Collect, Share and Use Identifiable Electronic Health Information G. An Industry-wide Testing and Certification Infrastructure H. Consistent Data Semantics I. Consistent Data Formats J. Secure, Standard Services K. Consistent, Secure Transport Techniques L. Accurate Individual Data Matching M. Health Care Directories and Resource Location 		Continuously, Maintain/Ensure access to health care directories and resources			
Outcomes <ul style="list-style-type: none"> N. Individuals Use 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. Track Progress and Measure Success 		Continuously, Maintain/Ensure consistent data semantics			
Exchange artifact, e.g.: HL7 v2 message, CDA/CCDA document or FHIR resource		Continuously, Maintain/Ensure consistent data formats			
Background: blue = ONC Interoperability Roadmap targets; green = affirmative trust decision; yellow = exchange unaltered content; yellow = exchange transformed content		Continuously, Maintain/Ensure secure, standard services			
ONC Interoperability Roadmap, Final Version 1.0		Continuously, Maintain/Ensure secure transport			
HL7 v2 Fast Health Interoperable Resources (FHIR) EHR-S Record Entry Level Implementation Guide (FHIR DSTU-2)		Continuously, Maintain/Ensure methods for accurate individual data/record matching			
Validation Matrix developed by: Gary Dickinson, Director, Healthcare Standards, CentilHealth, DRAFT 8 November 2015		Continuously, Maintain/Ensure access to health care directories and resources			
Trust Decision - Determination of Fitness for Purpose of Use: <ul style="list-style-type: none"> Primary Use: clinical care, interventions, decision making Secondary Use: most everything else 		Continuously, Maintain/Ensure consistent data semantics			

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)

End-to-End Interoperability of Health Data/Records - Validation Framework to ensure Affirmative Trust Decision		Basic Use Case - Data/Record Flow - Point of Collection/Origin to each Ultimate Point of Access/Use			
		In Real-Time...			
		Collect	Share	Receive	Use
ONC Interoperability Roadmap (2015)		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		1) Assume EHR/HIT system and source record of source record content 2) Transmit unaltered copy of source record content into exchange artifact 3) Retain Source Record Entry	1) Transmit unaltered copy of source record content into exchange artifact 2) Transmit exchange artifact 3) Retain Receiver Record Entry	1) Receive exchange artifact 2) Transform artifact into Receiver Record Entry 3) Access copy of Receiver Record Entry content for intended purpose	1) Assume EHR/HIT system and source record of source record content 2) Transmit unaltered copy of source record content into exchange artifact 3) Retain Receiver Record Entry 4) IF TRUSTED Use content for intended purpose
EXAMPLE: Based on HLT Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Event Implementation Guide (part of FHIR DSTU-2 2015)		• Define FHIR Resources documenting Action/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(s) • Provenance resource for Source Record Entry	• Where FHIR resources are implemented natively in receiver record entries • Action-related resource(s) • AuditEvent resource(s) • Provenance resource for Exchange Artifact	• Where FHIR resources are implemented natively in receiver record entries • Action-related resource(s) • AuditEvent resource(s) • Provenance resource for Receiver Record Entry
A. Supportive Payment and Regulatory Environment		• Develop, design supportive payment and regulatory environment	Continuously, Maintain/Ensure environment		
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 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 share - send permission to collect 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 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/inconsistent semantics	• In real-time, Access/Use health data/records w/inconsistent 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/inconsistent data formats	• In real-time, Access/Use health data/records w/inconsistent 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 matching	• In real-time, Capture/Collect 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					Can Direct It to Any Electronic Location and Relevant Sources
O. Provider Workflows and Practices Include Consistent Sharing and Use of Patient Information from All Relevant Sources					
P. Tracking Progress and Measuring Success					
Exchange artifact, e.g.: HLT v2 message, CDAC/CCDA document or FHIR resource					TRUST DECISION - Determination of Fitness for Purpose of Use: Primary Use: clinical care, interventions, decision making Secondary Use: most everything else
Background: blue = ONC Interoperability Roadmap targets; green = affirmative trust decision; light green = exchange unaltered content; yellow = exchange transformed content					
ONC Interoperability Roadmap, Final Version 1.0					
ISO/HL7 10781 Electronic Health Record System (EHR-S) Functional Model, Release 2					
HL7 Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Event Implementation Guide (FHIR DSTU-2)					
Validation Matrix developed by: Gary Dickinson, Director, Healthcare Standards, CentilHealth, DRAFT 8 November 2015					

ONC Interoperability Roadmap (blue background)

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

End-to-End Interoperability of Health Data/Records - Validation Framework to ensure Affirmative Trust Decision		Basic Use Case - Data/Record Flow - Point of Collection/Origin to each Ultimate Point of Access/Use			
ONC Interoperability Roadmap (2015)	Initially... (Establish)	Collect	In Real-Time...		Use
	<ul style="list-style-type: none">Design, Specify, Agree by ConsensusIdentify HIT System FunctionalityDeploy, Operationalize, Validate	Type: Source, e.g., System or device or Provider	Send	Receive	TRUST DECISION (Trusted and Fit for Use)
Key Standards for Trusted Health Data/Record Management	<ul style="list-style-type: none">Define Action/Observations in Record Entry content documenting Action/Observations	<ul style="list-style-type: none">1) Access source EHR/HIT system/database2) Original source Record Entry3) Retain Source Record Entry	<ul style="list-style-type: none">1) Transmit unaltered copy of source record content2) Transform/Translate source record content into exchange artifact3) Transmit exchange artifact	<ul style="list-style-type: none">1) Receive unaltered copy of source record content2) Receive exchange artifact3) Transform/Translate into Receiver Record Entry4) Retain Receiver Record Entry	<ul style="list-style-type: none">1) Access EHR/HIT system/database2) Access unaltered copy of source record content3) Access copy of Receiver Record Entry content4) 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)	<ul style="list-style-type: none">Define FHIR Resources documenting Action/Observations, including AuditEvent and ProvenanceFHIR Resource Implementation Typical pattern >>>	<ul style="list-style-type: none">Where FHIR resources are implemented natively in source record entriesAction-related resource(s)AuditEvent resourceProvenance resource for Source Record Entry	<ul style="list-style-type: none">Where FHIR resources are implemented as exchange artifacts or as system APIsAction-related resource(s)AuditEvent resourceExchange Artifact	<ul style="list-style-type: none">Where FHIR resources are implemented natively in receiver record entriesAction-related resource(s)AuditEvent resourceProvenance resource for Receiver Record Entry	
Drivers					
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 engines	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	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	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	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	In real-time, Capture/Collect health data/records w/inconsistent semantics	In real-time, Share (send and receive) health data/records w/inconsistent semantics	In real-time, Access/Use health data/records w/inconsistent semantics	
I. Consistent Data Formats	Design, specify consistent data formats	In real-time, Capture/Collect health data/records w/inconsistent data formats	In real-time, Share (send and receive) data/records w/inconsistent data formats	In real-time, Access/Use health data/records w/inconsistent 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			
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, CDAC/CCDA document or FHIR resource		TRUST DECISION - Determination of Fit(ness) for Purpose of Use: Primary Use: clinical care, interventions, decision making Secondary Use: most everything else			
Background: blue = ONC Interoperability Roadmap targets; green = affirmative trust decision; light green = exchange unaltered content; yellow = exchange transformed content					
ONC Interoperability Roadmap, Final Version 1.0					
ISO/HL7 10781 Electronic Health Record System (EHR-S) Functional Model, Release 2					
HL7 Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Event Implementation Guide (FHIR DSTU-2)					
Validation Matrix developed by: Gary Dickinson, Director, Healthcare Standards, CentilHealth, DRAFT 8 November 2015					

Basic Use Case:

- Collect – at source
(3rd column)
- Share – send/receive
(4th and 5th columns)
- Use – IF TRUSTED –
for purpose intended
(6th column)

End-to-End Interoperability of Health Data/Records - Validation Framework to ensure Affirmative Trust Decision		Basic Use Case - Data/Record Flow - Point of Collection/Origin to each Ultimate Point of Access/Use			
Initially...		In Real-Time...			
ONC Interoperability Roadmap (2015)		Establish	Collect	Share	Use
<ul style="list-style-type: none"> Design, Specify, Agree by Consensus Certify HIT System Functionality Deploy, Operate/Manage, Validate 		<ul style="list-style-type: none"> Define/Specify/Agree by Consensus Documenting Actions/Observations Define/Specify/Agree by Consensus Documenting Actions/Observations Define/Specify/Agree by Consensus Documenting Actions/Observations 	<ul style="list-style-type: none"> Access source EHR/HIT system/databases Original source Record Entry Transform/Translate source record content into exchange artifact Transmit exchange artifact Retain Source Record Entry 	<ul style="list-style-type: none"> Send Receive Transform/Translate source record content into exchange artifact Transmit exchange artifact Retain Receiver Record Entry 	<ul style="list-style-type: none"> Access EHR/HIT system/databases Access/Utilize copy of source record content Transform/Translate source record content into exchange artifact Transmit exchange artifact Access copy of Receiver Record Entry content IF TRUSTED Use content for intended purpose
Key Standards for Trusted Health Data/Record Management ISO 21089 - Health Information Trusted End-to-End Interoperable Flows (2004, in revision) HL7 10781 - Health Information - Electronic Health Record System (EHR-S) Functional Model Release 2 (2014)		Define FHIR Resource(s) documenting Action/Event(s), including Audit/Event and Provenance FHIR Resource Implementation Typical pattern >>>	[Where FHIR resources are implemented natively in source record entries.] Action-related resource(s) Audit/Event resource(s) Provenance resource(s) Source Record Entry	[Where FHIR resources are implemented as exchange artifacts or as system APIs.] Action-related resource(s) Audit/Event resource(s) Provenance resource(s) Exchange Artifact	[Where FHIR resources are implemented natively in receiver record entries.] Action-related resource(s) Audit/Event resource(s) Provenance resource(s) Receiver Record Entry
Drivers A. Supportive Policy and Regulatory Environment B. Technical Components C. Ubiquitous, Secure Network Infrastructure D. Verifiable Identity and Authentication of All Participants E. Consistent Representation of Authorization to Access Electronic Health Information F. Consistent Understanding and Technical Representation of Permission to Collect, Share and Use Identifiable Electronic Health Information G. Accurate, Industry-wide Testing and Certification Infrastructure H. Consistent Data Semantics I. Consistent Data Formats J. Secure, Standard Services K. Consistent, Secure Transport Techniques L. Accurate Individual Data Matching M. Health Care Directories and Resource Location		Develop, design supportive payment and regulatory environment Design, specify decision-making, rules of engagement and accountability Design, specify consistent, secure network infrastructure Design, specify infrastructure to verify identity and authentication of all participants Design, specify consistent representation of authorization to access electronic health information Design, specify consistent technical representation of permission to collect, share and use identifiable electronic health information Design, specify industry-wide testing and certification infrastructure Design, specify consistent data semantics Design, specify consistent data formats Design, specify secure standard services Design, specify consistent, secure transport techniques Design, specify methods for accurate individual data matching Design, specify infrastructure for health care directories and resource location	Continuously, Maintain/Ensure environment Continuously, Maintain/Ensure decision making, rules of engagement and accountability At startup, Identify/Authenticate networks, nodes and systems Continuously, Maintain/Ensure authenticated networks, nodes and systems In real-time, Identify/Authenticate all participants in Action Taken and health data/record collection In real-time, Verify authorization to access electronic health information Continuously, Maintain/Ensure consistent representation of permission to collect, share and use identifiable electronic health information In real-time, Verify specific permission to collect and receive Continuously, Maintain/Ensure industry-wide testing and certification infrastructure In real-time, Verify certification requirements regarding collection of health data/record content Continuously, Maintain/Ensure consistent data semantics In real-time, Share (send and receive) health data/records w/inconsistent semantics Continuously, Maintain/Ensure consistent data formats In real-time, Share (send and receive) data/records w/inconsistent data formats Continuously, Maintain/Ensure secure, standard services Continuously, Maintain/Ensure secure transport Continuously, Maintain/Ensure methods for accurate individual data/record matching In real-time, Capture/Collect health data/records with verifiably accurate individual data matching Continuously, Maintain/Ensure access to health care directories and resources	Send Receive Transform/Translate source record content into exchange artifact Transmit exchange artifact Retain Receiver Record Entry	Access EHR/HIT system/databases Access/Utilize copy of source record content Transform/Translate source record content into exchange artifact Transmit exchange artifact Access copy of Receiver Record Entry content IF TRUSTED Use content for intended purpose
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 Purpose of Use: Primary Use: clinical care, interventions, decision making Secondary Use: most everything else			
Exchange artifact, e.g.: HL7 v2 message, CDAC/CCDA document or FHIR resource Background: blue = ONC Interoperability Roadmap targets; green = affirmative trust decision; light green = exchange unaltered content; yellow = exchange transformed content		https://www.healthit.gov/policy-researchers-implementers-interoperability http://www.hl7.org/implement/standards/toolkit/docs/iso21089.html http://www.hl7.org/implement/standards/toolkit/docs/iso21089.html http://www.hl7.org/implement/standards/toolkit/docs/iso21089.html			
ONC Interoperability Roadmap, Final Version 1.0 ISO/HL7 10781 Electronic Health Record System (EHR-S) Functional Model, Release 2 HL7 Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Event Implementation Guide (FHIR DSTU-2) Validation Matrix developed by: Gary Dickinson, Director, Healthcare Standards, CentilHealth, DRAFT 8 November 2015					

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

End-to-End Interoperability of Health Data/Records - Validation Framework to ensure Affirmative Trust Decision		Basic Use Case - Data/Record Flow - Point of Collection/Origin to each Ultimate Point of Access/Use			
Initially...		In Real-Time...			
ONC Interoperability Roadmap (2015)		Collect	Share		Use
		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	• Design, Specify, Agree by Consensus • Certify HIT System Functionality • Deploy, Operationalize, Validate	1) Access source EHR/HIT system/databases 2) Original source Record Entry	1) Transmit unaltered copy of source record content 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	1) Access EHR/HIT system/databases 2) Access unaltered copy of source record content 3) Access copy of Receiver Record Entry content 4) If TRUSTED Use content for intended purpose
	• Define Actions/Observations • Define Record Entry content documenting Actions/Observations • EHRs and PHRs as Record Entry instance documents • Action Taken (by one or more parties) to support individual health (provide healthcare.)	3) Retain Source Record Entry		4) Retain Receiver Record Entry	
	EXAMPLE: Based on HL7 v2 Health Interoperable Resource (FHIR) EHR-S Record Lifecycle Implementation Guide (FHIR DSTU-2 2015) • Examples might include HL7 v2 messages or CDA/CDDA documents	• Define FHIR Resources documenting Actions/Observations, including AuditEvent and Provenance • FHIR Resource Implementation Typical Team >>> • Action-related resource(s) • AuditEvent resource • Provenance resource for Source Record Entry	[Where FHIR resources are implemented natively in source record entries.] [Where FHIR resources are implemented as exchange artifacts or as system APIs.]		[Where FHIR resources are implemented natively in receiver record entries.] [Where FHIR resources are implemented as exchange artifacts or as system APIs.]
			Action-related resource(s) • AuditEvent resource • Action-related resource(s) • AuditEvent resource		Action-related resource(s) • AuditEvent resource • Provenance resource for Receiver Record Entry
Drivers		Continuously, Maintain/Ensure environment			
A. Supportive Payment and Regulatory Environment		Continuously, Maintain/Ensure environment			
Policy and Technical Components		Continuously, Maintain/Ensure decision making, rules of engagement and accountability			
B. Shared Decision-Making, Rules of Engagement and Accountability		At startup, Identify/Authenticate networks, nodes and systems Continuously, Maintain/Ensure authenticated networks, nodes and systems			
C. Ubiquitous, Secure Network Infrastructure		At startup, Identify/Authenticate all participants in Action Taken and health data record collection Continuously, Maintain/Ensure consistent representation of authorization to access electronic health information			
D. Verifiable Identity and Authentication of All Participants		In real-time, Verify authorization to share - send and receive In real-time, Verify authorization to use			
E. Consistent Representation of Authorization to Access Electronic Health Information		Continuously, Maintain/Ensure consistent representation of permission to collect, share and use identifiable electronic health information			
F. Consistent Understanding and Technical Representation of Permission to Collect, Share and Use Identifiable Electronic Health Information		In real-time, Verify specific permission to collect and receive In real-time, Verify specific permission to share - send and receive Continuously, Maintain/Ensure industry-wide testing and certification infrastructure			
G. An 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 Continuously, Maintain/Ensure consistent data semantics			
H. Consistent Data Semantics		In real-time, Capture/Collect health data/records w/inconsistent semantics Continuously, Maintain/Ensure consistent data formats			
I. Consistent Data Formats		In real-time, Share (send and receive) health data/records w/inconsistent data formats In real-time, Access/Use health data/records w/inconsistent data formats			
J. Secure, Standard Services		Continuously, Maintain/Ensure secure, standard services			
K. Consistent, Secure Transport Techniques		Continuously, Maintain/Ensure secure transport			
L. Accurate Individual Data Matching		Continuously, Maintain/Ensure methods for accurate individual data/record matching In real-time, Share (send and receive) health data/records with verifiably accurate individual data matching			
M. 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/CDDA 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			
ONC Interoperability Roadmap, Final Version 1.0 ISO/HL7 10781 Electronic Health Record System (EHR-S) Functional Model, Release 2 HL7 Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Implementation Guide (FHIR DSTU-2) Validation Matrix developed by: Gary Dickinson, Director, Healthcare Standards, CentilHealth, DRAFT 8 November 2015		https://www.health.gov/policy-researchers-implementers-interoperability https://www.hl7.org/implement/standards/implement_interoperability https://www.hl7.org/implement/standards/implement_interoperability https://www.hl7.org/implement/standards/implement_interoperability			

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

End-to-End Interoperability of Health Data/Records - Validation Framework to ensure Affirmative Trust Decision		Basic Use Case - Data/Record Flow - Point of Collection/Origin to each Ultimate Point of Access/Use			
Initially...		In Real-Time...			
ONC Interoperability Roadmap (2015)		Collect	Share		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		1) Access source EHR/HL7 system/databases 2) Original source Record Entry 3) Retain Source Record Entry	1) Transmit untranslated copy of source record content 2) Transform/Translate source record content into exchange artifact 3) Transmit exchange artifact	1) Receive untranslated copy of source record content 2) Receive exchange artifact 3) Transform/Translate into Receiver Record Entry 4) Retain Receiver Record Entry	1) Access EHR/HL7 system/databases 2) Access untranslated 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 Action/Observations, including Audit/Event and Provenance FHIR Resource Implementation Typical pattern >>> • Action-related resource(s) • Audit/Event resource • Provenance resource for Record Entry	[Where FHIR resources are implemented natively in source record entries.] Action-related resource(s) Audit/Event resource Provenance resource for Exchange Artifact		[Where FHIR resources are implemented natively in receiver record entries.] Action-related resource(s) Audit/Event resource Provenance resource for Receiver Record Entry
Drivers					
A. Supportive Payment and Regulatory Environment		• Develop, design, support, implement and regulate...	• Continuously, Maintain/Ensure environment...		
Policy and Technical Components					
B. Shared Decision-Making, Engagement and Accountability		• Design, specify decision-making, rules of engagement and accountability	• Continuously, Maintain/Ensure decision making, rules of engagement and accountability		
C. Interoperable, Secure Network Infrastructure		• Design, specify ubiquitous, secure network infrastructure	• At scale, Identify/Authenticate networks, nodes and systems • Continuously, Maintain/Ensure authenticated network nodes and systems		
D. Verifiable Identity and Authentication of All Participants		• Design, specify infrastructure to identify and authenticate 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, recipient and encoders	• 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 share - send and receive	• In real-time, Verify authorization to use
F. Consistent Understanding of Technical Representation of Permission to Collect, Share and Use Available 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 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 use of health data/record content
H. Consistent Data Semantics		• Design, specify consistent data semantics	• Continuously, Maintain/Ensure consistent data semantics	• In real-time, Share (send and receive) health data/records w/inconsistent semantics	• In real-time, Access/Use health data/records w/inconsistent 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/inconsistent data formats	• In real-time, Access/Use health data/records w/inconsistent data formats
J. Secure, Standard Services		• Design, specify secure standard services	• Continuously, Maintain/Ensure secure, standard services	• In real-time, Share (send and receive) data/records	• In real-time, Access/Use data/records
K. Consistent, Secure Transport Techniques		• Design, specify consistent, secure transport techniques	• Continuously, Maintain/Ensure secure transport	• In real-time, Capture/Collect health data/records with verifiably accurate individual data matching	• In real-time, Access/Use health data/records with verifiably accurate individual data matching
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, 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					
ONC Interoperability Roadmap, Final Version 1.0 ISO/HL7 10781 Electronic Health Record System (EHR-S) Functional Model, Release 2 HL7 Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Event Implementation Guide (FHIR DSTU-2) Validation Matrix developed by: Gary Dickinson, Director, Healthcare Standards, CentilHealth, DRAFT November 2015		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 untranslated content; yellow = exchange transformed content TRUST DECISION - Determination of Fitness for Purpose of Use: Primary Use: clinical care interventions, decision making Secondary Use: most everything else https://www.healthit.gov/policy-researchers-implementers-interoperability https://www.hl7.org/implement/standards/implement_interoperability https://hl7.org/standards/implementers http://www.dickinsons.com			

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

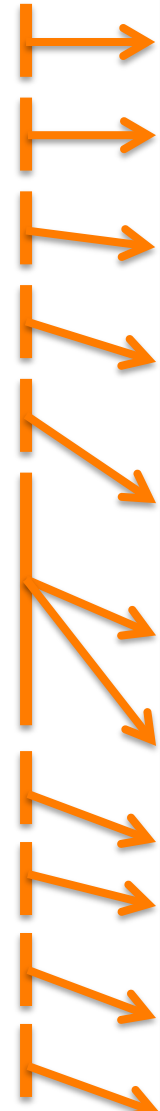
End-to-End Interoperability of Health Data/Records - Validation Framework to ensure Affirmative Trust Decision		Basic Use Case - Data/Record Flow - Point of Collection/Origin to each Ultimate Point of Access/Use			
Initially... (Establish)		Collect	In Real-Time... (Share)		Use
ONC Interoperability Roadmap (2015)	• Design, specify, agree by consensus • Certify, Agree on Functionality • Deploy, Collect, Analyze, Validate	Typically, e.g., • Agree on Functionality • Agree on Data • Agree on Data	Send	Receive	Decision (Fit for Use)
Key Standards for Trusted Health Data/Record Management	1) Agree on Action/Observation(s) in the Record Entry content documenting Action/Observation(s) 2) Agree on Source EHR/HIT system/datastore (EHR/S and PRRS are completed or more Action Taken or more Action/Observation(s) in the Record Entry to provide health care to provide health care.) 3) Retain Source Record Entry	1) Access/Use/Share EHR/HIT system/datastore 2) Aggregate source Record Entry 3) Retain Source Record Entry	1) Transform/unaltered copy of source record content 2) Transform/Translate source record content into exchange artifact 3) Transform exchange artifact into receiver Record Entry 4) Retain Receiver Record Entry	1) Receive unaltered copy of source record content 2) Receive exchange artifact of source record content 3) Receive exchange artifact of source record content 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
EXAMPLE: Basic HL7 FHIR Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Implementation Guide (see FHIR DSTU-2 2015) • Other use cases include HL7 v2 messages, CDAR/CCDA documents	• Define FHIR Resource(s) documenting Action/Observation(s) 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	[Where FHIR resources are implemented natively in receiver record entries.] Action-related resource(s) • AuditEvent resource • Provenance resource for Receiver Record Entry	[Where FHIR resources are implemented natively in receiver record entries.] Action-related resource(s) • AuditEvent resource • Provenance resource for Receiver Record Entry
A. Supportive Payment and Regulatory Environment	• Develop, design supportive payment and regulatory environment	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure environment		
B. Shared Decision-Making, Rules of Engagement and Accountability	• Design, specify decision-making rules of engagement and accountability	Continuously, Maintain/Ensure	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	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	Continuously, Maintain/Ensure	In real-time, Identify/Authenticate	In real-time, Identify/Authenticate
E. Consistent Representation of Authorization to Access Electronic Health Information	• Design, specify consistent representation of authorization to access electronic health information	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure
F. Consistent Understanding of Technical Representation of Permission to Collect, Share and Use Electronic Health Information	• Design, specify consistent technical representation of permission to collect, share and use identifiable electronic health information	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure
G. In-Industry Testing and Certification Infrastructure	• Design, specify industry-wide testing and certification infrastructure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure
H. Consistent Data Semantics	• Design, specify consistent data semantics	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure
I. Consistent Data Formats	• Design, specify consistent data formats	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure
J. Secure, Standard Services	• Design, specify secure standard services	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure
K. Consistent, Secure Transport Techniques	• Design, specify consistent, secure transport techniques	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure
L. Accurate Individual Data Matching	• Design, specify methods for accurate individual data matching	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure
M. Health Care Directories and Resource Location	• Design, specify infrastructure for health care directories and resource location	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure	Continuously, Maintain/Ensure
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, CDAR/CCDA document or FHIR resource					
Background: blue = ONC Interoperability Roadmap targets; green = affirmative trust decision; light green = exchange unaltered content; yellow = exchange transformed content					
ONC Interoperability Roadmap, Final Version 1.0					
ISO/HL7 10781 Electronic Health Record System (EHR-S) Functional Model, Release 2					
HL7 Fast Health Interoperable Resources (FHIR) EHR-S Record Lifecycle Implementation Guide (FHIR DSTU-2)					
Validation Matrix developed by: Gary Dickinson, Director, Healthcare Standards, CentilHealth, DRAFT 8 November 2015					

- 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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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



A vertical dashed line with orange arrows pointing from the assessment criteria on the left to the standards components on the right. The arrows indicate the following mappings: Network Infrastructure to C; Entity Identity, Authentication to D; Entity Authorization to E; Permissions, Consents to F; Testing and Certification to G; Information Models, Vocabularies, Data Types, Syntax, Formats, Exchange Artifacts to H, I, and J; Security to K; Transport to L; Individual Matching to L; and Directories, Resources to M.

Drivers	
A. A Supportive Payment and Regulatory Environment	
Policy and Technical Components	
B. Shared Decision-Making, Rules of Engagement and Accountability	
C. Ubiquitous, Secure Network Infrastructure	
D. Verifiable Identity and Authentication of All Participants	
E. Consistent Representation of Authorization to Access Electronic Health Information	
F. Consistent Understanding and Technical Representation of Permission to Collect, Share and Use Identifiable Electronic Health Information	
G. An Industry-wide Testing and Certification Infrastructure	
H. Consistent Data Semantics	
I. Consistent Data Formats	
J. Secure, Standard Services	
K. Consistent, Secure Transport Techniques	
L. Accurate Individual Data Matching	
M. Health Care Directories and Resource Location	

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