3 April 2015

Karen DeSalvo, MD
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Department of Health and Human Services
200 Independence Avenue, SW
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Dear Dr. DeSalvo,

Thank you for the opportunity to comment on "Connecting Health and Care for the Nation – A Shared Nationwide Interoperability Roadmap", Draft Version 1.0. We believe focus on this topic is essential to realize a safe and effective nationwide strategy for health information technology and for proper capture, management, exchange and use of health data/information, including safeguards for privacy and security.

Our general comments are arranged and enumerated by topic. Thereafter are comments on specific sections of the Draft Roadmap.

In brief: **You cannot achieve person-centeredness without an actual center that is the person. Make the Roadmap explicitly person-centered – with a real center for the thing described as most important – and thus focused to achieve person-centered integration and interoperability of individual health records.**

Thank you for your consideration.

Regards,

Gary Dickinson
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Co-Chair, Health Level Seven (HL7) Electronic Health Record (EHR) Work Group
Co-Facilitator, HL7 EHR Interoperability Work Group

<u>General Comments</u>

Interoperability Roadmap, page 12: "The purpose for which electronic health information is shared and used must drive the technical standards and methods selected for nationwide adoption through a coordinated governance process."

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1. Interoperability is Purpose-Based

Interoperability can only be described, measured and achieved if first understood as to its scope (what) and purpose (why).

<u>What</u>: are we striving to make interoperable?
A) Personal health and healthcare data/records?
B) Provider healthcare data/records?
C) Integration of data/records received from an external source?
D) Health data/record flows: point to point and/or end to end?
E) Data/record flows integral to process (work) flows?

<u>Why</u>: for what purpose?
F) To support primary use: clinical care, interventions and decision making?
G) To support secondary use: most everything else?
H) To ensure integrity of the clinical process, of the health system?
I) To ensure patient safety?
J) To render a facsimile representation of data/records (e.g., fax, photocopy, PDF) that is human readable?
K) To render a computable representation of data/records that is software process-able?
L) To render a precise copy of the original source provider health record: i.e., provider business, and evidentiary record for legal purposes?

The Roadmap seems indecisive in description of the intended purpose(s) for it's specification of interoperability. For this important topic, there should be no room for assumption and conjecture, please make this explicit.

[Roadmap search yielded: "primary use"/"secondary use" (no hits), "patient safety" or "safe care" (12 hits)]

2. Interoperability is Based on Fitness for Use

Interoperability ensures 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 (e.g., HL7 messages and documents) – once by the source/sending system and once again by the receiving system.

Use	Purpose	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**

Although fitness for use is implied in the IEEE definition of "interoperability", the Roadmap should make this explicit.

[Roadmap search yielded: "fit" (no hits in this context), "fitness"/"fitness for use"/"fitness for purpose"/"suitable"/ "suitability" (no hits), "transform"/"transformed"/"transformation" (one hit in this context)]

3. Interoperability is Based on Truth and Trust

Truth = factual, authentic = Facts are evident
Trust = assurance, reliance = I am assured, I trust, I rely on

The achievement of interoperability is primarily about truth and trust – as evidenced at each downstream point of access/use – to the ultimate primary or secondary user of health data/records.

Truth	as evidence for	Trust
✔ Identity is verified ✔ Source, origination and provenance is evident ✔ Signature is evident ✔ Signature/content binding is evident ✔ Content is un-altered ✔ Context is evident ✔ Completeness (or not) is evident ✔ Update(s) to original content are evident ✔ Chain of Trust (from source to use) is evident ✔ From origination to use ✔ Transformation(s) are evident (e.g., to/from exchange artifacts) ✔ Original "Source of Truth" is evident	➔➔➔	• Belief (believability) • Certainty • Reliance • Traceable to a "source of truth" • Based on – and manifest in – evidence presented

Although "trust" is mentioned many times in the Roadmap, there is no discussion of the predicate relationship between "truth" and "trust". Please make this explicit.

[Roadmap search yielded: "truth" (no hits), "fact"/"facts"/"factual" (no hits in this context), "authentic"/"authenticity"/ "veracity" (no hits), "assurance" (5 hits)]

4. Interoperability has a Source of Truth and Anchor Point

The source of truth is content captured at the point of health data/record origination. This is the anchor point for the chain of trust and is crucial to the achievement of interoperability. There can be no dispute there. For primary use – clinical care, interventions and decision making – the source of truth is unaltered source health data/record content. The receiving provider 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 most importantly, patient safety. From the perspective of the end user, the chain of trust starts at the point of health data/record origination/capture and continues to each point of access/use, traceably and without interruption.

Truth and trust as the anchor point for health data/record interoperability should be a key finding/lesson of the Learning Health System and the Roadmap should make this explicit.

[Roadmap search yielded: "anchor"/"anchor point"/"chain of trust"/"source of truth"/"traceable"/"traceability" (no hits), "integrity"/"data integrity" (5 hits in this context)]

HITECH Act (2009) Section 3001(c)(3)(A): "The National Coordinator shall, in consultation with other appropriate Federal agencies (including the National Institute of Standards and Technology), update the Federal Health IT Strategic Plan (developed as of June 3, 2008) to include specific objectives, milestones, and metrics with respect to the following:
"(i) The electronic exchange and use of health information and the enterprise integration of such information.
"(ii) The utilization of an electronic health record for each person in the United States by 2014…"

5.   A Person-Centered (Individual) Health Record

Thus far we have (via MU 1+2) incentivized and demonstrated integration/interoperability that follows the individual provider when their practice is wholly supported by an enterprise EHR system. On a large-scale basis, we have yet to incentivize, much less leverage or demonstrate, comparable approaches to integration/interoperability that follows the individual patient over time and across multiple providers.

The Roadmap assumption seems to be that the answer to the lack of 'person-centered care' is some form of interoperability, or more generally a configuration of services/institutions/ organizations from which person-centeredness will appear as an emergent phenomenon, without the need for any actual constituent part that unambiguously represents the person in the overall picture.

As described in the HITECH Act (sub-bullet (ii) above), it is incumbent on ONC to develop "specific objectives, milestones, and metrics with respect to… the *utilization of an electronic health record for each person in the United States* by 2014". This does not say "an electronic health record for each provider", yet a large fortune has been spent in incentives for provider-based EHR systems, thus ensuring that "each person" in the United States had a dozen different electronic health records – this is equivalent to, and perhaps worse than, having none.

Although beyond the specific focus of the Interoperability Roadmap, we believe ONC has done little to establish or promote a person-centered electronic health record, inclusive of health information over time from all providers. This was the point of the legislation. Taking better care of providers and their records has a tenuous connection at best to taking better care of patients.

[Roadmap search yielded: "person-centered" or "patient-centered" (29 hits)]

6.   Interoperability is Manifest by Integration

Also as described in the HITECH Act (sub-bullet (i) above), it is expected that ONC will focus on "the electronic exchange and use of health information and the enterprise integration of such information". Enterprise integration manifests interoperability of health data/records.

Over the past decade and more, we have witnessed the transformation of those healthcare providers equipped with the latest electronic health record (EHR) systems spanning their enterprise. Automation and information islands and fiefdoms have been bridged and gaps filled. In these settings, interoperability (actually, usually just the use of a single system, obviating interoperability) now facilitates better patient flow and work (process) flow combined

with information flow to improve the chance of getting the right data, at the right place, at the right time.

Interoperability as manifest by full integration should be a key finding/lesson of the Learning Health System and the Roadmap should exploit this as a foundational building block. Please make this explicit.

[Roadmap search yielded: "integrate"/"integrated"/"integration" (25 hits in this context)]

Interoperability Roadmap, page 108: "Measuring perceived accuracy, reliability, trustworthiness and utility of information exchanged will help understand variation in use of data. Additionally, information from the end user perspective on barriers to exchange and interoperability may ensure early identification of issues and addressing of concerns."

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7.   Interoperability is in the Eye of the Beholder

As described above and as the essential satisfaction premise of the IEEE "interoperability" definition, the affirmative decision to trust and use health data/records received is one ultimate signal of achievement (of interoperability). Each ultimate end user takes responsibility as an individual or organization to make a "trust decision" regarding the veracity of health data/record received and whether/when to use such information as the basis for subsequent clinical care, interventions and decision making (in primary use) or for other purposes.

A second key expectation of interoperability is that the end product of "interoperating" establishes a single, useful and usable understanding of the information *for each patient*. Any approach that sends data from place to place to be put into a file cabinet of patient information where it is available for "rummaging" by providers who lack the time to do so may have established connectivity, but definitely *not* interoperability.

The affirmative "trust decision" and the production of a single understood health record for each person as the achievement of interoperability should be key findings/lessons of the Learning Health System and the Roadmap should make this explicit.

See graphic at Appendix A. Also see additional observations regarding the IEEE definition in subsequent comments below.

[From Roadmap search: "end user" (once in this context, see citation above)]

8.   Properties/Qualities of Interoperability

What are key properties or qualities of health data/records that demonstrate (achievement of) interoperability to the end user? Consider what we we've learned from our experience with enterprise integration. Of course, the enterprise domain is typically well-bounded, protected and carefully curated with tight coupling of EHRs, other applications and devices.

	Enterprise integration enables interoperable health data/record content…	Qualities Manifest to End User
A	Known and verified as to identity: • Subject: patient • Provider: individual and organization	Identified, Attributable
B	Captured, consolidated from multiple sources within the enterprise	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 who did what when	Accountable
F	Tuned for consistency: e.g., data types, common units of measure, codes and value sets	Uniform
G	Tied to the "source of truth", showing provenance at point of data/record origination and thereafter	Factual, Authentic, Traceable
H	Bound to source, author's signature	Authenticated
I	With known context: clinical, administrative, operational	Contextual
J	Known to be unaltered since origination	Immutable
K	Known to be complete – or known to have missing elements	Whole or Partial
L	Known to be original – or known to be updated from original instance	Original/Revision Progression
M	Associated with like information	Correlated, Comparable

As noted in the right-most column, the described qualities are to ensure:
- Evidence of truth (authenticity); as the
- Basis of trust (assurance); and
- A useful representation of all available health data/records centered on an individual and as rendered to each end user.

A description of these properties/qualities of interoperable health data/records is vital and should stand as a key finding/lesson of the Learning Health System. The Roadmap should make this explicit.

9. **Transition to Interoperability**

So how have most healthcare enterprises achieved integration and interoperability? In implementing their encompassing enterprise-wide EHR system, the following table shows the typical pattern of transition from pre-integration to a fully integrated state.

	Pre Integration	➔	Full Integration
Applications	Multiple heterogeneous apps serving operating units	➔	Single, unified application suite across the enterprise
Data stores	Multiple data/record sub-domains and data stores	➔	Single, unified data/record domain and data store
Content, Format, Code Sets	Many variances in data/record content, format, code sets across applications	➔	Unified data/record content, format, code sets
Intra-Enterprise Exchange	Multiple point to point (1 to 1) and broadcast (1 to many) interfaces between heterogeneous apps	➔	Few heterogeneous applications, few interfaces
Exchange Standards	HL7 v2, CCDA and other exchange standards	➔	Limited use of HL7 v2, CCDA and other exchange standards

Our experience from enterprise integration brings us to two key conclusions:
A. Integration and interoperability did occur as the result of a common system, common vendor, common information model, overarching infrastructure and enterprise backbone;
B. Integration and interoperability did not occur as the linking of an unbridled proliferation of multiple disparate data sources and point to point interfaces between heterogeneous applications using well-known exchange standards.

These findings are particularly relevant in our pursuit of a solution for nationwide interoperability and thus should be made findings/lessons of the Learning Health System. The Roadmap should make this explicit.

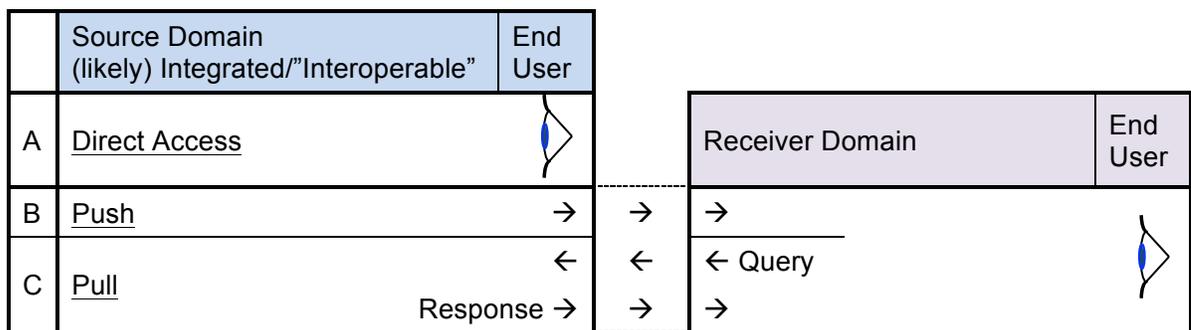## 10. Interoperability Within and Without

We know conclusively that interoperability can be achieved (through integration) within the healthcare enterprise. Either we bring the end user (of health data/records) into this sphere of interoperability or we determine how to extend interoperability to that user. The Roadmap is largely silent on the former and relies on the premise that the later is both desirable and achievable. Please make this explicit.

11. Interoperability Access/Exchange Methods, Initiators and Limitations

Let's look at three possible methods of achieving health data/record access (if not interoperability) – as beheld by the end user. Each method has a specific type of initiation and each method has limitations in terms of scope of data availability. Methods B & C rely on system-to-system exchange to convey data/records to the end user, whereas Method A takes the end user to the source system where data/records are already likely integrated and thus interoperable (but only within that domain).

	Method	Initiated by…	Limitations
A	Allow End User Direct Access to Source Domain	• Login to initiate user session	• Limited to health data/records available in source domain
B	Push Source Data to End User Domain	• Source trigger event	• Limited to data pushed • May be missing full context
C	Pull Source Data to End User Domain	• Receiver trigger event or • User inquiry	• Limited to data pulled • May be missing full context

For each method (A-C), the following shows the end user and their domain of access to health data/records.

	Source Domain (likely) Integrated/"Interoperable"	End User			Receiver Domain	End User
A	Direct Access	⟩				
B	Push	→	→	→		
C	Pull	←	←	← Query	⟩
	Response →	→	→		

Limitations and challenges of these access/exchange methods (to achieve interoperability) should be made findings/lessons of the Learning Health System and the Roadmap should make this explicit.

12. Interoperability Takes Leadership, Planning and Concise Implementation

It is important to keep in mind that some provider enterprises persisted for 20, 30 and more years with islands of automation and scattered health data/records before achieving integration across their domain. It took decisive leadership, diligent planning and meticulous implementation of a broad-based backbone EHR system to bring order, integration and thus interoperability.

There are multiple methods and techniques of achieving integration and interoperability offered by provider enterprises with that experience. This should be a key finding/lesson of the Learning Health System and the Roadmap should make it explicit.

13. Interoperability that Isn't

[Reference Comments #2 and #9 above.] We've well demonstrated that an interface-based scheme of standards-based messages and documents facilitating exchange across multiple disparate application systems leads neither to integration or interoperability. Often these exchange artifacts become odd assemblages of fragmented, disjoint data sets/elements lacking context, chronology, consistency, useful classification and comparability. (For example, observe the typical live mash-up of CCDA-based patient summaries from multiple disparate sources inbound to a provider EHR system). It is troubling that the Roadmap presumes to double-down on this strategy without showing any compelling (or, for that matter, non-compelling) evidence that these thriving points of failure can be overcome.

The obvious stalemate to integration and interoperability is right before us. It is no less than what is demanded by exchange artifact requirements of Meaningful Use 2 (e.g., HL7 v2 messages and CCDA documents). Although claimed as "interoperability", the current charade of disparate applications disgorging fragments of disjoint data content via standards-based exchange artifacts offers substantive and ongoing evidence of misdirection and misguidance. Pronouncements of success in the face of obvious failure (to interoperate) should be a key finding/lesson of the Learning Health System and the Roadmap should make this explicit.

14. Evidence of Interoperability and the Affirmative Trust Decision

[Reference Comment #3 above.] Establishing truth and trust as a key foundation for interoperability leads us to consider the current repertoire of standards-based exchange artifacts (messages and documents) and to examine their capability to convey key elements of truth (upon which end user trust can be based). The following table poses key questions/ challenges in our quest to substantiate the end user trust decision.

Truth (at source)	Exchange Artifact	Receiver
✔ Identity is verified	Is identity conveyed?	Within common identity domain? Is identity manifest?
✔ Source, origination and provenance is evident	Is it conveyed?	Is it manifest?
✔ Signature is evident	Is signature conveyed?	Is signature manifest?
✔ Signature/content binding is evident	Is signature/content binding conveyed?	Is signature/content binding manifest?
✔ Content is un-altered	Is non-alteration conveyed?	Is non-alteration manifest?
✔ Context is evident	Is context conveyed?	Is context manifest?
✔ Completeness (or not) is evident	Is completeness/ incompleteness conveyed?	Is completeness/ incompleteness manifest?
✔ Update(s) to original content are evident	Are updates conveyed?	Are updates manifest?
✔ Chain of Trust is evident ✔ From origination to use	Is Chain of Trust conveyed?	Is Chain of Trust manifest?
✔ Transformation(s) are evident (e.g., to/from exchange artifacts)	Are transformations conveyed?	Are transformations manifest?
✔ Original "Source of Truth" is evident	Is original "source of truth" conveyed?	Is original "source of truth" manifest?

Most objective observers agree that the current set of Standards-based exchange artifacts fall far short of conveying necessary truth attributes – to say nothing of the limitations of receiving systems to manifest those attributes – to the end user who must make a trust decision.

Evidence to support successful achievement of health data/record interoperability combined with the end user's affirmative trust decision is a crucial finding/lesson to the Learning Health System and the Roadmap should make this explicit.

15. Interoperability via Transformation and Fragmentation?

As described in previous comments, substantial amounts of health data/record content are now captured – at the point of service or point of care – and retained in integrated provider EHR 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. 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, chronologies, trends and relationships between encounters, problems, 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.

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 not).

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, very limited health data/record secondary uses but not primary use (clinical care, interventions and decision making).

Health data/record fragmentation, transformation and loss of context are real barriers to interoperability and should be a key finding/lesson of the Learning Health System and the Roadmap should make this explicit.

[From Roadmap search: "transform"/"transformed"/"transformation" (no hits in this context), "fragment"/ "fragmentation" (5 hits)]

16. IEEE Interoperability is not Sufficient

As described in previous Comments, it is self-evident that the IEEE "interoperability" definition falls far short of what is needed for trusted exchange and use of health data/records.

IEEE 1990	IEEE 2014	Interoperability Claim
Exchange	Exchange	(Technical)
Use	Use	(Semantic)
	→ Without user intervention	(Plug and Play)

Interoperability is not something that finally comes into play once data is transformed to exchange artifacts and queued for transmission to an external system (at point of exchange). As described in Comment #8, key qualities of health data/records are essential and must be in place before exchange artifacts are created or exchange itself occurs. Most of these qualities (e.g., source/authorship, provenance, attestation, non-alteration) are either captured at the data/record source or are intrinsic to data/record management up to the point of exchange. In addition, the transformative processes essential to take many disparate sources and transform that information, while maintaining the relevant trust attributes, into a multi-source, useable and useful integrated representation around each individual are fundamental to effective interoperability.

It is clear that a valid interoperability Roadmap for health data/records must invariably start at the source – point of data/record origination – and continue uninterrupted to each ultimate point of access/use, potentially traversing one or more points of exchange along the way and resolving itself in the final outcome to an integrated individual health record.

Deficiencies of the IEEE "interoperability" definition should be made findings/lessons for the Learning Health System and the Roadmap should expand its definition sufficient for true end-to-end health data/record interoperability.

17. Interoperability Enabled by the Chain of Trust

In previous Comments we have described the convergence of integration, truth and trust as vital pillars to support/achieve health data/record interoperability. The following table offers an end-to-end perspective from point of data/record origination to each ultimate point of data/record access/use. Information flow is traceable via a "chain of trust", itself enabled by the succession of audit and provenance events that capture related metadata. In this example, health data/record flow is top to bottom.

Health Data/Record Chain of Trust from Point of Origination to each Point of Access/Use					
Flow	Point of Health Data/Record…	(For primary clinical use)	Audit Event	DPROV Event	Original Content (primary use)
Source System					

↓	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
↓	Transformation	From Source Record Entry to Exchange Artifact: e.g., HL7 message or document	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
↓	Access, view • Trust Decision	By End User	X		Is accessed, viewed

The Chain of Trust is shown as successive Events (2nd/3rd column) in health data/record management – starting at the point of origination (the "source of truth") – with AuditEvent (4th 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 (5th column) capture related metadata at Events 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 (6th column) and is a paramount success factor to achieving health data/record interoperability. The Chain of Trust provides evidence for the Trust Decision by each ultimate end user.

Chain of trust is essential to achievement of interoperability and the affirmative trust decision and should be a key finding/lesson for the Learning Health System. The Roadmap should make this explicit.

[AuditEvent and Provenance are two HL7 Fast Health Interoperability Resources (FHIR), currently on ballot at HL7 as part of FHIR DSTU 2 and profiled together in the HL7 FHIR Record Lifecycle Event Implementation Guide, also on ballot.]

[From Roadmap search: "anchor"/"anchor point"/"chain of trust"/"end to end"/"traceable"/"traceability" (no hits)]

18. **Interoperability Relies on Audit, Provenance and Traceability**

As noted in previous Comments, much of what makes interoperability evident is audit logs, provenance and traceability. Standards with this specific focus include:
• ISO 21089, "Trusted End-to-End Information Flows" (first published 2004),
• HL7 EHR Interoperability Model DSTU, 2007
• HL7 EHR Lifecycle Model DSTU, 2008
• ISO/HL7 10781 EHR System Functional Model Release 2, 2014

Since May 2014, an HL7 Project Team has focused on health data/record lifespan – and lifecycle events occurring within that lifespan – in context of implementations using HL7 Fast Healthcare Interoperability Resources (FHIR). Record lifecycle events include: originate, retain/maintain, update/amend, verify, attest, translate/transform, disclose, transmit, receive, archive, delete/destroy and more. The Team started with Standards-based requirements (for audit, provenance, traceability and more) and profiled FHIR AuditEvent and Provenance resources to capture applicable metadata at each lifecycle event. Resulting from this effort is a new Record Lifecycle Event Implementation Guide (RLE IG) for HL7 FHIR. The RLE IG is currently in HL7 ballot as part of FHIR Draft Standard for Trial Use Release 2, opening 3 April and closing 4 May 2015.

Consistent, broad-based adoption of fundamental audit, provenance and traceability for health data/records is essential to any interoperability solution.

Vital requirements for audit, provenance and traceability are foundational to interoperability. This should be a key finding/lesson for the Learning Health System and the Roadmap should make this explicit – including specific references to the family of ISO/HL7 Standards – and to the HL7 FHIR RLE IG – referenced above.

[From Roadmap search: "audit" (6 hits), "provenance" (8 hits), "traced" (1 hit), "traceable"/"traceability" (no hits)]

19. **Interoperability Relies on End-to-End Standards**

Reference: ISO 21089, Trusted End-to-End Information Flows

Interoperability relies on trusted end-to-end management of health data/records from the point of origination to each ultimate point of data/record access/use, encompassing data at rest and data in motion. This Standard is agnostic as to the type of system (EHR, PHR, HIS, Ancillary or other system), but rather as to its system role in end-to-end information flow. This Standard provides guidance for US and international communities, promoting a common infrastructure and uniformity in management of end-to-end information flow implementations worldwide.

International Standards for trusted end-to-end information flows focus on universal solutions for health data/record interoperability. This should be a finding/lesson for the Learning Health

System and the Roadmap should make this explicit – including specific reference to ISO 21089.

20. Interoperability Relies on EHR, PHR (and other) System Functionality Standards

Reference: ISO/HL7 10781 Electronic Health Record System Functional Model (EHR-S FM), Release 2, and ISO/HL7 16527 Personal Health Record System Functional Model (PHR-S FM), Release 1.

Interoperability relies on common constructs and functional support for health data/record capture, update, retention, management and exchange. The ISO/HL7 Functional Model Standards provide guidance for US and international communities, promoting common functionality between and across EHR and PHR systems. For example, the EHR-S FM Record Infrastructure Section describes basic record management functions for EHR record entries, including functions to support record entry lifespan and lifecycle.

Key international Standards for EHR/PHR system functionality provide a common framework for interoperability, both US and worldwide. This is a key finding/lesson for the Learning Health System and the Roadmap should make this explicit – including specific references to ISO/HL7 10781 and ISO/HL7 16527.

21. Interoperability is an International Objective which Requires Collaboration

Health data/record interoperability is a universal theme, not just a US pursuit. Via international standards development organizations (such as ISO TC215, HL7, CDISC and DICOM), we have worked collaboratively to establish foundational standards (as noted above) that can be universally applied, that offer unified and unifying constructs and that promote common interoperability solutions. The Roadmap is largely silent on how it might fit, engage and find harmony, with the broader international health and healthcare community on interoperability solutions.

Establishing universal (international) requirements for health data/record interoperability and supporting international collaboration are a key findings/lessons for the Learning Health System and the Roadmap should make this explicit.

[From Roadmap search: "international" (3 hits in this context), "collaboration" (11 hits, most all in context of US entities)]

22. Interoperability From/To Provider Business/Legal Records

With the advent of enterprise-wide EHR Systems, most all of the provider health data/record is there committed. This record serves:
A. Business purposes – as a an account of operations, processes and services provided;
B. Legal purposes – as evidence of who did what when, which may be attested for purposes of accountability and substantiation (e.g., of claims for payment) and as the legal record for reporting, administrative and court proceedings;
C. Professional purposes – as an account of actions taken by providers in support of individual health and provision of healthcare.

Most providers take great care to ensure their business/legal record is precise, accurate, complete and properly maintained. The business/legal record is a chronicle and key asset of every health provider enterprise.
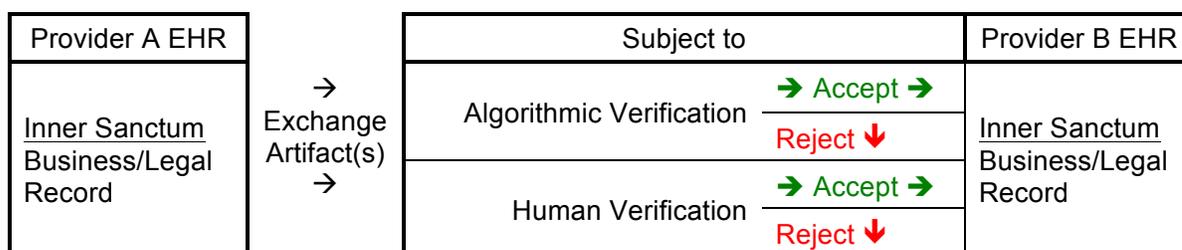
In April 2013, the HIT Policy Committee offered a set of recommendations for ONC consideration of "legal health record". The recommendations offered the basis for a "legal health record" framework as (in part) an underpinning for nationwide interoperability of health data/records from/to enterprises with established business/legal record systems.

Provider business/legal records are the foundation for trusted and interoperable end-to-end information flow. Included are all parties engaged in, and accountability for, enterprise operations, processes and services provided. This is a key finding/lesson for the Learning Health System and the Roadmap should make this explicit.

[From Roadmap search: "business record"/"legal record" (no hits)]

23. Interoperability Doesn't Require Manual Interception before Committal

A basic challenge for most providers capturing exchange artifacts from external sources is acceptance (acceptability) criteria including what to accept automatically – algorithmically verified but without human review. They maintain meticulous control within their enterprise and must ensure their pristine, carefully curated business/legal record is safeguarded and not contaminated by invalid/incomplete/disjoint data/record content from external sources. The following shows a typical pattern of exchange:

Provider A EHR		Subject to		Provider B EHR
Inner Sanctum Business/Legal Record	→ Exchange Artifact(s) →	Algorithmic Verification	➜ Accept ➜	Inner Sanctum Business/Legal Record
			Reject ↓	
		Human Verification	➜ Accept ➜	
			Reject ↓	

In most cases, algorithmic verification always precedes human verification. Competent human review is costly, increasing in time/cost as more inbound data/records are received. Human review may still be inconclusive (e.g., often the human has no access or ability to compare inbound content to original source content). The Roadmap is silent on the current challenge of inbound data quality and the need for human review.

Data quality and integrity issues include accuracy, consistency, context, completeness and more. Lack of inbound data quality and limitations of software algorithms and even human review stand as barriers to interoperability. This should be a key finding/lesson for the Learning Health System and the Roadmap should make it explicit.

[From Roadmap search: "verify"/"verified"/"verification" (1 hit in this context)]

24. Interoperability Relies on Common Constructs

One of the best paths to interoperability is to open the breadth of common constructs between source and receiver systems. In 2011, the S&I Simplification Work Group was formed as an all-volunteer Initiative under the Standards and Interoperability Framework (S&I). This WG has taken 20 mostly heterogeneous S&I Use Cases, with 44 different Scenarios, and analyzed each for elemental and common constructs, including:
• Requirements: incl. Assumptions, Pre/Post Conditions, System Functional Requirements
• Actors and Roles
• Scenarios, Events and Actions

- Data Objects and Elements

A substantial set of common constructs were identified and are now catalogued in the S&I Simplification Core Matrix v3.3, in the AHRQ-hosted US Health Information Knowledgebase (USHIK) and in the Federal Health Information Model (FHIM).

The Learning Health System should take a lesson from the S&I Simplification approach and the Roadmap should make this explicit.

25. Interoperability Leveraged across Heterogeneous Use Cases

Following the previous comment, it is important to note that the S&I Simplification analysis did more than find and catalog commonalities across S&I Use Cases. It also applied a common health data/record management framework (record lifespan and lifecycle events) to each Use Case Scenario, tracing data/record points of capture (origination), update (amendment), verification, attestation, access/view, exchange (transmit, receive) and more. This analysis was facilitated in part by requirements from ISO 21089, Trusted End-to-End Information Flow, and ISO 10781, EHR System Functional Model Release 2.

The Learning Health System should take a lesson on interoperability from this common health data/record management framework across multiple disparate Use Case Scenarios and the Roadmap should make this explicit.

26. Superstructure without First Infrastructure for Interoperability?

The Roadmap focuses substantially on expected outcomes (good results) once interoperability is achieved, but much less on architectural and infrastructure requirements and broad-based commonalties to support its progression and build-out. With these basics missing or left to assumption we wonder if the Roadmap isn't more a chronicle of past journeys in the so-far vain pursuit of interoperability.

Our comments have intentionally focused on key requirements and fundamentals for interoperability to be realized. We understand that this may be at odds with a lot of smart thinkers but we see wisdom in focusing on the rudiments, integrals and bindings. Superstructure without first infrastructure is a paradox we can't afford. It assuredly has been close to a complete failure in the EHR rollout (#1 cause of provider dissatisfaction, panned by virtually everyone) and the HIE rollout (almost all HIEs without Beacon grants shut down) to date. More of the same will just cause eye rolling among the vast provider community and, eventually, a legislative push to have all of this scrapped.

27. Interoperability as a Destination

A Roadmap shows where I am and leads me to where I want to go (uniformly implemented interoperability and integration of health data/records). In this map, we want to establish that regardless of your current (stakeholder-perceived) location all roads lead to a single nationwide interoperability solution. So…
- Does the Roadmap give us a proper starting point?
- Does the Roadmap properly pinpoint the destination?
- And offer a reasoned path from here to there?

Part of the Learning Health System lesson plan should be a view from key stakeholder perspectives offering their route forward – with milestones – and how they will come to

recognize their destination (useful and useable integration and interoperability) when they see it. The Roadmap should make this explicit.

Specific Comments

Page 8, Executive Summary

Roadmap Page 8, Executive Summary – Introduction, 1st paragraph: "Health information technology (health IT) that facilitates the secure, efficient and effective sharing and use of electronic health information when and where it is needed…"

28.   Needed is "health IT that facilitates" from the point of health data/record origination, retention to the point of exchange (sharing) then use. Health data/records don't magically become interoperable at the point of exchange. Point of origination (as the "source of truth") is the anchor point for health data/record interoperability. The Roadmap should make this explicit.

Roadmap Page 8, Executive Summary – Introduction, 1st paragraph: "To achieve this, however, the health IT community must expand its focus beyond institutional care delivery and health care providers, to a broad view of person-centered health. This shift is critical for at least two reasons:

"1. Health care is being transformed to deliver care and services in a person-centered manner and is increasingly provided through community and home-based services that are less costly and more convenient for individuals and caregivers; and "2. Most determinants of health status are social and are influenced by actions and encounters that occur outside traditional institutional health care delivery settings, such as in employment, retail, education and other settings.

"This shift [to a broad view of person-centered health] requires a high degree of information sharing between individuals, providers and organizations and therefore a high degree of interoperability between many different types of health IT, such that systems can exchange and use electronic health information without special effort on the part of the user."

29.   From this statement it seems like steps 2 to 9 have been omitted and you are at step 10. Everything that then follows is basically an account of some hoped-for magical nationwide HIE. All that is needed is "one last push" and somehow repeating the insanity will work the nth time. There is no hint of a health care design for how person-centeredness is to be embodied in an architecture, other than as some diffuse overall property of the behavior of all the elements.

        A person remains the figment of the imagination of institutional systems. Without an appreciation of this point, commenting on the rest feels like a waste of time – a debate over the best choice for how to do the wrong thing.

30.   Reference Comment #16 and last Roadmap paragraph above (where the IEEE "interoperability definition is referenced). As described in previous Comments, the IEEE "interoperability" definition seriously misses the mark for interoperable health data/records and is a recipe for failure of the Roadmap vision.

Page 9, Figure 1, Principles of Interoperability

31.   The first building block statement that we should "build on existing health IT infrastructure" assumes that we have proven infrastructure in place that demonstrates (achievement of) interoperability. In the absence of full integration, we have not proven interoperability, particularly that focused on primary use of health data/records. The Roadmap is silent on this and offers no plausible alternative (to full integration). Since many believe (and there is little counter-evidence) that the current Health IT infrastructure has done little to get to patient-

centric health, perhaps a different infrastructure should be considered that has an integrated patient record at its center.

32. Building a foundation for interoperability is imperative but is not the same as "build[ing] on existing health IT infrastructure". In previous Comments, we've outline key foundational requirements to achieve interoperable health data/records. The Roadmap should make this explicit.

Page 10, 2nd paragraph

33. It is stated that "workflow… is out of scope for this Roadmap" yet this is a mischaracterization of interoperability. Integrating data flow with work (process) flow is the essence of interoperation and interoperability.

The IEEE "interoperability" definition gets this right: exchange then use. "Use" is applying content of health data/records received to subsequent actions taken: e.g., individual care, interventions and decision making. The Roadmap should make this explicit.
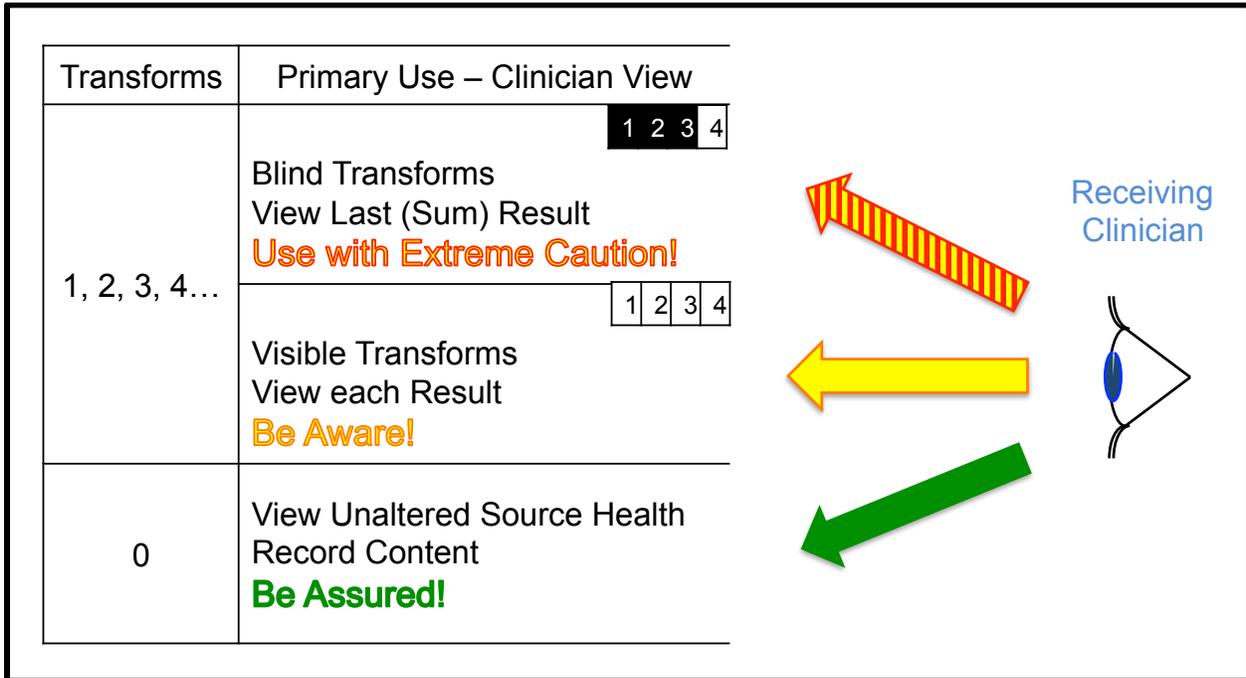
Page 83, List of Standards

34. As described in previous Comments, the Roadmap should include:
   • ISO 21089, "Trusted End-to-End Information Flows", 2004 (currently in revision)
   • HL7 EHR Interoperability Model DSTU, 2007
   • HL7 EHR Lifecycle Model DSTU, 2008
   • ISO/HL7 10781 EHR System Functional Model Release 2, 2014
   • ISO/HL7 16527 PHR System Functional Model Release 1, 2014

Page 163, Appendix H – Priority Interoperability Use Cases

35. This enumeration is almost embarrassing and not because it is long per-se. It actually reflects a complete lack of strategic health care design – how someone's care will work in this new world. We would scrap all of these cases and just start with something like: "when a person is considering their health and care, or receiving care from a care provider, they must be able to know and interpret the information of most importance to their overall health and care".

That means any sort of provider, in any sort of setting, for any reason – and includes 'active' care – i.e., systems that are monitoring care and advising action before help is sought. Everything else flows from that, and you can prioritize the elements of what you do according to your starting point. Most any other case is a loss of the forest for a long list of trees.

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!

Receiving Clinician

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