Comments on: Proposed Interoperability Standards Measurement Framework

Source: US Department of Health and Human Services
Office of National Coordinator for Health Information Technology

Date: 31 July 2017

Submitted by: Gary Dickinson
Director, Healthcare Standards, CentriHealth
Co-Chair, Health Level Seven (HL7) Electronic Health Record (EHR) Work Group
Co-Facilitator, HL7 EHR Interoperability Work Group

Thank you for the opportunity to comment on the proposed ONC "Interoperability Standards Measurement Framework". We believe it is crucial to focus on measurement of interoperability standards in actual use, the resulting achievement of true and useful interoperability as evident in health data/record integrity and fitness for use.

Evaluating interoperability is much more than counting transaction volumes (quantitative assessment) and ultimately must include the full measure of success (complete qualitative assessment).

Interoperability should result in a continuous and consistent yield of gold nuggets from an avalanche of often unrelated and irrelevant exchanged health data/record fragments. The true "gold nuggets" – as the result of interoperability – must:

- be readily accessed and discoverable,
- show provenance from their source,
- bear evidence of truth,
- be shown in full context without loss of meaning,
- be fully relevant (to the condition/task at hand), and
- be immediately actionable.

See parallel comments submitted on 30 June 2017 regarding the "National Quality Forum – DRAFT Measurement Framework to Assess Nationwide Progress related to Interoperable Health Information Exchange to support the National Quality Strategy" (attached).

[Submitted electronically.]

Questions posed:

1a) Is a voluntary, industry-based measure reporting system the best means to implement this framework?

Yes, if such reporting system is based on:
• First-hand experience and objective assessment, not anecdotal evidence, speculation or subjective opinion.
• Broad and balanced industry input: patients, providers, payers, public health, accreditation surveys...

1b) What barriers might exist to a voluntary, industry-based measure reporting system?

Barriers include:
• The notion that periodic subjective surveys are sufficient means to measure anything useful.
• The current intransigency that the collection of so-called "interoperability standards" offer a proper path toward achieving anything close to true interoperability – in fact interoperability that properly supports primary use (clinical care, interventions and decision making).
• Widespread ignorance that the current scheme of health data/record exchange (so-called interoperability) is not itself malpractice, creating data integrity faults and posing enormous ongoing risks to clinical practice and MOST IMPORTANTLY TO PATIENT SAFETY.

1c) What mechanisms or approaches could be considered to maximize this system's value to stakeholders?

Value to stakeholders will be maximized through introduction of substantive qualitative measures to ensure data integrity and fitness for use. This includes interoperability measures which include assurance of: attestation/attribution, non-alteration of content, context, provenance, meaning. See also response to Question 2 (following).

2) What other alternative mechanisms to reporting on the measurement framework should be considered (for example, ONC partnering with industry on an annual survey)?

Imbedded software that captures the details of what happens to health data/records end-to-end in the path from point of origination (source) to each point of access/use. This should be facilitated by software creating real-time audit log entries at each data/record lifecycle event (e.g., origination/retention, update/amendment, attestation, transmittal, receipt/retention, access/use). See record lifecycle events as specified in ISO/HL7 10781 EHR System Functional Model Release 2 (2015) and ISO 21089 Trusted End-to-End Information Flow (approved and at publication stage 2017). [ONC has been forwarded current copies of these Standards with permission of the ISO TC215 Secretariat.]

See also NQF Report Comments 2, 3, 12, 13, 14 and 15 (attached).

3) Does the proposed measurement framework include the correct set of objectives, goals, and measurement areas to inform progress on whether the technical requirements are in place to support interoperability?

Absolutely not. See response to Question 2 above.

4) What, if any gaps, [SIC] exist in the proposed measurement framework?

See responses to Questions 1 and 2 above.

5) Are the appropriate stakeholders identified who can support collection of needed data? If not, who should be added?

All stakeholders who are creators/authors of health data/record content and all stakeholders who use that content for primary or secondary purposes should be included. See NQF Report Comments 6 and 11.

6a) Would health IT developers, exchange networks, or other organizations who are data holders be able to monitor the implementation and use of measures outlined in the report?

Only if they are actual health data/record users who can (have the ability to) compare what was originally captured vs. what was presented for use, is fit for use and then actually used (e.g., in primary use: clinical care, interventions and decision making). See NQF Report Comments 2, 3, 4, 6, 13, 14, 15.

6b) If not, what challenges might they face in developing and reporting on these measures?

Per our response to Question 6a, they have no basis to assess or measure the state of interoperability. Was it achieved or not?

7a) Ideally, the implementation and use of interoperability standards could be reported on an annual basis in order to inform the Interoperability Standards Advisory (ISA), which publishes a reference edition annually. Is reporting on the implementation and/or use of interoperability standards on an annual basis feasible? If not, what potential challenges exist to reporting annually? What would be a more viable frequency of measurement given these considerations?

While it may be feasible, it is more likely useful if the emphasis is on qualitative rather than on quantitative measurement of interoperability achievement. Enumerating transaction volumes without measuring real fitness for use (of exchanged health data/record content) is of little value, interest or impact, whether done annually or at some other frequency.

8) Given that it will likely not be possible to apply the measurement framework to all available standards, what processes should be put in place to determine the standards that should be monitored?

The process should focus on standards which have the most immediate and consequential (positive or negative) impact on primary use (clinical care, interventions and decision making). This includes assurance of end-to-end data integrity to support clinical (process) integrity and most importantly, PATIENT SAFETY.

9) How should ONC work with data holders to collaborate on the measures and address such questions as: How will standards be selected for measurement? How will measures be specified so that there is a common definition used by all data holders for consistent reporting?

Data holders? Instead ONC should work with creators/authors of health data/record content and all stakeholders who use that content for primary purposes. Primary use comes first and must be of primary consideration and thus secondary use (e.g., reporting measures) must be a secondary consideration.

10) What measures should be used to track the level of "conformance" with or customization of standards after implementation in the field?

Per our response to Question 2, all measures must be traceable to health data/record lifecycle events and related conformance requirements as specified in ISO/HL7 10781 EHR System Functional Model Release 2 (2015), Record Infrastructure Section and ISO 21089 Trusted End-to-End Information Flows (approved and at publication stage, 2017).

Comments on: National Quality Forum – DRAFT Measurement Framework to Assess Nationwide Progress related to Interoperable Health Information Exchange to support the National Quality Strategy

Date: 30 June 2017

Submitted by: Gary Dickinson
Director, Healthcare Standards, CentriHealth
Co-Chair, Health Level Seven (HL7) Electronic Health Record (EHR) Work Group
Co-Facilitator, HL7 EHR Interoperability Work Group

Thank you for the opportunity to comment on the NQF DRAFT Report. We believe it is vital to focus on assessment of interoperability and interoperation. This is an often ignored topic that should ultimately serve to validate the billions of taxpayer $$$s expended to achieve the objective of EHR adoption and ubiquitous interoperability/interoperation of EHR/HIT systems and health data/records.

Interoperability does not just facilitate one way (single direction) exchange, but rather the ability for software interoperation – two or more ways – across two or more EHR/HIT systems.

Evaluating interoperability is much more than counting transaction volumes (quantitative assessment) but rather it's about attaining the maximum measure of success (full qualitative assessment). Ultimately, this means continuously and consistently yielding gold nuggets from an avalanche of often irrelevant exchanged data fragments. The true "gold nuggets" in health data/records must (as the result of interoperability):

- be readily accessed and discoverable,
- show provenance from their source,
- bear evidence of truth,
- be shown in full context without loss of meaning,
- be fully relevant (to the condition/task at hand), and
- be immediately actionable.

This is where interoperability and interoperation come to full fruition.

Our comments consist of these sections:

[Submitted electronically.]

1. Interoperability and Interoperation

Interoperability is the term used yet *interoperability* in context of the NQF DRAFT Report seems to involve one-way transmission of health data/records (source → receiver), as identified by the focus on exchange/use. EHR/HIT systems that are interoperable should in fact be capable of *interoperation* as a two-way engagement of software functionality (source ←→ receiver). Consider:

Interoperability/interoperation is engaged...		
Collect (at source of truth)	**Share**	**Use** (if fit and trusted)
Human, System/Device, Enterprise 1	One Way → ← Both Ways →	Human, System/Device, Enterprise 2,3,4...
Human (User) 1	Transmitting to → ← Interacting with →	Human (User) 2,3,4...
System/Device 1	Transmitting to → ← Interoperating with →	System/Device 2,3,4...
Enterprise 1		Enterprise 2,3,4...

From our perspective, it is precisely the focus on interoperability in the narrow context of point to point "exchange and use" that has caused/resulted in our current failure to achieve broad-based interoperability or in fact, interoperation of HIT/EHR systems. We address this further in comments following.

The NQF Report must address both interoperability and interoperation beyond the single dimension of point to point exchange (one source to one receiver).

2. Essential Characteristics/Properties/Qualities of Interoperability/Interoperation

What are key characteristics, properties and qualities of health data/records that demonstrate (achievement of) interoperability to the end user? Consider what we we've learned from our experience with information integration and interoperability within the domain of a healthcare enterprise. Of course, the enterprise domain is typically well-bounded, diligently protected and carefully curated with tight coupling of EHR/HIT systems, devices and software. See following table for key properties/qualities of interoperability/interoperation...

Key characteristics of interoperable health data/records and interoperation of EHR/HIT systems/devices/software...		Properties/Qualities Evident to End User
A	Known and verified (verifiable) as to identity: • Subject: patient • Provider: individual and organization • Systems, devices and software	Identified, Attributed
B	Captured, consolidated from multiple sources	Unified, Integrated
C	Oriented to support real-time care delivery	Timely, Ready
D	Oriented to what has happened (past), what is now in progress (present), what is anticipated (future)	Chronological, Longitudinal
E	Oriented to actions taken: who did what when, where & why	Accountable, Transparent
F	Captured with action facts, findings and observations	Explicit, Specific, Detailed
G	Tuned for consistency: e.g., data types, common units of measure, common codes and value sets	Uniform, Congruent
H	Tied to the "source of truth", showing source, origination and provenance at point of data/record origination and thereafter	Factual, Authentic, Traceable

Key characteristics of interoperable health data/records and interoperation of EHR/HIT systems/devices/software...		Properties/Qualities Evident to End User
I	With known context: clinical, administrative, operational	Context, Condition(s), Factor(s), Circumstance(s)
J	Bound to author, author's signature (when appropriate)	Authorship, Attestation
K	Known to be unaltered since collection/origination	Immutable, Enduring
L	Known to be complete – or known to have missing elements	Whole or Partial
M	Known to be original – or known to be updated from original instance	Original, Revised with Progression
N	Associated with like information	Correlated, Comparable

As noted in the right-most column, the described properties/qualities are to ensure:

- **Evidence of truth (authenticity)**; as the
- **Basis of trust (assurance)**;
- **For all end use(s) and to all end user(s)**.

Each of the identified characteristics/properties/qualities of interoperable health data/records is vital and should stand as a key finding of the NQF Report.

3. Extending Properties/Qualifiers to Show Evidence of Interoperability/Interoperation

Let's now extend these same properties/qualifiers and apply them to interoperability assessment:

Key Characteristics (from above)		In the Exchange Artifact...	To Receiver/ End User...
A	Known and verified (verifiable) as to identity: • Subject: patient • Provider: individual and organization • Systems, devices and software	Is identity fully conveyed?	Is it manifest?
B	Captured, consolidated from multiple sources within the enterprise	Is it fully conveyed?	Is it manifest?
C	Oriented to support real-time care delivery	Is it fully conveyed?	Is it manifest?
D	Oriented to what has happened (past), what is now in progress (present), what is anticipated (future)	Is chronology fully conveyed?	Is it manifest?
E	Oriented to actions taken: who did what when, where and why	Are actions and accountabilities fully conveyed?	Is it manifest?
F	Captured with action facts, findings and observations	Are action facts, findings and observations fully conveyed?	Is it manifest?
G	Tuned for consistency: e.g., data types, common units of measure, common codes and value sets	Are consistency characteristics fully conveyed?	Is it manifest?
H	Tied to the "source of truth", showing source, origination and provenance at point of data/record origination and thereafter	Is the "source of truth" fully conveyed?	Is it manifest?
I	With known context: clinical, administrative, operational	Is context fully conveyed?	Is it manifest?
J	Bound to author, author's signature (when appropriate)	Is authorship and content binding fully conveyed?	Is it manifest?
K	Known to be unaltered since collection/origination	Is unaltered source content fully conveyed?	Is it manifest?
L	Known to be complete – or known to have missing elements	Is complete/incomplete status fully conveyed?	Is it manifest?
M	Known to be original – or known to be updated from original instance	Are original content and successive updates fully conveyed?	Is it manifest?
N	Associated with like information	Are associations fully conveyed?	Is it manifest?

In our opinion, there is nothing more important for interoperability assessment than rigorous measurement of the key properties/qualities identified above, both in terms of full conveyance in the exchange artifact but also as manifest to the receiver/end user. We recommend supplementing the proposed assessments described in NQF DRAFT Report Appendix A (List of Measure Concepts) to add qualitative measures to the (mostly) quantitative measures currently described.

4. Basic Interoperability Assessment 1 – Comparison Across Point(s) of Exchange

One basic form of interoperability assessment follows the pattern of collect, share and use.

Interoperability Assessment measures (at minimum)...		
Collect (at source of truth)	**Share**	**Use** (if fit and trusted)
Input – Health data/records as collected (originated/retained)	= (identical) or ≠ (not)	Output – Health data/records as received, integrated and ready for use
What originated (began as)		What transpired (resulted in)
What the human (author) sees		What the human (user) sees
↑	**Assessment – Measures Results of Comparison**	↑

The NQF Report will not be considered complete unless it clearly focuses on the pattern of collect, share and use, and therefore offers a plan for assessment by comparison of health data/records at the point of collection/origination to those ultimately intended for use, after being shared/exchanged.

5. Basic Interoperability Assessment 2 – Comparison after Round-trip Exchange

A second form of interoperability assessment is based on a simple round-trip exchange of health data/records...

System A	Exchange	System B
1. Extracting from source health record entries, sends a clinical payload using any single or combination of exchange artifact(s)	→ → →	**2.** Instantiates payload in health record entries
4. Instantiates payload in a new set of health record entries	← ← ←	**3.** Extracting directly from those health record entries, sends the same clinical payload back using any single or combination of exchange artifact(s)
Assessment – Measures Results of Round Trip: Is there any loss of content, context, provenance, meaning or fidelity when comparing original System A record entries to System A record entries resulting from the round-trip (1 + 2 + 3 + 4)?		

Other Patterns:
1) Reverse Roles of Systems A & B
2) System A → System B → System C → System A

Exchange Artifact(s): e.g., HL7 or NCPDP messages, HL7 CDA/CCDA documents, HL7 FHIR resources

The NQF Report should also include the capability for interoperability assessment afforded by round-trip exchange of health data/record.

[Note that Assessment 2 was developed in collaboration with the Health Record Banking Alliance (HRBA) and members of the US Technical Advisory Group (TAG) to ISO TC215.]

6. Interoperability Assessment to Support "Fitness for Use" and Affirmative Trust Decision by the End User

Regarding Comments 2-4 above, it occurs that these properties/qualities are the same as those that demonstrate truth (traceable to the source of truth) and enable an affirmative trust decision by the end user. In other words, if these properties/qualities are evident the end user can readily determine whether the health data/records presented are in fact trustworthy and "fit for use" in terms of the intended purpose (whether primary or secondary use). Shouldn't interoperability assessment in fact be designed to ensure "fitness for use" and support the end user's affirmative trust decision?

This should be made explicit in the NQF Report.

NQF DRAFT Report, Introduction, Page 5, Paragraph 2: "The definition of interoperability with respect to health IT means health information technology that (1) enables secure exchange and use of electronic health information without special effort by the user; (2) allows for complete access, exchange, and use of all electronically accessible health information for authorized use..."

---

7. Interoperability Definition is Fundamental to Proper Interoperability Assessment

A key shortcoming of the NQF DRAFT Report is that it relies on a definition of interoperability usually attributed to IEEE. The IEEE definition started as "exchange/use" (in 1990), and was later updated to include "without user intervention" (in 2014). The IEEE definition was never scoped nor intended to describe interoperability of health data/records nor interoperation of EHR/HIT systems. A key deficiency of this definition is that it leaves out the **vital source of truth** (point of health data/record collection), to which everything downstream (or subsequent) – sending, receiving, finding, integrating, using – must be anchored.

<u>If you don't take into account the full lifespan and lifecycle of health data/records (collect, share and use) you have no basis to assess/measure interoperability because you have no source of truth or starting/anchor point (point of collection) upon which to compare any manifestation of health data/records downstream, whether at the point of exchange or ultimately at each point of use. Further you have no way to determine if the health data/records you wish to exchange and/or use are valid in the first place.</u>

The NQF Report, to offer more than a vanishing echo of the past, must encompass the full lifespan and lifecycle of health data/records, over time and across one or more exchange instances.

NQF DRAFT Report, Introduction, Page 5, Paragraph 2: "For two systems to be interoperable, they must be able to exchange data in an agreed-upon format according to a standard and subsequently present that data in a way that a user can understand."

8. Interoperability Assessment Should Focus Far Beyond "Fire and Forget"

"For two systems to be interoperable..." OK, as far as it goes, but we really need to be talking about more than one-way exchange of health data/records. As described in previous comments, interoperability is really about the interoperation of two or more systems with two-way or multi-way exchange amongst them. We have to consider more than single dimensional, point to point exchange. This is another reason that our efforts to achieve interoperability (using this approach) are at best little more than traditional "fire and forget" anachronisms, struggling to get beyond 1970s-era serial asynchronous (often RS-232-based) exchange schemes.

NQF DRAFT Report, Introduction, Page 6, Paragraph 1: "NQF convened an expert, multistakeholder Interoperability Committee to provide input and help guide the creation of a framework. Throughout this project, NQF solicited input from a multistakeholder audience, including NQF membership and public stakeholders."

9. Interoperability Assessment Requires a Vision of the Future

From the content of the NQF DRAFT Report, there is offered vanishingly little basis to believe that these convened "expert" stakeholders, however astute, collectively share a vision of the necessary future state of interoperability, indeed trusted interoperation, of multiple systems leveraging a common consistent set of health data/records.

NQF DRAFT Report, Introduction, Page 6, Paragraph 2: "Since many of these articles focus on technical aspects of interoperability rather than the potential impact of interoperability, NQF did an expanded review that included papers that focus on the use, effectiveness, or outcomes of health information exchange (HIE). The environmental scan used the ONC Roadmap as a guide to understanding the key components of interoperability including: (1) infrastructure and services needed to effectively support the capability to exchange information; (2) the flow of information from and between systems and its usage among providers, patients, and payers; and (3) how that information would have a measurable impact on the development of a learning healthcare system."

10. Interoperability Assessment without an Actual Source of Truth?

Given that the NQF DRAFT Report fails to start at (or even consider) the source of truth – the point of health data/record collection/origination – it occurs that this Report offers little substance beyond a rehash of what is known (and well-proven) to have failed thus far (in our pursuit of interoperability/ interoperation of EHR/HIT systems).

11. Purpose of Use is Paramount to Interoperability Assessment

Critical to defining interoperability and the assessment thereof is to consider the purpose(s) of use. Are health data/records being conveyed for primary use (i.e., clinical care, interventions and decision making) or are they for secondary use (i.e., most everything else)? The **fundamental principle for primary use** is that successful interoperability ensures that source health data/records are collected, (retained), shared and used without alteration of content, context, provenance or meaning. While it's convenient to assume that two systems are "able to exchange data in an agreed-upon format according to a standard and subsequently present that data in a way that a user can understand and

use", there's absolutely no value in this assumption unless the **fundamental principle for primary use** is applied and can be demonstrated/validated in all cases.

The NQF DRAFT Report offers no recognition of unique interoperability requirements to support primary use, such as: attestation/attribution, non-alteration of content, context, provenance, meaning. This distinction is critical to any proposal for interoperability assessment and must be included.

12. Interoperability Assessment and Content Transformation in the Course of Exchange

As described in previous comments, achievement of interoperability/interoperation must ensure fitness for use (purpose) at each ultimate point of health data/record access/use. The following table shows the challenging paradigm of data/record exchange between heterogeneous systems and the risk to fitness (for use/purpose) posed by data transformations. Double transformations often occur during the course of exchange when health data/record content is transformed to/from exchange artifacts – once by the source/sending system and once again by the receiving system. Exchange artifacts include those required in US Meaningful Use and MACRA regulations, e.g., HL7 v2 messages, NCPDP messages, HL7 CDA/CCDA documents and now HL7 FHIR resources. Also see illustrative graphics at Appendices A and B.

<table>
<tr><th rowspan="2">Use</th><th rowspan="2">Purpose</th><th colspan="3">Health Record Content Exchange</th><th rowspan="2">Post Exchange
Fit for Use/Purpose?</th></tr>
<tr><td>Source</td><td>→ → →</td><td>Receiver</td></tr>
<tr><td rowspan="2">Primary</td><td rowspan="2">Clinical Care, Interventions and Decision Making</td><td colspan="3">Without Transformation
(maintains/ensures fidelity to source)</td><td>YES</td></tr>
<tr><td colspan="3">With Transformation(s)</td><td>Often NO</td></tr>
<tr><td>Secondary</td><td>Most Everything Else</td><td colspan="3">With Transformation(s)</td><td>Often YES</td></tr>
</table>

To be complete, the NQF Report must consider data transformation in the course of exchange and the resulting "fitness for use" (or not) as a key metric for interoperability assessment. Primary and secondary use are distinct and will have different thresholds of acceptance/acceptability.

13. Measuring Clinical Context, Chronology, Provenance, Consistency, Useful Classification and Comparability

Under Meaningful Use (2011, 2014 and 2015 Editions), we've well demonstrated that a health data/record exchange scheme of standards-based messages and documents across multiple disparate EHR/HIT systems often achieves something far short of integration, interoperability or interoperation. The required exchange artifacts are routinely created as odd assemblages of fragmented, disjoint data sets/elements lacking clinical context, chronology, provenance, consistency, useful classification and comparability. (For example, observe the typical real-time mash-up of CCDA-based patient summaries from multiple disparate sources inbound to a EHR system, subject to review and interpretation by an (often-overwhelmed) clinical user.)

Given the ONC Interoperability Roadmap and the assessment strategy outlined in the NQF DRAFT Report, there is scant evidence that these thriving points of failure will soon be overcome, but at least measurement is likely to shine intense light on current shortcomings of the MU – and now MACRA/MIPS – exchange artifacts and methods.

The NQF should specifically focus on measuring clinical context, chronology, provenance, consistency, useful classification and comparability as key determinants in interoperability assessment.

14. Interoperability via Transformation and Fragmentation?

Substantial amounts of health data/record content are now collected (captured/originated) – at the point of service/point of care – and retained as source content in integrated provider EHR/HIT systems. This data is immediately available and seamlessly interoperable with a broad range of other information within that domain. The essential qualities of truth are established and the trust decision is most always affirmative. This is the case BEFORE exchange occurs.

We then take that same information and rend it from its integrated and interoperable habitat – slicing, dicing, fragmenting and transforming source health data/record content into the form and format required for the standards-based exchange artifact. Structured content becomes unstructured and vice-versa, data types are transformed, coded values are mapped (often incorrectly, or even if correctly, losing important context) into the classification conventions of various external code/value sets and vocabularies. Code and value set derived data is mapped one to many and many to one. Some source data attributes lack corresponding attributes in the exchange artifact and must be dropped. Some codes have no equivalent value and are not included. [See table at Appendix B.]

In patient summary oriented exchange artifacts, data relationships are often sundered. For example, clinical content, chronologies, correlations, trends and relationships between encounters, problems, assessments, clinical decisions, diagnoses, orders, medications, results, diagnostics, interventions, observations, therapies and care plans are lost or become unrecognizable.

And so far we've only described what happens on the source/sending side of exchange. On the receiving side, all of the above slicing, dicing, fragmentation and transformation occurs once again, as receiver health data/record are populated with content from the exchange artifacts.

It is a simple fact that transformations to/from exchange artifacts often create (introduce) alterations, omissions and errors in health data/record content. Data items that were integrated and seamlessly interoperable in the source system are no longer so. Data once fit for primary (clinical) use may now only be fit for secondary use (or maybe not). [See graphic at Appendix A.]

As an industry we've also demonstrated that in practice, standards-based exchange artifacts mostly yield to the lowest common denominator benchmark. This has proven sufficient to support some very limited health data/record secondary uses but not primary use (clinical care, interventions and decision-making).

Health data/record content fragmentation, transformation and loss of provenance and context are substantive barriers to interoperability and thus are crucial areas of focus to any serious attempt at interoperability assessment.

To be complete, the NQF Report should make this explicit and include corresponding measurement in the proposed interoperability assessment approach.

15. Chain of Trust

Ultimately metrics must be built into certified EHR/HIT systems that collect, share and allow access/use of health data/records. Software can account for actions, whether initiated by a human

user, rules engine or algorithm, following each progressive step in the chain of trust as health data/records are collected, then shared, then used. Below is an example, following health data/record flow from source to use (top to bottom):

	Health Data/Record Chain of Trust from Point of Collection to each ultimate Point of Use to Support the Affirmative Trust Decision for Primary Clinical Use					
	Flow	Point of Health Data/Record…	(For primary clinical use)	Audit Event	Provenance Event	Original Content
	Source System					

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

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

The Chain of Trust is shown as successive Events (3rd/4th columns) in health data/record management – starting at the point of origination (the "source of truth") – with AuditEvent (5th column) captured at each Event. With this metadata the Chain of Trust traces source health data/record content and its path to each ultimate end user/use. Data Provenance (DPROV) Events (6th column) capture related metadata at points when health data/record content is new or updated. Primary Use requires original data/record content to be evident at each ultimate point of data/record access use (7th column) and is a paramount success factor to achieving health data/record interoperability. The Chain of Trust provides evidence to support the Trust Decision by each ultimate end user.

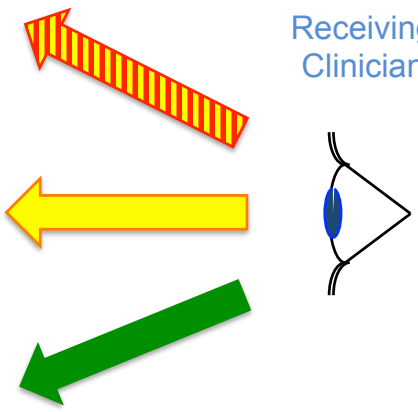
Chain of trust is essential to assessment of the success/achievement of interoperability. The NQF Report should make this explicit.

AuditEvent and Provenance are two HL7 Fast Health Interoperability Resources (FHIR), which are part of FHIR STU-3 (published in March 2017) and profiled together in the HL7 FHIR Record Lifecycle Event Implementation Guide, also part of FHIR STU-3.

In addition, the work of the Data Provenance (DPROV) Initiative under the ONC Standards and Interoperability (S&I) Framework offers a detail progression following the collect/share/use pattern. See the one page **DPROV System Event Matrix** as an example of patient summary exchange and included as an attachment to this response.

Appendix A – Trust and the End User Perspective

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



Appendix B – 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

608

609 ## Appendix A: List of Measure Concepts

610

Domain	Subdomain	Measure Concept	Estimated Timeframe
Exchange	Availability of Electronic Health Information	Were the clinical staff trained on accessing data?	Short-Term
Exchange	Availability of Electronic Health Information	Type of health information exchanged per month per patient and to what stakeholder	Short-Term
Exchange	Availability of Electronic Health Information	Relevant clinical and nonclinical care providers who could electronically view, download, and transmit health information from their own site	Short-Term
Exchange	Availability of Electronic Health Information	Picture Archiving and Communication Systems (PACS) images that were sent or accessible between electronic health record systems.	Short-Term
Exchange	Availability of Electronic Health Information	Data elements that were captured electronically but not exchanged between at least two entities	Short-Term
Exchange	Availability of Electronic Health Information	Available structured elements that were electronically exchanged per patient	Short-Term
Exchange	Availability of Electronic Health Information	Number of EHR systems generating Continuity of Care Documents (CCD) or Continuity of Care Record (CCR) to exchange	Short-Term
Exchange	Availability of Electronic Health Information	Number and type of users participating in exchange by role (i.e., doctors, nurses, care coordinators, etc.)	Short-Term
Exchange	Availability of Electronic Health Information	Number and type of users actively exchanging electronic information	Short-Term

Gary Dickinson 6/28/2017 08:03
Comment [1]: Staff training as a measure of interoperability? Seems tangential.

Gary Dickinson 6/27/2017 19:38
Comment [2]: Is it fit for use? Or just "available"? At best a quantitative, not qualitative measure.

Gary Dickinson 6/27/2017 19:39
Comment [3]: Is it fit for use? Or just "available"? At best a quantitative, not qualitative measure.

Gary Dickinson 6/27/2017 20:04
Comment [4]: Is it fit for use? Or just "available"? At best a quantitative, not qualitative measure.

Gary Dickinson 6/27/2017 20:04
Comment [5]: Was it available, but not fit for purpose (of end use), e.g. primary or secondary use?

Gary Dickinson 6/27/2017 20:04
Comment [6]: Is it fit for use? Or just "available"? At best a quantitative, not qualitative measure.

Gary Dickinson 6/27/2017 20:10
Comment [7]: Quantitative not qualitative measure. More importantly to show achievement of true interoperability, how many CCDs/CCRs captured authorship, provenance, full clinical context, showed transformation from source and/or evidence of non-alteration from point of collection/origination?

Gary Dickinson 6/27/2017 20:12
Comment [8]: Quantitative not qualitative measure. How many users where able to make an affirmative trust decision based on health data/records received via exchange? What were the evident properties/qualities of the exchanged information that gave them that assurance?

Gary Dickinson 6/27/2017 20:19
Comment [9]: Quantitative not qualitative measure. What was the purpose of use for the exchange (e.g., primary or secondary use)? Were they able to make affirmative trust decisions based on health data/records received? What percentage of received information was so trusted? What were the evident properties/qualities of the exchanged information that ensured their trust? How confident were they that the information received was non-altered from source, was offered in the same context, with the same meaning? Were they able to discern the purpose of capture and intent of the author? Could they determine authorship, credentials of the author, whether the information was actually attested (signed) as complete and accurate by the author or other preceptor?

611

Domain	Subdomain	Measure Concept	Estimated Timeframe
Exchange	Availability of Electronic Health Information	Amount of health data exchange done through application programming interfaces (APIs) conforming to nationally certified standards through the Department of Health and Human Services (HHS)	Short-Term
Exchange	Availability of Electronic Health Information	How often patient's experience includes increased electronic access to their health information, which increases their participation in shared decision making with the clinical care team	Short-Term
Exchange	Availability of Electronic Health Information	How often patient's experience includes increased electronic access to their health information as well as electronic tools to improve health behaviors.	Short-Term
Exchange	Quality of Data Content	Percentage of available, electronically exchanged data elements that were valid and related directly to the patient	Short-Term
Exchange	Quality of Data Content	Available, electronically exchanged data elements received from the sender that were related directly to the patient	Short-Term
Exchange	Method of Exchange	Percentage of applicable standards recommended by the US Department of Health and Human Services (DHHS) that are implemented	Short-Term
Exchange	Method of Exchange	Number of systems adopting certified messaging and vocabulary standards recommended by the U.S. Department of Health and Human Services (HHS) for diagnoses, procedures, medications, lab orders, and results	Short-Term

Gary Dickinson 6/27/2017 20:25

Comment [10]: Yet another quantitative not qualitative measure. Did the API allow unaltered source content to be conveyed? Did the API require content to be transformed (e.g., from one coding/classification system to another, from one human language to another)? Did the API allow authorship and author's credentials to be conveyed (at the data element level)? Did the API allow attestation (for completeness/accuracy) to be conveyed? Did the API allow full clinical context and meaning to be conveyed?

Gary Dickinson 6/27/2017 20:38

Comment [11]: So this suggests to measure "increased patient access to their health information" which is the result of interoperability (exchange), as opposed to patient access via a portal to the source health record (as common to most all EHR platforms)? Also this suggests to measure to what degree the interoperability (exchange) actually "increases [patient] participation in shared decision making with the clinical care team"?

Gary Dickinson 6/27/2017 20:41

Comment [12]: As with the prior comment… So this suggests to measure "how often patient's experience include increased access to their health information" again as a function of interoperability (exchange) rather than direct access via a portal to the source health record? And it suggests to measure use of "electronic tools to improve health behaviors" as the result of interoperability? WOW!!

Gary Dickinson 6/27/2017 20:45

Comment [13]: OK, so it is suggested to measure "available, electronically exchanged data elements that were valid"? As compared to what: unaltered source data elements, in full clinical context, without loss of meaning, as originally coded/classified, with original units of measure, with original reference ranges, etc.?

Gary Dickinson 6/27/2017 20:49

Comment [14]: So here it is suggested that "exchanged data elements received from the sender" can be measured as being "directly related to the patient"? As compared to what: source records where those same data elements are inextricably bound to the patient's identity?

Gary Dickinson 6/27/2017 20:50

Comment [15]: Quantitative not qualitative measure. Does this consider purpose of use?

Gary Dickinson 6/27/2017 20:52

Comment [16]: Yet another quantitative not qualitative measure. What about document-oriented standards (e.g., CCD/CCDA) and FHIR resources?

612

Domain	Subdomain	Measure Concept	Estimated Timeframe
Exchange	Method of Exchange	Number of data elements that could not be parsed or interpreted by a receiving system	Short-Term
Exchange	Method of Exchange	The use of nationally recognized standards and clinical vocabularies within a clinical environment to communicate with nonclinical systems	Long-Term
Usability	Completeness	Reduction of provider identified errors in the patient's medical record	Short-Term
Usability	Relevance	Frequency of electronically exchanged information that has been viewed	Short-Term
Usability	Relevance	Users who had an available, relevant minimum data set that were electronically exchanged for the decision/action	Short-Term
Usability	Relevance	Electronically exchanged structured elements present for a given decision/action	Mid-Term
Usability	Relevance	Number of times a complete and current medical record was accessible to a patient and a provider during a clinical encounter	Short-Term
Usability	Relevance	Amount of time a provider had to spend searching for available information	Short-Term
Usability	Relevance	Number of clicks and/or sign-ons a provider has to do when accessing available information	Short-Term
Usability	Relevance	How often information accessed by a provider was out of date	Short-Term
Usability	Relevance	Amount of provider time spent searching for information that could have been available electronically (e.g., allergies, immunizations)	Short-Term

Gary Dickinson 6/28/2017 08:20
Comment [17]: Quantitative not qualitative measure. If data elements are not parsed or interpreted, it means that some information is getting lost, such as context, meaning, authorship, provenance, attestation. Isn't this a clinical integrity and more importantly, a crucial issues for patient safety?

Gary Dickinson 6/27/2017 20:59
Comment [18]: How is this relevant? Why do non-clinical system care (have need for) clinical vocabularies? As codes for billing?

Gary Dickinson 6/28/2017 08:16
Comment [19]: Measures to assess completeness of health data/record content (given interoperability) should be considered separately from measurement of "reduction of provider identified errors in the patient's medical record". Errors may be in the form of misidentified patients, organizations, healthcare professionals, locations, dates/times, chronology, unintelligible content, missing or unrelated context, loss of meaning, unspecified authorship or authors credential ... [1]

Gary Dickinson 6/27/2017 21:07
Comment [20]: Quantitative not qualitative measure. How about frequency of electronically exchanged information that has NOT BEEN viewed (as a measure of irrelevance).

Gary Dickinson 6/27/2017 21:29
Comment [21]: Quantitative measure of users "that were electronically exchanged for the decision/action". Not clear what this means?

Gary Dickinson 6/28/2017 07:52
Comment [22]: Primarily quantitative. What about structured elements NOT present for a given decision/action? What is missing? Do missing elements represent a failure of interoperabil ... [2]

Gary Dickinson 6/28/2017 07:55
Comment [23]: Quantitative not qualitative. How can it be determined what a "complete and current medical record" is? How is it possible to determine what is missing? Are the missing ... [3]

Gary Dickinson 6/28/2017 07:57
Comment [24]: Quantitative not qualitative. How is this a function of interoperability? Is the provider firing queries to multiple potential sources and waiting for responses?

Gary Dickinson 6/28/2017 07:59
Comment [25]: Quantitative not qualitative. Seems like a user interface/usability measure. Not clear how this is interoperability related.

Gary Dickinson 6/28/2017 08:02
Comment [26]: Quantitative not qualitative. How might it be determined that "information accessed... was out of date"? It must then be known when information becomes stale (out ... [4]

Gary Dickinson 6/28/2017 08:07
Comment [27]: Quantitative not qualitative. How is it known what "information could have been available electronically" but presumable wasn't? It's easy to know what you have but not necessa ... [5]

613

Domain	Subdomain	Measure Concept	Estimated Timeframe
Usability	Comprehensibility	How often information was difficult to understand because of formatting	Short-Term
Usability	Comprehensibility	How often information was difficult to understand for other reasons (reasons should be defined)	Short-Term
Application	Computable	Data could not be parsed or interpreted by a receiving system	Short-Term
Application	Computable	Data could not be used by the provider or members of the care team in the provision of care	Short-Term
Application	Computable	Percentage and frequency of quality metrics generated with electronically exchanged discrete data	Short-Term
Application	Computable	Number of medication discrepancies among different medication lists (i.e., pre-admission list, home medication list, etc.)	Short-Term
Application	Human Use	Frequency of reconciliation/incorporation of electronically exchanged information	Short-Term
Application	Human Use	Frequency of electronically exchanged discrete data used in a clinical decision	Long-Term
Impact	Care Coordination	Number of longitudinal care plans that both patients and clinicians use in the delivery of care	Long-Term
Impact	Care Coordination	Number of closed loop referrals to providers	Short-Term
Impact	Cost Savings	Presence of duplicate labs/imaging	Mid-Term
Impact	Cost Savings	Number of duplicated/reduction of labs and imaging over time on provider and payer side	Mid-Term

Gary Dickinson 6/28/2017 08:29
Comment [28]: How often: quantitative not qualitative. This is a very subjective measure. How might it be discovered that "information was difficult to understand because of formatting"? Is it anticipated that healthcare professionals will log each instance? Seems unlikely.

Gary Dickinson 6/28/2017 08:19
Comment [29]: How often: quantitative not qualitative. Reasons, as noted previously, might include: misidentified patients, organizations, healthcare professionals, locations, dates/times, chronology, missing or unrelated context, loss of meaning, unspecified authorship or authors credentials, ambiguous attestation, miscoding or miss-classification, missing or inappropriate units of measure, missing or inappropriate reference ranges, etc.

Gary Dickinson 6/28/2017 08:25
Comment [30]: As stated in previous comments: Quantitative not qualitative measure. If data elements are not parsed or interpreted, it means that some information is getting lost, such as context, meaning, authorship, provenance, attestation. Isn't this a clinical integrity and more importantly, a crucial issues for patient safety?

Gary Dickinson 6/28/2017 08:28
Comment [31]: How might this be assessed? Is it anticipated that healthcare professionals will log each instance when "data could not be used by the provider or members of the care team in the provision of care"? Seems unlikely.

Gary Dickinson 6/28/2017 08:30
Comment [32]: This measure is unclear. What is intended to be assessed? How does it relate to interoperability?

Gary Dickinson 6/28/2017 08:35
Comment [33]: Quantitative not qualitative. Are the "medication discrepancies among different medication lists" the result of interoperability failures? How might these be detected? Is it anticipated that healthcare professionals will ... [6]

Gary Dickinson 6/28/2017 08:40
Comment [34]: Quantitative not qualitative measure. At least as important are the reasons why (or criteria for) human reconciliation of ... [7]

Gary Dickinson 6/28/2017 09:14
Comment [35]: Quantitative not qualitative. What factors are used in the affirmative trust decision to ensure particular data was "fit fo ... [8]

Gary Dickinson 6/28/2017 09:34
Comment [36]: Quantitative not qualitative.

Gary Dickinson 6/28/2017 09:34
Comment [37]: Quantitative not qualitative.

Gary Dickinson 6/28/2017 10:35
Comment [38]: "Duplicate labs/imaging" likely result from duplicate orders. How is it known there are duplicate orders/labs/imaging if interope ... [9]

Gary Dickinson 6/28/2017 09:52
Comment [39]: Quantitative not qualitative. See previous comment.

614

Domain	Subdomain	Measure Concept	Estimated Timeframe
Impact	Patient/Caregiver Engagement	How often patient's experience includes increased electronic access to their health information and electronic tools, which increases the frequency they set and track their individual health goals	Short-Term
Impact	Patient/Caregiver Engagement	How often patient's experience includes increased electronic access to their health information and electronic tools, which increases the frequency that they review and follows their clinical care team's instructions for treatment or care	Short-Term
Impact	Patient/Caregiver Engagement	Number of care plans that include the patient's personal health goals, personal health concerns, and family caregivers	Mid-Term
Impact	Patient/Caregiver Engagement	Impact of patients' use of their health information (e.g., shared decision making, medication adherence, patient activation, change of health behaviors)	Mid-Term
Impact	Patient/Caregiver Experience	Patient/caregiver satisfaction with the transfer of personal electronic health information from provider to provider	Mid-Term
Impact	Patient/Caregiver Experience	Patient/caregiver satisfaction with provider care due to provider having personal electronic health information from another provider	Mid-Term
Impact	Patient Safety	Number of instances a medication was not given for patient who came from outside healthcare facility	Mid-Term

Gary Dickinson 6/28/2017 10:18
Comment [40]: Quantitative not qualitative. Assume this means via interoperability and NOT where a "patient's experience includes increased electronic access to their health information and electronic tools" which occurs via a patient portal to the source health record?

Gary Dickinson 6/28/2017 10:14
Comment [41]: Quantitative not qualitative. See previous comment.

Gary Dickinson 6/28/2017 11:21
Comment [42]: Quantitative not qualitative. Assume enabled by interoperability NOT by patient portal to source health record?

Gary Dickinson 6/28/2017 10:49
Comment [43]: How might you measure impacts? Seems unrelated to measures for interoperability assessment.

Gary Dickinson 6/28/2017 10:55
Comment [44]: How visible is the "transfer of personal electronic health information from provider to provider" to the patient and thus to their satisfaction? Is the transfer complete, partial, automatic, on demand?

Gary Dickinson 6/28/2017 10:58
Comment [45]: How might a patient discern whether they are satisfied with provider care and that their satisfaction (or not) has anything to do with "having personal electronic health information [exchanged] from another provider". Seems a bit far-fetched.

Gary Dickinson 6/28/2017 11:01
Comment [46]: Quantitative not qualitative. Assumes interoperability is the factor in why medication doses are missed subsequent to a patient transfer "from an outside healthcare facility".

615

Domain	Subdomain	Measure Concept	Estimated Timeframe
Impact	Patient Safety	Number of Adverse Drug Events with newly prescribed drugs where offending other drug not in prescriber's EHR	Mid-Term
Impact	Productivity	Number of times that a look-up is done for prior outside imaging studies, lab orders, or medications, before ordering a new imaging study, labor order, or prescription	Long-Term

Gary Dickinson 6/28/2017 11:05

Comment [47]: Quantitative not qualitative. Assumes that it can be known that the critical medication information was missing as the result of lack of interoperability between systems. The medication was recorded/accessible in one system but not in the (new) prescriber's EHR.

Gary Dickinson 6/28/2017 11:10

Comment [48]: Quantitative not qualitative. Assumes that the lookup is successful and that all sources for possible look-ups are (or can be) known.

Page 20: [1] Comment [19] **Gary Dickinson** **06/28/2017 08:16**

Measures to assess completeness of health data/record content (given interoperability) should be considered separately from measurement of “reduction of provider identified errors in the patient’s medical record”. Errors may be in the form of misidentified patients, organizations, healthcare professionals, locations, dates/times, chronology, unintelligible content, missing or unrelated context, loss of meaning, unspecified authorship or authors credentials, ambiguous attestation, miscoding or miss-classification, missing or inappropriate units of measure, missing or inappropriate reference ranges, etc.

Page 20: [2] Comment [22] **Gary Dickinson** **06/28/2017 07:52**

Primarily quantitative. What about structured elements NOT present for a given decision/action? What is missing? Do missing elements represent a failure of interoperability? This should also be assessed.

Page 20: [3] Comment [23] **Gary Dickinson** **06/28/2017 07:55**

Quantitative not qualitative. How can it be determined what a “complete and current medical record” is? How is it possible to determine what is missing? Are the missing parts irrelevant?

Page 20: [4] Comment [26] **Gary Dickinson** **06/28/2017 08:02**

Quantitative not qualitative. How might it be determined that “information accessed... was out of date”? It must then be known when information becomes stale (out of date) and whether there is more recent information that would supercede the information accessed.

Page 20: [5] Comment [27] **Gary Dickinson** **06/28/2017 08:07**

Quantitative not qualitative. How is it known what “information could have been available electronically" but presumable wasn’t? It’s easy to know what you have but not necessarily what you don't have. Back to the old adage: "you don't know what you don't know" or maybe "you can't know what you don't know".

Page 21: [6] Comment [33] **Gary Dickinson** **06/28/2017 08:35**

Quantitative not qualitative. Are the “medication discrepancies among different medication lists” the result of interoperability failures? How might these be detected? Is it anticipated that healthcare professionals will log each such instance?

Page 21: [7] Comment [34] **Gary Dickinson** **06/28/2017 08:40**

Quantitative not qualitative measure. At least as important are the reasons why (or criteria for) human reconciliation of “electronically exchanged information” when decisions are made as to what is accepted or in fact rejected.

Page 21: [8] Comment [35] **Gary Dickinson** **06/28/2017 09:14**

Quantitative not qualitative. What factors are used in the affirmative trust decision to ensure particular data was “fit for use” in clinic decision support: e.g., known source, authorship, author credentials, provenance, evidence of non-alteration, preservation of clinical context and meaning...

Page 21: [9] Comment [38] **Gary Dickinson** **06/28/2017 10:35**

"Duplicate labs/imaging" likely result from duplicate orders. How is it known there are duplicate orders/labs/imaging if interoperability (exhange) is not in place? Is duplication the result of (or lack of) interoperability? Another question is what was the purpose of each order? Is it a duplicate if it occurs on the same day, the next day, the next week, the next month or six months later? Is it really a duplicate or possibly intended to watch variance or change over time?

S&I Data Provenance		Source EHR System Events						Exchange	Receiving EHR System Events				TRUST Decision
HITSC DPROV TF Verbs →		Create (Originate)	Maintain (Retain)	Change (Update)	Assemble	Compose	Export (Transmit)	→→→	Import (Receive)	Disassemble	Decompose	Maintain (Retain)	Access (Use/View)
EHR System Function?		Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
w/Human Participant?		Human or Device	No	Yes	No	Yes	No	No	No	No	Yes	No	Yes
Prov-enance Event?	Exchange No Transform	Yes (new source record entry)	No	Yes (changed source record entry)	N/A	N/A	No	No	No	N/A	N/A	No	No
	Exchange w/Transform	Yes (new source record entry)	No	Yes (changed source record entry)	Yes (new exchange artifact)	Yes (new exchange artifact)	No	No	No	Yes (new receiver record entry)	Yes (new receiver record entry)	No	No
Audit, Traceability Event?		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
WHO - Entities													
Person		Person who is part of Action Taken and/or identified in record entry created	Person who is identified in maintained record entry	Person who is identified in changed record entry	Person who is identified in assembled exchange artifact	Person who is identified in composed exchange artifact	Person who is identified in exported exchange artifact	→→→	Person who is identified in imported exchange artifact	Person who is identified in disassembled exchange artifact	Person who is identified in decomposed exchange artifact	Person who is identified in maintained record entry	Person who is identified in accessed record entry
Organization		Organization who is source of record entry	Organization who maintains record entry	Organization who is source of changed record entry	Organization who is assembler of exchange artifact	Organization who is composer of exchange artifact	Organization who exports exchange artifact		Organization who imports exchange artifact	Organization who is disassembler of exchange artifact	Organization who is decomposer of exchange artifact	Organization who maintains record entry	Organization who views/accesses record entry content
System, Device or Software		System, device or software creating record entry	System, device or software maintaining record entry	System, device or software changing record entry	System, device or software assembling exchange artifact	System, device or software composing exchange artifact	System, device or software exporting exchange artifact		System, device or software importing exchange artifact	System, device or software disassembling exchange artifact	System, device or software decomposing exchange artifact	System, device or software maintaining record entry	System, device or software providing view/access to record entry
WHO - Entity Roles													
Subject/Target		Patient/Person who is subject of Action Taken and target of record entry	N/A	Patient/Person who is subject/target of record entry	Patient/Person who is subject/target of exchange artifact	Patient/Person who is subject/target of exchange artifact	N/A	→→→	N/A	Patient/Person who is subject/target of record entry	Patient/Person who is subject/target of record entry	N/A	N/A
Device Author		Device who authored record entry		N/A	N/A	N/A					N/A		
Accountable Author		Person who authored record entry		Person who authored change to record entry		Person who composed exchange artifact					Person who decomposed exchange artifact		
Enterer		Person or device who entered record entry		N/A		N/A				N/A	N/A		
Verifier		Person who verified record entry											
Attester		Person who attested record entry											
Performer		Person who is performer of Action Taken											
Informant		Person who is informant to Action Taken											
Participant		Person who is participant in Action Taken											
Viewer, Accesser, User		N/A											Person who views/accesses record entry content
WHAT													
Action Taken		What Action was taken, as documented in record entry	N/A	N/A	N/A	N/A	N/A	→→→	N/A	N/A	N/A	N/A	N/A
Chain of Trust Event		What event occurred: originate	What event occurred: maintain (retain)	What event occurred: change (update)	What event occurred: assemble	What event occurred: compose	What event occurred: export (transmit)		What event occurred: import (receive)	What event occurred: disassemble	What event occurred: decompose	What event occurred: maintain (retain)	What event occurred: access (use/view)
Provenance Event		N/A	N/A	• Original source record entry content (retained) • New record entry content (retained)	• Original source record entry content (retained) • New exchange artifact originated	• Original source record entry content (retained) • New exchange artifact originated	N/A		N/A	• Exchange artifact content (retained or deleted?) • New receiver record entry content	• Exchange artifact content (retained or deleted?) • New receiver record entry content	New receiver record entry content (retained)	N/A
WHEN													
Action Date/Time		When Action was taken	N/A	N/A	N/A	N/A	N/A	→→→	N/A	N/A	N/A	N/A	N/A
Action Duration		Duration of Action											
Data Event		When record entry was created	When record entry was maintained/ retained	When record entry was changed	When exchange artifact was assembled	When exchange artifact was composed	When exchange artifact was exported		When exchange artifact was imported	When exchange artifact was disassembled	When exchange artifact was decomposed	When record entry was maintained/ retained	When record entry was viewed/accessed
WHERE													
Action Physical Location		Physical location where Action taken	N/A	N/A	N/A	N/A	N/A	→→→	N/A	N/A	N/A	N/A	N/A
Data Location		Network address where record entry was created	Network address where record entry was maintained/ retained	Network address where record entry was changed	Network address where exchange artifact was assembled	Network address where exchange artifact was composed	Network address where exchange artifact was exported		Network address where exchange artifact was imported	Network address where exchange artifact was disassembled	Network address where exchange artifact was decomposed	Network address where record entry was maintained/ retained	Network address where record entry was viewed/accessed
WHY													
Action Reason		Why Action was taken	N/A	Why Action was taken	N/A	N/A	N/A	→→→	N/A	N/A	N/A	N/A	Why record entry was accessed/viewed
Data Reason		Why record entry content was created		Why record entry content was changed	Why exchange artifact was assembled	Why exchange artifact was composed	Why exchange artifact was exported			Why exchange artifact was disassembled	Why exchange artifact was decomposed		
Additional Provenace Metadata													
Author Signature		Digital signature of record entry author	N/A	Digital signature of record entry change author	N/A	Digital signature of exchange artifact composer	N/A	→→→	N/A	N/A	Digital signature of exchange artifact decomposer	N/A	N/A
System, Device or Software Signature		Digital signature of system, device or software creating record entry		Digital signature of system, device or software changing record entry	Digital signature of system, device or software assembling exchange artifact	Digital signature of system, device or software composing exchange artifact	Digital signature of system, device or software exporting exchange artifact			Digital signature of system, device or software disassembling exchange artifact	Digital signature of system, device or software decomposing exchange artifact		