

Truth and Trust
Fitness for Use (Purpose)

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Start with the...

Fundamentals

- Ensuring
 - Patient Safety
 - Integrity of Clinical Process
- Fitness for Purpose/Use
 - Primary Use = clinical care, interventions, decision making
 - Secondary Use = most everything else
- Reference IEEE exchange/use “interoperability” definition
 - (Despite key missing elements)

Of-Cited (by ONC)...

IEEE “Interoperability” Definition

IEEE 1990	IEEE 2014	Type of Interoperability
Exchange	Exchange	Technical
Use	Use	Semantic
	→ Without user intervention	Plug and Play

- According to IEEE, achievement of interoperability is successful **exchange then use** of health data/records, **without user intervention**.
- Implied: **for the intended purpose of use** (primary or secondary)

Primary and Secondary Use

Fitness for Use/Purpose

Use	Purpose	Clinical Health Record Content Exchange		Post Exchange Fit for Use?
		Source	Receiver	
Primary	Clinical Care, Interventions and Decision Making	Without Transformation (maintains/ensures fidelity to source)		YES
		With Transformation(s)		Often NO
Secondary	Most Everything Else	With Transformation(s)		Typically YES

For Primary Use

Source of Truth

The **source of truth** for all primary use – clinical care, interventions and decision making – **is unaltered source health data/record content.**

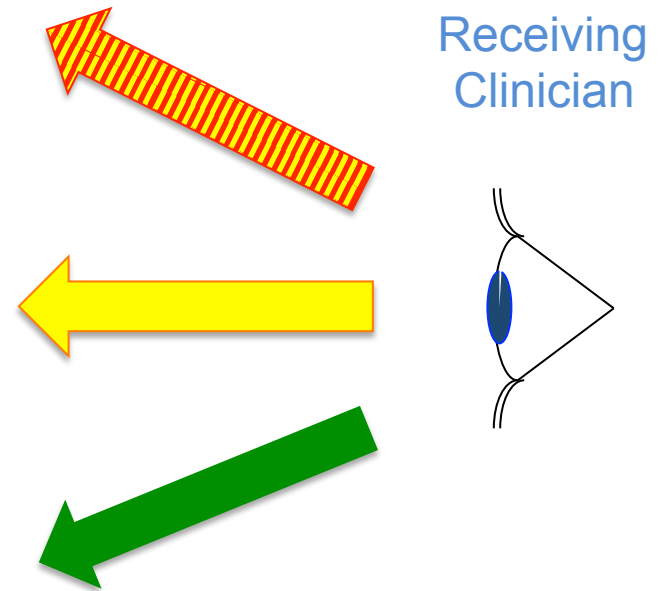
- The receiving **clinician will first and always trust** (rely on) this **direct evidence** of clinical facts, findings and observations.

Data integrity (including fidelity to source) **is fundamental** to all aspects of clinical integrity and patient safety.

Truth and Trust

Receiving Clinician View

Transforms	Primary Use – Clinician View
1, 2, 3, 4...	<div style="text-align: right; border: 1px solid black; padding: 2px;">1 2 3 4</div> Blind Transforms View Last (Sum) Result Use with Extreme Caution!
	<div style="text-align: right; border: 1px solid black; padding: 2px;">1 2 3 4</div> Visible Transforms View each Result Be Aware!
0	View Unaltered Source Health Record Content Be Assured!



Measuring Interoperability

- So how do we measure the achievement of interoperability?
 - In terms of fitness for Primary Use? Secondary Use?
 - When viewed at each ultimate (downstream) point of health data/record access/use?
- With achievement based on:
 - Truth = authentic, factual
 - Trust = assurance, certainty, reliance
- Evidence of Truth (at each ultimate point of access/use), is key Trust determinant.

At Each Ultimate Point of Access/Use...

Evidence of Truth (Authenticity)

- Identity verification
 - Patient, Provider (individual and organization)
- Evidence of content source/authorship
 - Provenance: who, what, when, where, why
 - System/Device Signature, bound to content
 - Author's Signature, if any, bound to content
- Evidence of indelibility, non-alteration of content
- Evidence of update or amendment, if any
 - Showing original content and each subsequent amendment

At Each Ultimate Point of Access/Use...

Evidence of Truth (Authenticity)

- Chain of Trust
 - Showing traversal from point of origination to point of access/use
 - Showing transformation of content: typically pre/post points of exchange – to/from “standard” exchange artifact
 - e.g., to/from HL7 v2 message or CCDA document
 - Carrying “source of truth” (original) content alongside transformed content

At Each Ultimate Point of Access/Use...

Determinants of Trust (Assurance)

- Trust (assurance) is based on what is believed (believable, reliable, certain)
- Trust is traceable to a “source of truth”, in this case: unaltered, original source health data/record content
- Trust is based on, and manifest in, evidence presented
 - Per Evidence of Truth (previous 2 slides)

Trust is based on

Evidence of Truth

Truth	as evidence for	Trust
Identity is verified	→→→	<p>Is:</p> <ul style="list-style-type: none">• Belief (believability)• Certainty• Reliance• Traceable to a “source of truth”• Based on – and manifest in – evidence presented
Source, origination and provenance is known		
Signature is present		
Content is un-altered		
Update(s) to original content are known		
Chain of Trust is evident		
• From origination to use		
• Showing transformation(s)		
• Carrying original “Source of Truth”		

	Truth → → Chain of Trust → → Trust										
	Source EHR System					→	Receiving System				
	At Point of Health Data/Record...										
Test and Verify	Capture, Origination (Source of Truth)	Retention	Attestation, apply/bind signature, to content	Transformation to Exchange Artifact	Transmit Exchange Artifact, including original	Exchange	Receipt of Exchange Artifact	Transformation from Exchange Artifact	Retention	User Access/View (Trust Decision)	
Certify Source Role	<<EHR System A>>										
Certify Receiver Role						<<EHR System A>>					
Certify System A → B	<<EHR System A>>					→	<<EHR System B>>				
Implement A → B	<<EHR System A>>					→	<<System B>>				
Production A → B	<<EHR System A>>					→	<<System B>>				
Ensuring	Original Content → → → → → → →										



Building the Chain of Trust

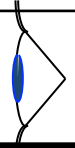
Point of Health Data/Record...		Original Content
Capture, Origination • Source of Truth • Anchor Point for Chain of Trust	Identities are established: <ul style="list-style-type: none"> • Patient: subject of care • Provider: organization and/or individual • Author of data/record content Provenance is captured: <ul style="list-style-type: none"> • Who, what, when, where, why Clinical Context is captured	Is captured
Retention	Of Source Record Entry	Is retained
Attestation	<ul style="list-style-type: none"> • Application of Signature • Bound to data/record content 	Is attested/ signed
Transformation	From Source Record Entry to Exchange Artifact • e.g., HL7 v2 message or CCDA document	Is carried
Transmission	Of Exchange Artifact	Is carried

Receiving System

Building the Chain of Trust

Point of Health Data/Record...		Original Content
Receipt	Of Exchange Artifact	Is carried
Transformation	From Exchange Artifact to Receiver Record Entry	Is carried
Retention	Of Receiver Record Entry	Is retained
Access, view • Trust Decision	By Provider	Is accessible, viewable

Chain of Trust –
Current MU 1/2
Testing and
Certification
Program

	Truth → → Chain of Trust → → Trust										
	Source EHR System					→	Receiving System				
	At Point of Health Data/Record...										
	Capture, Origination (Source of Truth)	Retention	Attestation, apply/bind signature, to content	Transformation to Exchange Artifact	Transmit Exchange Artifact, including original	Exchange	Receipt of Exchange Artifact	Transformation from Exchange Artifact	Retention	User Access/View (Trust Decision)	
Certify Source Role	?	?	No	Yes	No						
Certify Receiver Role							No	No	No	No	
Certify System A → B	No	No	No	No	No	→	No	No	No	No	
Ensuring Chain of Trust A → B	Original Content → → → → → → → 										

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Reference Slides Follow...

Alterations, Errors and Omissions

Wither Transformation?

Transformation during Exchange... | typically Alters... | and may INTRODUCE Errors and Omissions in... | [Clinical Health Record Content](#)

Types of Transformation

- One Code Set to Alternate Code Set (e.g., HL7, ICD, LOINC, SNOMED)
- One Value Set to Alternate Value Set
- One Human Language to Another Human Language
- One to many, many to many, many to one

Alterations, Errors and Omissions

Transformation Disjunctions

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

Alterations, Errors and Omissions

Interoperation or Mis-Operation?

For primary clinical use, any transformation of source clinical content in the course of exchange introduces – or makes it susceptible to – errors and omissions in:

- Clinical facts, findings and observations
- Clinical content, context and meaning

Instead of promoting/achieving...	We see...
<ul style="list-style-type: none">• Interoperation – Interoperability	<ul style="list-style-type: none">• Mis-operation – Dis-operability
<ul style="list-style-type: none">• Exchange and <u>Use</u>	<ul style="list-style-type: none">• Exchange and reject• Exchange and use w/extreme caution
<ul style="list-style-type: none">• Fidelity to Source – Immutability	<ul style="list-style-type: none">• Focus on point-to-point mapping and data transformation <u>not</u> end-to-end fidelity, data integrity, clinical efficacy and most importantly, patient safety