

Health IT Standards Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT



Semantic Standards Workgroup

Interoperability Roadmap Recommendations

James Ferguson, co-chair
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Members	Organization
Co-Chairs	
Jamie Ferguson	Kaiser Permanente
Becky Kush	Clinical Data Interchange Standards Consortium (CDISC)
Members	
John Carter	Apelon, Inc.
Todd Cooper	Center for Medical Interoperability
Stan Huff	Intermountain Healthcare
Rosemary Kennedy	eCare Informatics, LLC, Thomas Jefferson University
Harry Rhodes	AHIMA
Eric Rose	Intelligent Medical Optics (IMO)
John Speakman	New York University Langone Medical Center
Asif Syed	American Medical Association (AMA)
Andy Wiesenthal - liaison member	Deloitte Consulting, LLP
Ex Officio Members	
Steve Brown	Veterans Administration (VA)
Margaret Haber	Enterprise Vocabulary Services, National Cancer Institute (NCI)
Betsey Humphreys	National Library of Medicine (NLM)
Mitra Roca	Food and Drug Administration (FDA)
ONC Staff Lead	
Patricia Greim	Office of the National Coordinator for Health IT



Workgroup	Semantics Standards
General Questions (as they apply to the assigned Roadmap section)	<ul style="list-style-type: none">• Are the actions proposed in the draft interoperability Roadmap the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term?• What, if any, gaps need to be addressed?• Is the timing of specific actions appropriate?• Are the right actors/stakeholders associated with critical actions?
Roadmap Sections	<ul style="list-style-type: none">• J. Consistent Data Formats and Semantics
Charge / Question(s)	<ul style="list-style-type: none">• Which data elements in the proposed common clinical data set list need to be further standardized? And in what way?

Common Themes 1 of 4

Additional Focus Areas



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1. Need a shared understanding of the importance of information models and terminology bindings
2. Need agreement on highly granular information models bound to terminologies for information exchange
3. Data standards (e.g., for performance and quality measures, public health) should reflect the semantics implemented in EHR systems and semantics in EHR should be the same across settings
4. Need attention to challenges of data aggregation, for example for resolving duplicates, when data is assembled from multiple sources
5. It is critically important for data provenance to be workable and practical for semantic interoperability
6. Reject usefulness of National Information Exchange Model (NIEM) related to healthcare interoperability
7. Usage of FDA Unique Device Identifiers (UDIs) should be more explicit in the roadmap. Device identifiers should be captured and included in a patient's EHR to identify the source of information acquired from healthcare devices. This includes devices that are used for laboratory tests and whose results are included in a patient's EHR. The identifiers also enable post-market surveillance of healthcare device performance and regulatory authority safety reporting.

Common Themes 2 of 4

Missing Or Misconstrued Items



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1. Need to prioritize additional diagnostic studies/reports (e.g. EKG) for patient and provider decision making
2. Need to support semantic web standards including OWL and RDF
3. Recommend minimizing mapping between different standards because mapping is imprecise
4. Support the use of interface terminologies that allow accurate and precise use of target standards
5. Need to support semantic interoperability by multiple mechanisms, including:
 - a) Data exchange - standards for moving copies of data between entities
 - b) Access to data at its source – need shared access to patient centered data sources
 - c) Combinations of a and b including access to aggregated data
6. The roadmap should include the seamless integration and use of healthcare device information (e.g., physiological monitors, infusion pumps, ... personal health and public health), including unique identifiers, observations, settings, alerts and waveforms using standards such as UDI, ISO/IEEE 11073, LOINC and SNOMED CT

Common Themes 3 of 4

Clarification Needed



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1. Need a clear plan for achieving the objectives laid out in the Roadmap
2. Need clarity about how to achieve coordinated governance of semantic standards
3. The reference to “technical architecture” is too vague
(p. 84, Table 10, J2)
4. The reference to “translation and adapter services” is unclear
(p. 85, Table 10, J4)
5. Common data elements are not necessarily standards and a definition needs to be developed, preferably based upon ISO 11179
6. The common clinical data set from the roadmap needs more specificity, needs to be vetted broadly, and to be harmonized with other common clinical data sets

Common Themes 4 of 4

ONC Coordination With SDOs



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1. Need ONC to work more closely with (and within) accredited SDOs
2. Need closer coordination of US semantic standards with international standards organizations (e.g., via the Joint Initiative Council on SDO Global Health Informatics Standardization)
 - a) Reduce overlap and improve coordination
 - b) Improve operations e.g. release schedules
3. Suggested vocabularies and code sets do not align well with widely used research and clinical standards, including those defined by US and international agencies and SDOs such as CDISC

Interoperability Roadmap Section J

Consistent Data Formats and Semantics



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Questions for Workgroup	<ul style="list-style-type: none"> • Which data elements in the proposed common clinical data set list need to be further standardized? And in what way? 	
Common Clinical Data Elements	<ol style="list-style-type: none"> 1. Patient name 2. Sex 3. Date of birth 4. Race 5. Ethnicity 6. Preferred language 7. Smoking status 8. Problems 9. Medications 10. Medication allergies 11. Laboratory test(s) 	<ol style="list-style-type: none"> 11. Laboratory value(s)/result(s) 12. Vital signs 13. Care plan field(s), including goals and instructions 14. Procedures 15. Care team members 16. Immunizations 17. Unique device identifier(s) for a patient's implantable device(s) 18. Notes/narrative
Proposed	Prioritize the list with clinicians	Further specify the standards
Proposed	Diagnostic Reports	Critical need for radiology, cardiology, etc. reports
Proposed	Culture Results/Microbiology	Is this included under Laboratory tests?
Proposed	Surveillance Interventions	electronic submissions
Proposed	Change 7 Smoking status	Align with IOM report tobacco use
Proposed	Harmonize with CDASH	Includes models and metadata to support FDA/PMDA/research

Interoperability Roadmap Section J. 1. (1 of 3)

Consistent Data Formats and Semantics



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J. 1. Common, list of interoperability standards	Are these the right actions?	What gaps need to be addressed?	Is the timing appropriate?	Are the right stakeholders associated with critical actions?
<p>J. 1. 1. ONC will annually publish and update a list of the best available standards and implementation guides. ONC will facilitate an open transparent process/minimize cost/promote innovation.</p>	<p>No – We need to transmit human readable reports for expensive useful diagnostic studies Ex: electronic FAX</p>	<p>Need access models in addition to transactional data movement-Need the availability of past studies and reports (such as CT/MRI/ EKG tracings/nerve conduction studies/Operative Reports/Discharge Summaries) Device informatics standards should be included and supported accordingly, including UDI</p>	<p>Annual Changes are unworkable - stability is desirable. New standards are additive so costs and resource burden increase as they are added. Focus first on document exchange of reports and prioritize the Common Data Set</p>	<p>What is the relationship of the standards advisory with rulemaking? Engagement with implementers for lessons learned is key/ transparency is critical/ avoid including content without prior FACA and community discussions (RadLex) Standards are not replaced, but layered</p>
<p>2015-2017 Send, receive, find, use common clinical data set</p>	<p>Need to include access to clinical data</p>		<p>Prioritize diagnostic reports</p>	
<p>2018-2020 Expand HIT and users</p>			<p>Prioritized subset for prioritized scenarios</p>	
<p>2021-2024 Achieve LHS</p>			<p>Continue to work from prioritized list</p>	

Interoperability Roadmap Section J. 1. (2 of 3)

Consistent Data Formats and Semantics



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J. 1. Common, list of interoperability standards	Are these the right actions?	What gaps need to be addressed?	Is the timing appropriate?	Are the right stakeholders associated with critical actions?
<p>J. 1. 2. Implementers and decision-makers should use ONC's list of the best available standards when making decisions about the standards they will use to enable specific use cases</p>	<p>If the focus is on mature standards (not Draft Standards for Trial Use) and if they avoid unnecessary variation. Harmonization of V 2.3, V2.5, and V2.8 should be pursued. (We now have five versions of HL7 V2.x, versions of CCDA, and infinitely flexible FHIR)</p>	<p>Greater coordination among standards versions are important. Feedback loops from implementers need to be strengthened. Documentation of pros/cons and lessons learned will promote informed decisions</p>		<p>Harmonization should be pursued with SDOs. ONC should work more closely with Standards Development Organizations</p>
<p>2015-2017 Send, receive, find, and use common clinical data set</p>	<p>Need to include access to clinical data</p>		<p>Focus on unstructured reports and prioritize diagnostic reports</p>	
<p>2018-2020 Expand HIT and users</p>			<p>Prioritized subset for prioritized scenarios</p>	
<p>2021-2024 Achieve LHS</p>			<p>Continue to work from prioritized list</p>	

Interoperability Roadmap Section J. 1. (3 of 3)

Consistent Data Formats and Semantics



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J. 1. Common, list of interoperability (Continued)	Are these the right actions?	What gaps need to be addressed?	Is the timing appropriate?	Are the right stakeholders associated with critical actions?
<p>J. 1. 3. Developers will update their systems to align with ONC list of best available standards</p> <ul style="list-style-type: none"> C-CDA 2.0, vocabulary standards and code sets that support the common clinical data set 	<p>Change is costly and stability supports interoperability.</p>	<p>Vocabulary advice needs more detail.</p> <p>Description of planned ONC enforcement authority as well as incentives and penalties are missing</p>	<p>Designating C-CDA 2.0 is premature</p>	<p>Needs of the Research community are missing.</p>
<p>2015-2017 Send, receive, find, use common clinical data set</p>	<p>Need to include access to clinical data</p>		<p>Focus on unstructured reports</p>	
<p>2018-2020 Expand HIT and users</p>			<p>Prioritized subset for prioritized scenarios</p>	
<p>2021-2024 Achieve LHS</p>			<p>Continue to work from prioritized list</p>	

Interoperability Roadmap Section J. 2. (1 of 2)

Architecture in Support of Standards Activities



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J. 2. Architecture in Support of Standards Activities	Are these the right actions?	What gaps need to be addressed?	Is the timing appropriate?	Are the right stakeholders associated with critical actions?
<p>J. 2. 1. Through coordinated governance, public and private stakeholders will establish and maintain a prioritized set of use cases and associated functional requirements (see Appendix H for Priority Interoperability Use Cases).</p>	<p>How this will be done should be explained (e.g.) ONC will facilitate a process by which public and private stakeholders will establish and maintain...”</p>	<p>Missing a subset of high value use cases for collaborative focus</p>		<p>The role of public and private stakeholders should be to set priorities not just to comment on them -Ensure there’s open, transparent and balanced representation of diverse stakeholders</p>
<p>J. 2. 2. Through coordinated governance, public and private stakeholders will develop a nationwide technical architecture</p>	<p>Technical Architecture is ambiguous, depending on the scope this may not be achievable</p>	<p>Missing definitions for what is meant by technical architecture</p>		

Interoperability Roadmap Section J. 2. (2 of 2)

Architecture in Support of Standards Activities



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J. 2. Architecture in Support of Standards Activities	Are these the right actions?	What gaps need to be addressed?	Is the timing appropriate?	Are the right stakeholders associated with critical actions?
<p>J. 2. 3. Through coordinated governance, public and private stakeholders will define a necessary set of standards activities that support the prioritized use cases and functional requirements and the agreed upon architecture.</p>	<p>Architecture is not defined. The role of ONC is not defined.</p> <p>Substantially more work needs to be done on prioritizing use cases.</p>	<p>As an example of the need for use case prioritization, use cases do not adequately address post-market surveillance and/ or integration of EHRs with clinical research.</p> <p>So far, use cases do not address failure to rescue (FTR). Failure to synthesize information and make decisions has been found to account for 57% of FTR events. Use case prioritization needs more transparency</p> <p>Support the inclusion of use cases that focus on the use of device-acquired semantic content</p>		<p>Need engagement of front line clinicians who exchange information across care settings and experienced implementers</p>

Interoperability Roadmap Section J. 3. (1 of 3)

Develop and Pilot New Standards



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J. 3. Develop and pilot new standards for priorities.	Are these the right actions?	What gaps need to be addressed?	Is the timing appropriate? 2015-2017 Send ?	Are the right stakeholders associated with critical actions?
J. 3. 1. SDOs will advance and accelerate semantic standards for lab orders, other orders...	Orders are not included in the Common Data Set and standards for e-prescribing are being addressed	ONC direct engagement in SDOs, including the Joint Initiative Council needs to be strengthened	Consider standardizing orders later rather than sooner	Priorities need to be revisited with all affected stakeholders
J. 3. 2. Research and clinical trial communities will pilot the use of the common clinical data set.	It is not clear if there is a role for the Common Clinical Data Set in research .	Need a way to extend the common data set. Consider pilots in high dollar/high value Long Term Care use cases.		Stronger research and post surveillance engagement is needed.
J. 3. 3. SDOs will advance consumer-friendly terminologies.	Consumer friendly terminologies can sometimes obscure the precision needed in diagnostic studies and reports related to interoperability.		Reconsider the priority and timing consumer friendly terms	

Interoperability Roadmap Section J. 3. (2 of 3)

Develop and Pilot New Standards



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J. 3. Develop and pilot new standards for priorities.	Are these the right actions?	What gaps need to be addressed?	Is the timing appropriate? 2015-2017 Send ?	Are the right stakeholders associated with critical actions?
J. 3. 4. Health IT developers and SDOs should advance systems in support of human-centered design, including the ability to provide information to individuals with varying levels of health literacy in their primary language.	It is not clear how human-centered design is key to interoperability		Move to later timeframe	
J. 3. 5. Technology developers, providers and individuals will pilot data format and vocabulary standards and provide feedback to the SDOs.	Semantic Web Standards should be considered (OWL and RDF)	<p>Missing reference to intensional vs. extensional model paradigm</p> <p>Missing reference to concept models in Semantic Standards (e.g. SNOMED CT)</p>		

Interoperability Roadmap Section J. 3. (3 of 3)

Develop and Pilot New Standards



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J. 3. Develop and pilot new standards for priorities.	Are these the right actions?	What gaps need to be addressed?	Is the timing appropriate? 2015-2017 Send ?	Are the right stakeholders associated with critical actions?
J. 3. 6. States and other stakeholders explore NIEM with regards to supporting health care and human services interoperability.	The use case for NIEM outside of government information exchange is not clear.	Missing coordination between NIEM and SDOs. Missing a focus on high priority use cases for Interoperability	Not applicable	
J. 3. 7. SDOs and industry will collaborate on best practices and provide guidance on the exchange of unstructured data such as a physician note	Very important, especially for diagnostic reports.	Electronic replacement of FAX	Most immediate and urgent need to support direct patient care	Professional societies and Consumer groups
2015-2017 Send, receive, find, use common clinical data set	Need to include access to clinical data		Unstructured data	
2018-2020 Expand HIT and users 2021-2024 LHS			Need prioritized use cases for structured data	

Interoperability Roadmap Section J. 4.

Vocabulary Approach



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J. 4. Vocabulary Approach	Are these the right actions?	What gaps need to be addressed?	Is the timing appropriate?	Are the right stakeholders associated with critical actions?
<p>J. 4. 1. Through coordinated governance, public and private stakeholders will work with SDOs to define a standard approach to federated distribution of centrally maintained code sets.</p>	<p>Agree ONC needs stronger coordination with SDOs. Federated or Centrally maintained? We have a federated distribution of vocabularies through NCI/NLM/CDC for example</p>	<p>Missing references to intensional vs. extensional modeling of value sets Missing attention to web standards</p>	<p>Federated distribution works now</p>	<p>Include distributors: NCI/NLM/CDC</p>
<p>J. 4. 2. Health IT developers will provide accurate translation and adapter services where needed in order to support priority LHS use cases (see Appendix H for Priority Interoperability Use Cases).</p>	<p>Remove the word accurate and change it to say : HIT developers will enable code mapping and vocabulary look up services where needed</p>	<p>Resolve ambiguity. Prioritize use cases and focus on “very high” priority use cases Translator and adaptor services should support device informatics</p>	<p>No, it will take longer</p>	<p>Yes</p>

Interoperability Roadmap Section J. 5.

Maintain and Improve Standards

J. 5. Maintain and Improve Standards	Are these the right actions?	What gaps need to be addressed?	Is the timing appropriate?	Are the right stakeholders associated with critical actions?
J. 5. SDOs will maintain and improve existing standards based on implementation feedback	Feedback from implementers is critical and feedback loops are variable among SDOs. How will this be accomplished?	Need opportunities for candidate standards to be implemented and generate lessons learned		Seek lessons learned from experienced Implementers including CDISC
2015-2017 Send, receive, find, use common clinical data set	Need to include access to clinical data		Focus on unstructured reports and prioritize diagnostic reports	
2018-2020 Expand HIT and users			Prioritized subset for prioritized scenarios	
2021-2024 Achieve LHS			Continue to work from prioritized list	

Interoperability Roadmap Section J. 6.

New Standards for New Requirements



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J. 6. New Standards for New Requirements	Are these the right actions?	What gaps need to be addressed?	Is the timing appropriate? 2015-2017 Send ?	Are the right stakeholders associated with critical actions?
<p>J. 6. 1. Through coordinated governance, public and private stakeholders will advance the development and maintenance of data format and vocabulary standards and implementation guidance necessary to support priority learning health system use cases (see Appendix.)</p>	<p>How will this be done? Is this describing actions that OC will take to coordinate stakeholders? Proposals become powerful when they are prioritized and resourced.</p>	<p>Missing reference to content model of terminology standards Missing reference to the intensional and extensional modeling component.</p>	<p>Depending on priorities and resources.</p>	<p>SDOs, Professional Societies, Federal Agencies, Consumer Groups, Health Care Providers Institutions, and Vendors,</p>
<p>2015-2017 Send, receive, find, use common clinical data set</p>			<p>Focus on unstructured reports and prioritize diagnostic reports</p>	
<p>2018-2020 Expand HIT and users</p>			<p>Prioritized subset for prioritized scenarios</p>	
<p>2021-2024 Achieve LHS</p>			<p>Continue to work from prioritized list</p>	



- Page 85, J.4.2. Health IT developers will provide accurate translation and adapter services where needed
 - Change the term, “translation and adapter services,” to, “mapping and terminology services”
- Page 79, 2nd to last paragraph
 - Change sentence to “... (LOINC) for laboratory tests, vital signs and other observations,” in order to promote consistency with LOINC being indicated as such elsewhere.
- Pages 85, the phrase code sets appears to be used as a synonym for value sets, as currently be stored in the NLM VSAC. Recommend using the term value sets more consistently throughout the document